GI Dynamics, Inc. – ASX Announcement

CORPORATE PRESENTATION

LEXINGTON, Massachusetts, United States and SYDNEY, Australia – 6 May 2015 – GI Dynamics, Inc. (**ASX: GID**) (**GI Dynamics** or the **Company**), confirms as previously announced that Michael Dale, the Company's president and chief executive officer, is hosting a briefing call to discuss the financial results for the quarter ended 31 March 2015 and the results of the Company's strategic review at 8 a.m. AEST on Wednesday, 6 May 2015 (6 p.m. U.S. EDT on Tuesday, 5 May 2015).

The materials being presented on the briefing call are attached hereto. A copy of these materials is also being filed with the U.S. Securities and Exchange Commission and posted under the Investor Relations section of the Company's website at investor.gidynamics.com.

About GI Dynamics

GI Dynamics, Inc. (ASX: GID) is the developer of EndoBarrier®, the first endoscopically-delivered device therapy approved for the treatment of obese type 2 diabetes with BMI ≥ 30 kg/m^2, or obese patients with BMI ≥ 30 kg/m^2 with ≥ 1 comorbidities, or obese patients with BMI >35 kg/m^2. The liner is indicated for a maximum implant duration of 12 months. 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. GI Dynamics is conducting a pivotal clinical trial of EndoBarrier in the U.S. for the treatment of patients who have uncontrolled type 2 diabetes and are obese. Founded in 2003, GI Dynamics is headquartered in Lexington, 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 centres 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 possibility that 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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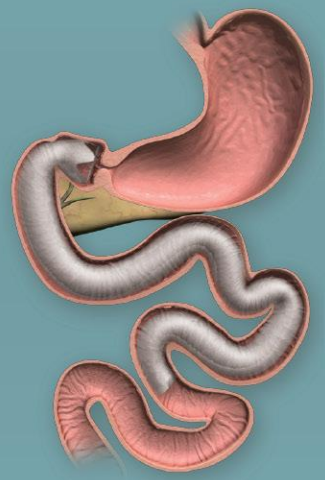
Q1’15 Earnings & Strategic Review Conference Call



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Important Notice

Currency References

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

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Disclaimer

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Conference Call Agenda

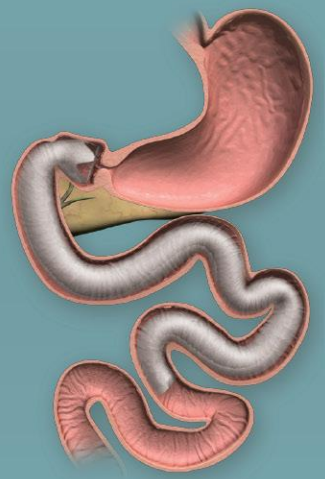
- High-level summary of Q1’15 financial and operating performance
- Outcomes from strategic review
- Update on ENDO Trial
- Financial guidance for 2015 & operating priorities

Q1’15 Summary

- Revenue:
  - $0.6 million, down $0.3 million y/y
- Operating expenses:
  - $9.6 million, down $0.5 million y/y
- Net loss:
  - $10.3 million, up $0.6 million y/y
- Cash and cash equivalents:
  - US$40.0 million at 31 March 2015, compared to US$51.2 million at 31 December 2014, a decrease of US$11.2 million.
- Organization-wide focus on regulatory activities in Q1
- Commercial execution impacted by efforts to manage regulatory requirements and organization realignment as part of strategic review
- ENDO Trial enrollment hold has and will likely continue to adversely affect commercial operations

Strategic Review

Introduction & Summary



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Strategic Review: Overview

- Standard planning process
  - Emphasis on situation analysis and understanding strengths, weaknesses, opportunities, and threats
  - Clarification of value proposition and related gaps versus vision
  - Necessary goals and strategy for the future
- Participants
  - All GID employees
  - Board of Directors
  - Experienced EndoBarrier users
- Duration
  - Q4’14 to Q1’15

Strategic Review: Validation of Our Business Purpose

Mission

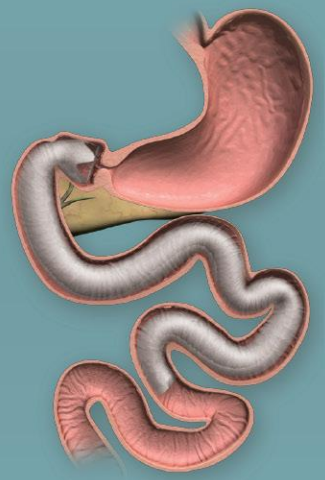
- We aim to restore health and improve quality of life through the design and application of device and management solutions for the treatment of metabolic disease.

Vision

- To establish **EndoBarrier® Therapy** as a valued treatment option for patients suffering from type 2 diabetes and obesity by restoring more manageable blood sugar levels and a healthier body weight.

Outcomes of Strategic Review

Validation of EndoBarrier Therapy Opportunity



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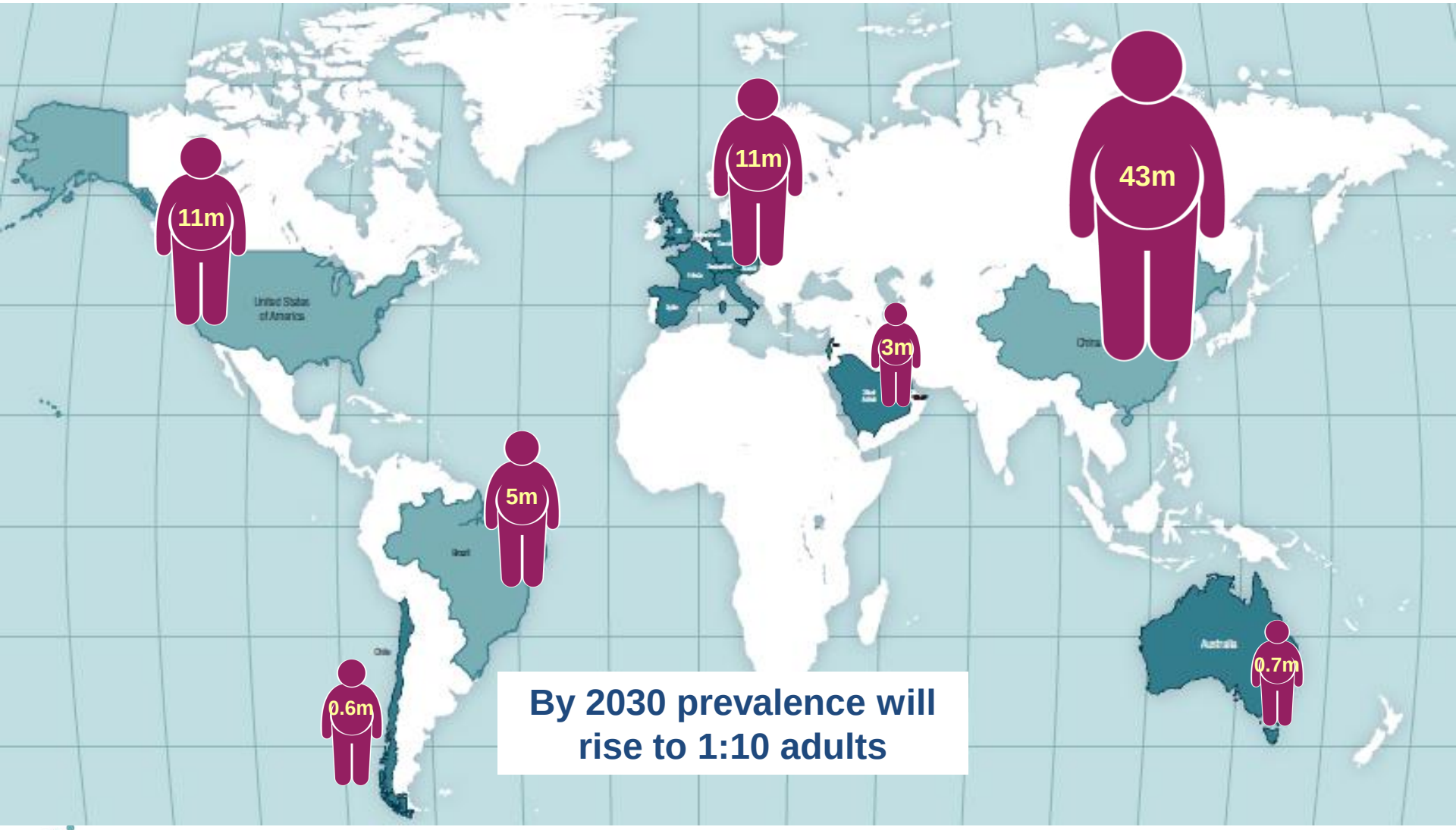
Validation of EndoBarrier Therapy Opportunity

Type 2 diabetes and obesity are a global challenge



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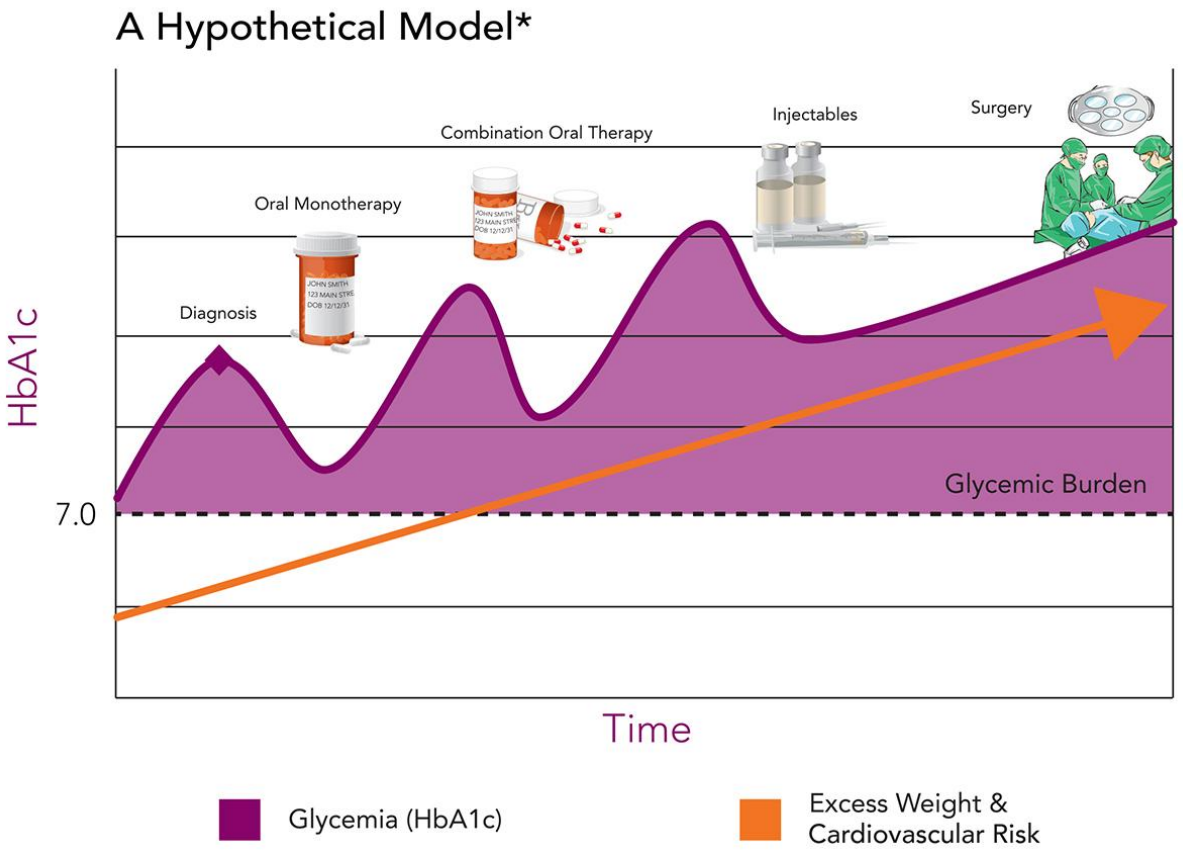
Validation of EndoBarrier Therapy Opportunity

Existing treatment options fail over time

Typical Progression of Type 2 Diabetes, Obesity and Associated Cardiovascular Risks when Treated with Conventional Therapies



*Adapted from DelPrato S, et al., Int J Clin Pract., 2005; 59: 1345-1355

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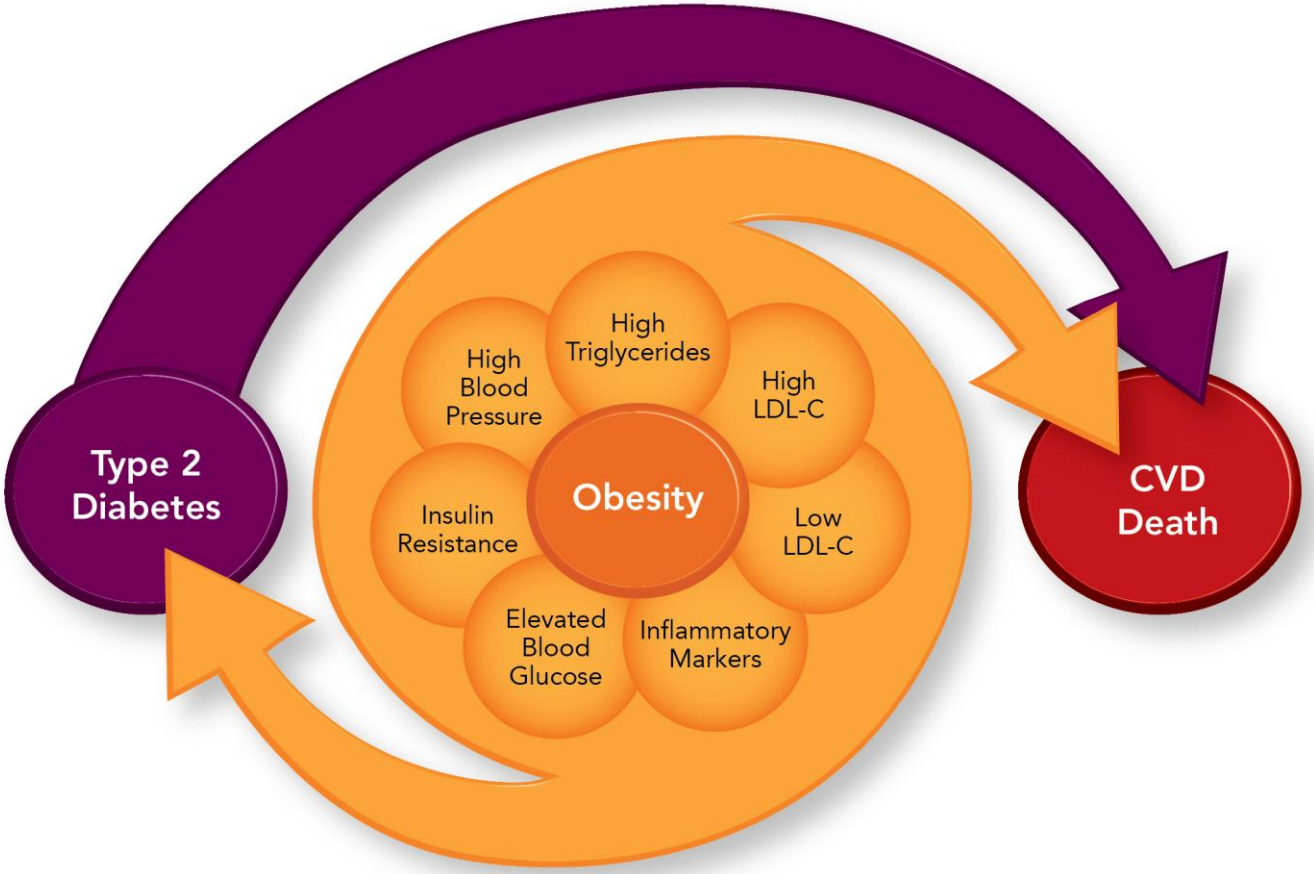
Validation of EndoBarrier Therapy Opportunity

Disease management requires a dual approach

- **Obesity is at the core of type 2 diabetes and its morbidity**
- **Weight loss must be a cardinal focus of its treatment**

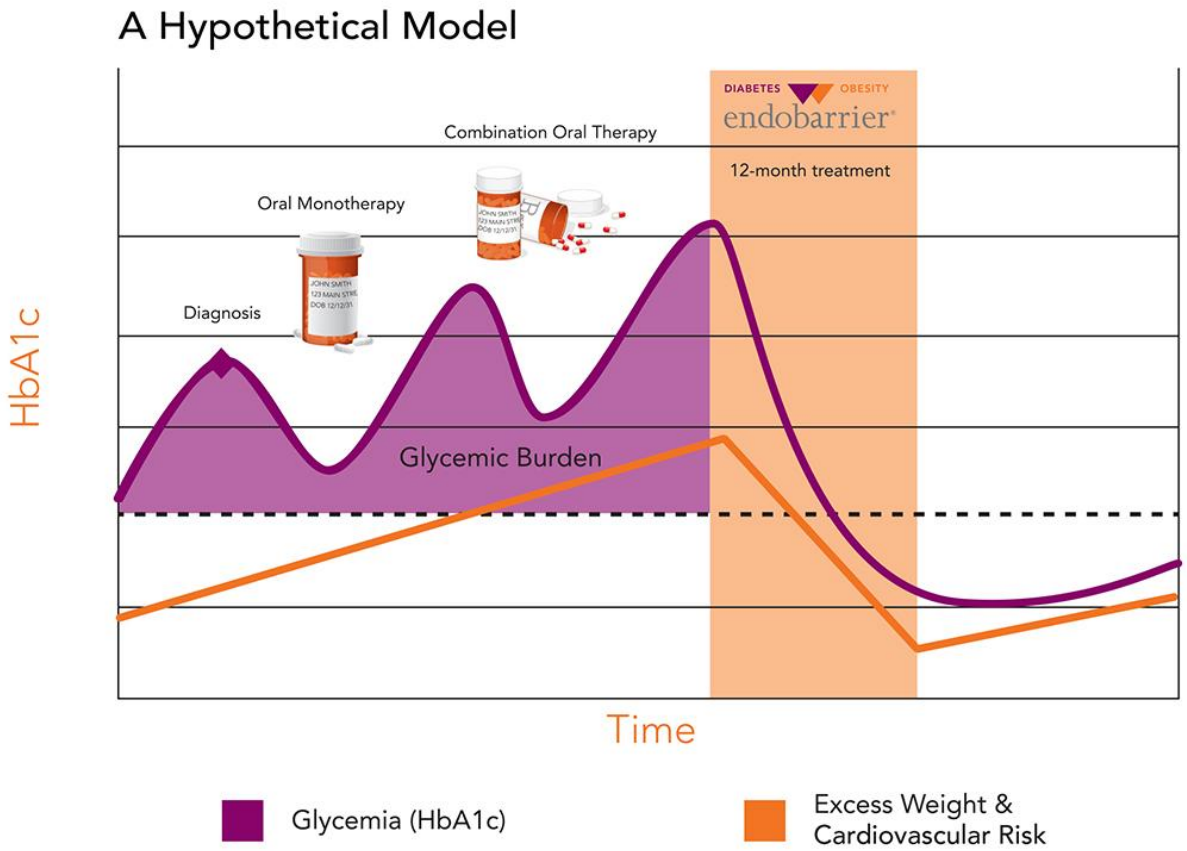


Gelfand EV *et al*, 2006; Vasudevan AR *et al*, 2005

Validation of EndoBarrier Therapy Opportunity

A single solution with dual effects

EndoBarrier Therapy Interrupts the Chronic Progression of Type 2 Diabetes and Obesity and Potentially Improves Cardiovascular Risk Factors



EndoBarrier Therapy: Customer Value Proposition

- EndoBarrier is a duodenal-jejunal bypass liner that provides patients living with type 2 diabetes and obesity with the only incision-free, endoscopic solution for immediate glycemic control and weight reduction, giving them the opportunity to change the course of their disease and improve their quality of life.

EndoBarrier Therapy: Unique Advantages

- EndoBarrier is the only incision-free, non-anatomy-altering solution designed to mimic the duodenal-jejunal exclusion that gastric bypass surgery creates.
- EndoBarrier is the only endoscopic procedure indicated to treat obese patients with type 2 diabetes.
- Because EndoBarrier is a passive device, its functional benefits are obtained independently of patient adherence to complex nutritional changes or intensive follow-up care.

EndoBarrier Therapy: Impact

Glycemic Control

- Immediate and sustained reduction of A1c
- 55% of patients reach therapeutic goal
- Improved fasting and postprandial glucose control
- No increased risk for hypoglycemia

Weight Loss

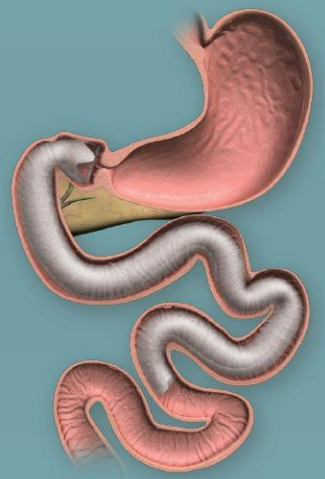
- Average 13% total body weight loss
- Reduces central adiposity
- 18-cm reduction in waist circumference at 12 months

Improved QOL

- Significant reductions in blood pressure, total cholesterol, low density lipoproteins, and triglycerides
- Reduced or optimized medical therapy

Outcomes of Strategic Review

Validation of the primary challenges to broad commercial adoption



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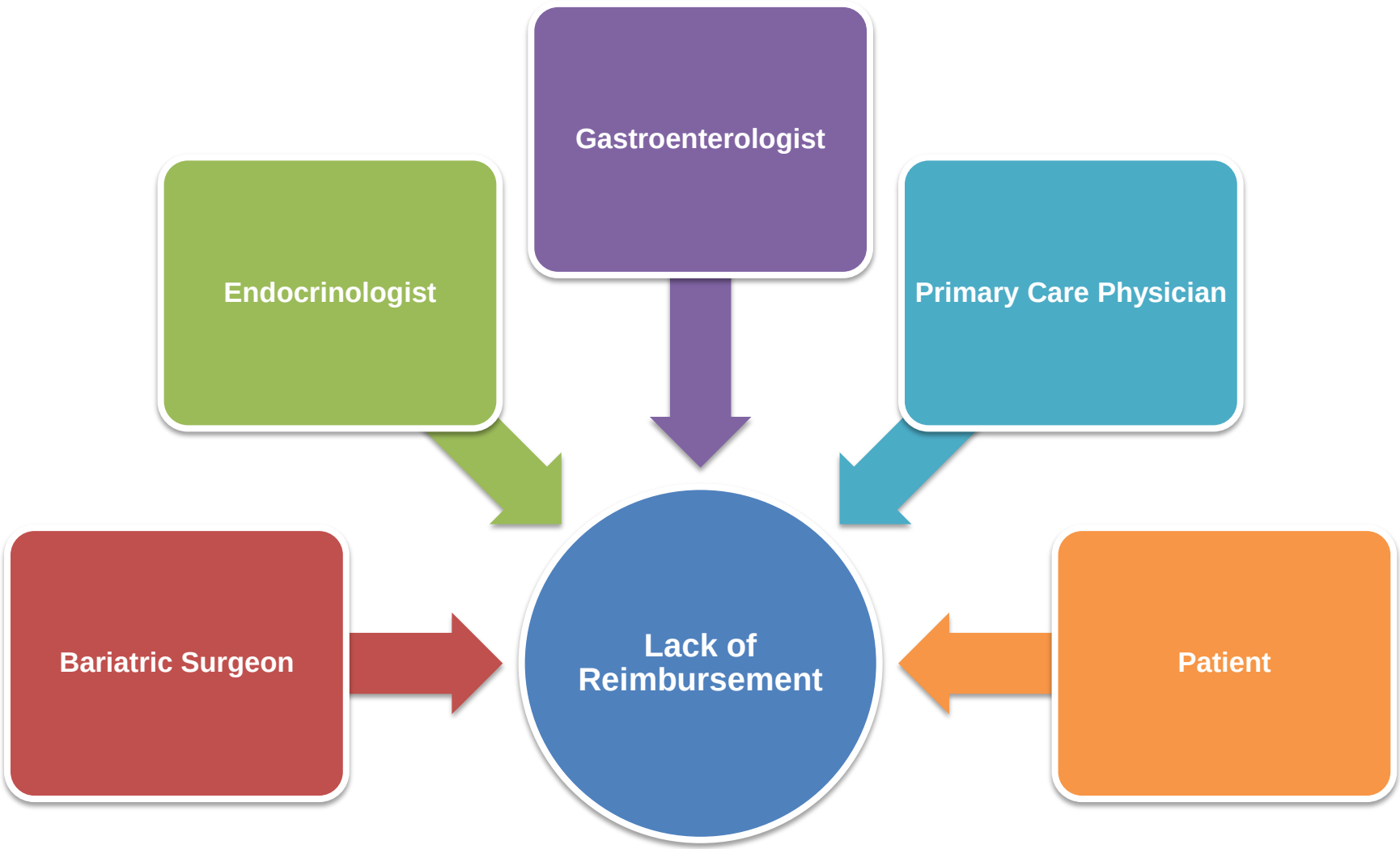
Outcomes of Strategic Review

Primary challenges to broad commercialization

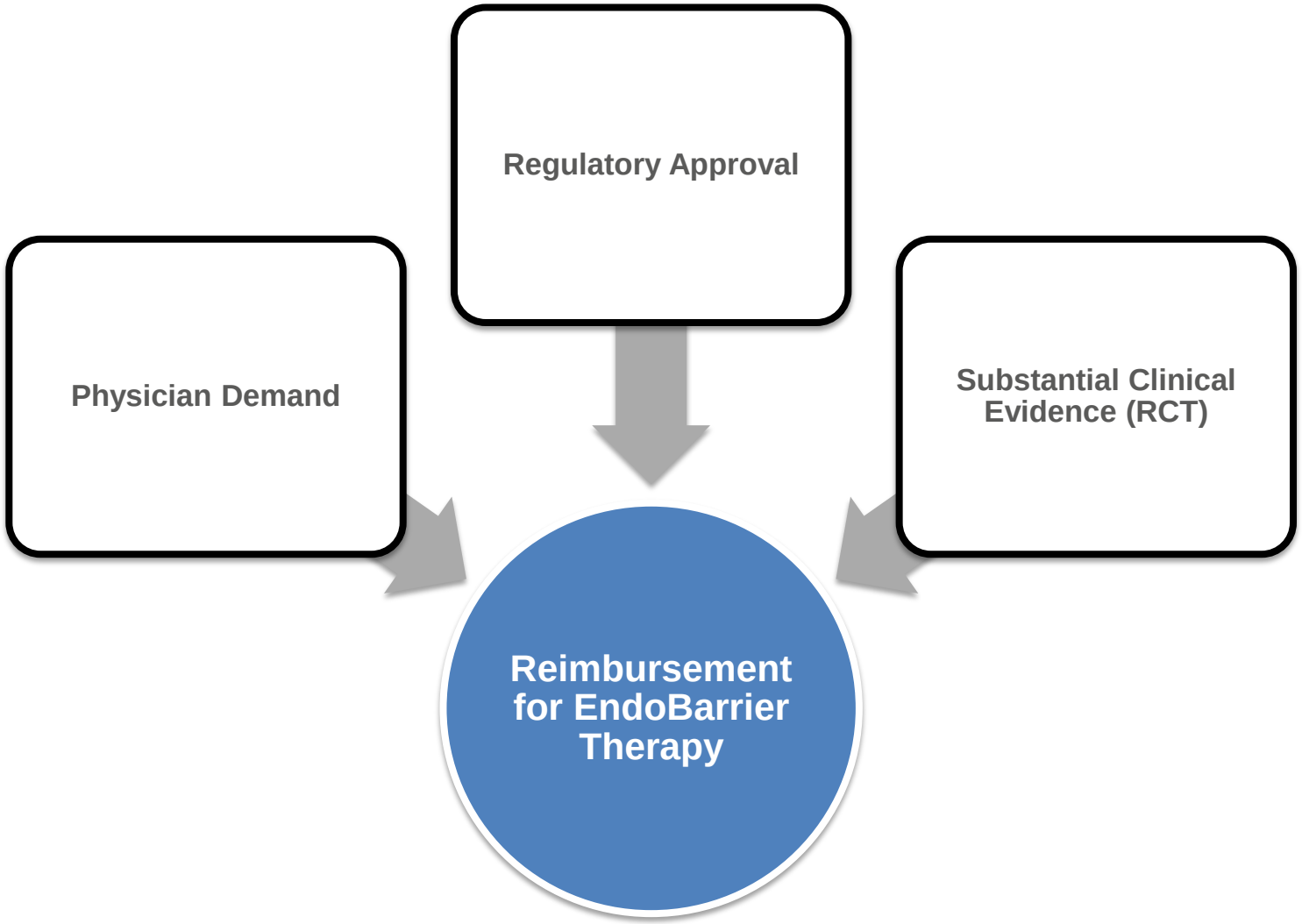
Primary issue(s) identified:

- Addressing multiple customer audiences
- Lack of reimbursement (coding, coverage & payment) for novel medical technology
- GID's distribution strategy
- Awareness of EndoBarrier risk:benefit profile
- Product enhancement and platform expansion
- Lack of randomized control trial evidence

Serve Multiple Customer Audiences



Lack of Reimbursement



GID's Distribution Strategy

Primary issue(s) identified:

- EndoBarrier Therapy is a novel technology that requires development of multidisciplinary care pathways for optimal patient management.
- Because of its novelty, formal reimbursement does not exist for the device, nor for the services associated for therapy delivery.
- Market development efforts to establish payment for EndoBarrier and physician training require significant investment.
- GID distribution models need to be adapted to encourage traditional partnering and cost sharing, and to establish clear lines of responsibility and leverage local market knowledge

Areas of Focus Required for Vision Fulfillment

Evidence

- RCT clinical evidence
- Best practice treatment algorithms

Process

- Quality culture and systems
- Business models

Product

- Ease of use
- Safety
- COGS

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What is the ENDO Trial?

A multi-center, double-blinded, randomized, controlled trial to evaluate the safety and effectiveness of the EndoBarrier Gastrointestinal Liner System on glycemic control.

Objectives:

- To determine if EndoBarrier significantly improves glycemic control
- To determine if EndoBarrier can be safely used to improve glycemic control

Primary Endpoints:

- Efficacy: Mean change in HbA1c at 12 months
- Safety: Rate of device removal due to device-related serious adverse events (SAEs) at 12 months

Significance:

- The first examination of device intervention in the diabetes space in a U.S. population - applying pharmaceutical-like standards to trial design
- A true diabetes trial with the primary endpoint being change in A1C, while accommodating body weight and cardiometabolic endpoints

Inclusion Criteria for Subjects

- Age ≥21years and ≤65 years
- Diagnosis of type 2 diabetes for ≤ 20 years
- HbA1c ≥7.5 and ≤10.0%
- BMI ≥30 and ≤55 kg/m^2
- Stable doses of up to two anti-diabetes medications (MET and/or a SU and/or a DPP-4i and/or a TZD) for a minimum of three months prior to screening
  - With at least one of these at or above a threshold dose as outlined in protocol:
    - MET: ≥ 1500 mg/day
    - SU, DPP-4i, TZD: based on pre-defined doses in protocol
- Documented negative pregnancy test in women with childbearing potential

ENDO Trial Update: Enrollment Hold

- GID's Progress with the FDA since investor call on March 5, 2015:
  - GID has worked closely with FDA on several fronts, submissions and correspondences include:

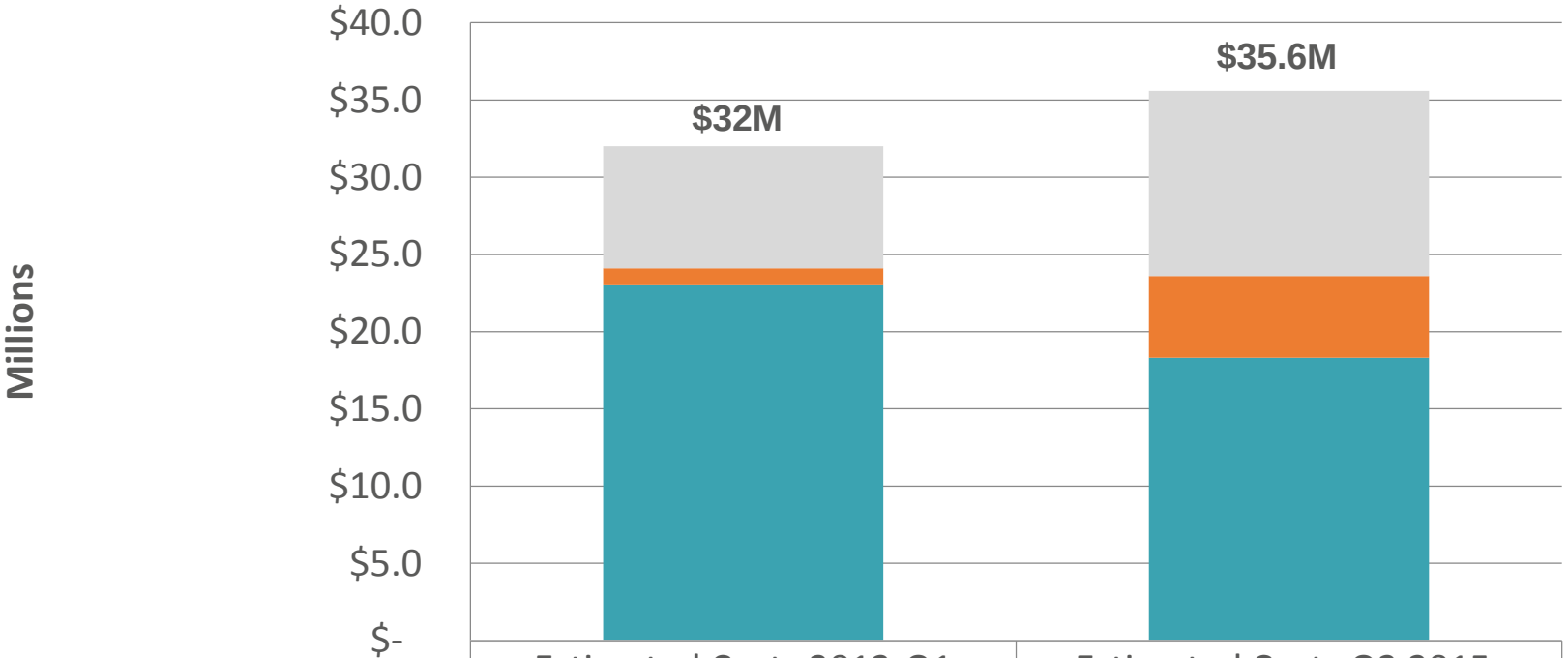
Item	Description	GID Action	Status with FDA
Compassionate/emergency use	Authorizes explants in the U.S. for OUS patients (case-by-case)	Response submitted	Properly accepted
Annual product reports	Multiple inquiries for additional information	Responses submitted	Submitted
Mitigation action plans	To address mitigation of the severity of hepatic abscess	Response submitted	Submitted
Futility analysis	Determine whether efficacy signal is large enough to warrant trial continuation	Completed on April 16, 2015	Submitted
Final submission to FDA	To include updated "HA" mitigation strategy and benefit:risk analysis	Responses submitted for all inquiries and requests from FDA	Filed

ENDO Trial Update: Estimated Timeline

Milestone	Estimated Timing
First patient enrolled in trial	2013
Subjects enrolled as of end April 2015	325
Approval to restart trial from FDA	Q2'15 ("T")
Patient screening begins	Q2'15 ("T" + 1 day)
Rolling site approvals	Q3'15 ("T" + 45 days)
Patient randomization begins (Pt. #326)	Q4'15 ("T" + 90 days)
Patient enrollment completed	Q4'16
Data analysis begins	Q4'17
PMA submission	Q2'18

Note: Planned U.S. clinical timeline. These dates are estimates and are subject to change.

ENDO Trial Cost Breakdown



	Estimated Costs 2012-Q1 2015	Estimated Costs Q2 2015-2018
FTEs/Overhead	$7.9	$12.0
OLE Sub-Study	$1.1	$5.3
ENDO Study Direct Costs	$23.0	$18.3

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GID's Process

Quality systems & regulatory affairs update

Progress since Q4'14:

- Continue effort to build and simplify quality system (QS) – surveillance audits will serve to validate these efforts in 2015.
- GID has addressed all previous CARs from notified body
- GID shipment hold lifted in Dec 1, 2014 – resulted in a modification to the *Indication For Use*, which since then has been aligned to be the same in all markets.
- GID has closed FSN/FSCA with all 85+ customers and 10 competent authorities in EU + AUS + Chile + Israel WW.
- Continue to build credibility and relationship with all competent authorities
- Continued demonstration of compliant vigilance reporting system

Ongoing objectives:

- Continue QS enhancements
- Continue to build quality culture and organization to support business needs
- Resolve UADE correspondence with FDA to re-start ENDO Trial

GID's Distribution Strategy

Prudent business models

- Direct investment will be limited to Germany and Australia
  - German operations are dedicated to care pathway development and reimbursement development.
    - Six direct employees
    - German EndoBarrier registry
  - Australia operations are dedicated to support of experienced EndoBarrier user base. We believe the self-pay market can support break-even operations within two years. Reimbursement in Australia will require market registry data and RCT data.
    - Two direct employees
    - Australian EndoBarrier registry
    - TGA-approved consumer advertisement
- Beginning in Q2 2015, all prior distribution arrangements will be cancelled and, where common interests align, will be served by traditional, independent distributor arrangements
    - Based on ability to support market development
      - Customer training
      - Self-payment or country-specific reimbursement development
      - Quality control

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Product Vision for EndoBarrier

Planned Evolution	Procedural complexity will be reduced, lowering cost and supporting adoption
	Safety profile will continue to improve through device and procedural improvements
	Product use will expand into additional high unmet disease states
	Future treatment will be based on measurable medical endpoints versus time of exposure
	Repeat therapy or serial treatment will be used for maintenance of responding patients

Product Enhancement and Platform Expansion

Opportunities to improve and leverage our technology across existing and expanded indications within the obese and/or T2DM population

- **EndoBarrier Liner with EndoBarrier Restrictor**
  This device combines our EndoBarrier liner with the EndoBarrier Restrictor, a combination intended to treat diabetes and create greater weight loss than either device alone.

- **EndoBarrier Restrictor**
  This device is targeted for short-term weight loss or weight loss in a patient who is not obese. The device employs the same anchoring technology as EndoBarrier, but has a cover with a small hole to slow emptying of the patient's stomach and create a feeling of satiety.

- **Next Generation EndoBarrier**
  Product enhancements for greater safety and ease of use
  Accommodates wider indications for use
  Allows for serial use of EndoBarrier Therapy based on anchoring technique and ease of use.

- **Bariatric Surgery Solutions**
  Fistula repair—uses a variation of EndoBarrier to repair leaks after bariatric procedures, such as sleeve gastrectomy. Present treatment includes stenting, distal-enteral feeding, antibiotics and drainage. Hospital stay can be weeks.

EndoBarrier with Restrictor™

The Restrictor is a temporary implant that promotes weight loss by reducing the flow of chyme through the GI tract, which delays gastric emptying and creates a lasting feeling of satiety

- Placed endoscopically, with or without the duodenal-jejunal bypass liner, using GI Dynamics' anchoring technology

- Restriction is adjustable to adapt to individual patient requirements.

EndoBarrier® Restrictor

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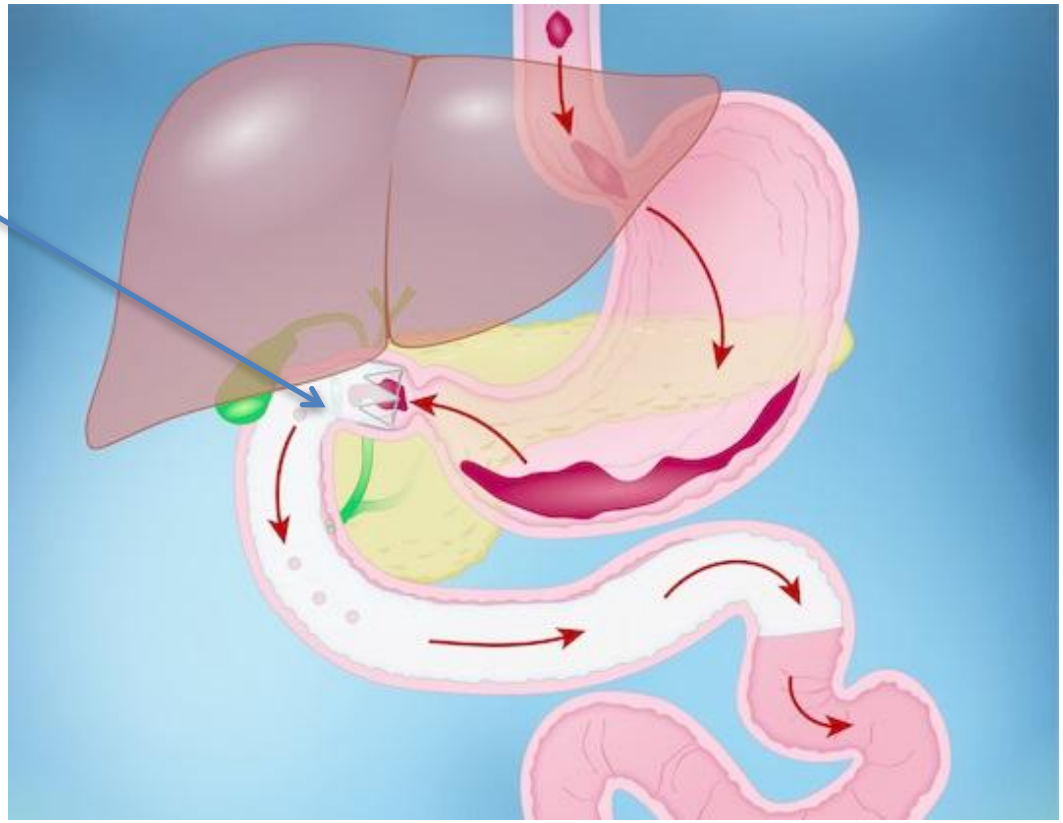
Placement & Independent Therapy Period

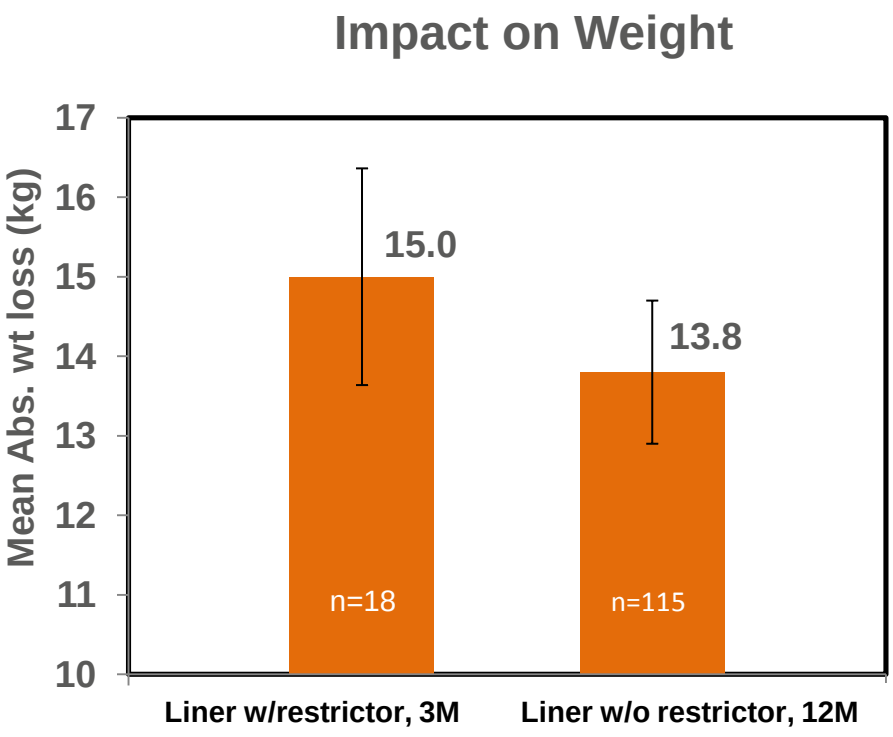
Placement:
The fluoropolymer Restrictor sits in the EndoBarrier liner approx. five centimeters below the anchor crown, creating a 'funnel' which slows the passage of chyme into the liner.

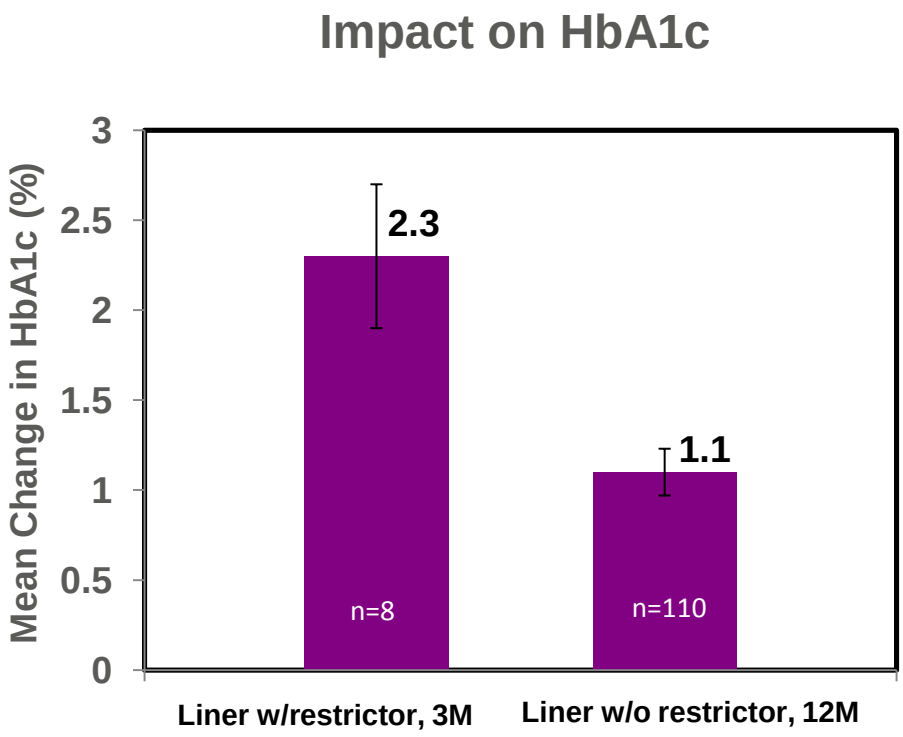
The rate of flow through the Restrictor 'funnel' can be adjusted for patient comfort.

Tx Period:
The therapy period of the Restrictor element in the combo Restrictor/liner device does not need to match the placement period of the liner which may remain *in situ* up to 12 months.



Comparison of Liner with & without Restrictor





The above studies, featuring the restrictor with liner (61 cm), were completed in human subjects. Data on file, GI Dynamics, Inc.

Expanded Indications to Serve High Unmet Needs

Disease segment	Concentrated in..	Current treatment	Morbid/mortal outcome	Device intervention impact ± evidence
Pre-surgery weight loss	Obese	Limited options	Anaesthesia risk → Death	Yes
Polycystic Ovarian Syndrome	Obese (±T2D)	IVF	Infertility	Likely + clinical anecdote
Fatty liver	Obese T2D	Limited options	Cirrhosis → Transplant	Likely + limited data
Sleep apnea	Obese T2D	O_2	↓QOL → Death	Likely + clinical anecdote

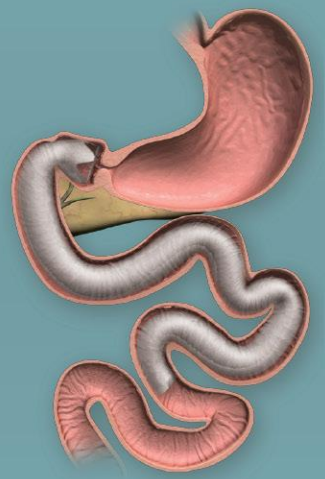
- High unmet need metabolic conditions
- Preliminary evidence that they may be responsive to device intervention

Transforming Disease Management with Early Device Intervention

Disease segment	Concentrated in..	Current treatment	Morbid/mortal outcome	Device intervention impact ± evidence
Adolescent obesity	Obesity	Surgical	↓QOL Progress → T2	Likely + limited data
Pre-T2D	Obese	Limited options	Progress → T2	Likely
New onset T2D with morbid obesity	Obese T2D	SOC (diabetes)	SOC will not address obesity	Yes

- Disease progression from obesity → T2D is currently unabated
- Standard of care is inadequate in altering progression with the exception of metabolic surgery
- Device intervention may become an important option
- Attention to risk:benefit is key

Financial Guidance and Operating Goals



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Financial Guidance for 2015

- **Revenue**
  - Assuming enrollment restarts October 1, 2015 and includes related overhang impacting the business in 1H'15, we now expect revenue in the range of $2.0 million to $2.5 million
- **Balance sheet & cash flow:**
  - At March 31, 2015, the Company had approximately $40.0 million in cash and cash equivalents, which it believes is sufficient to fund its operations through March 2016.
  - Due to the nature and timing of the cash flows related to our ENDO Trial, we do not believe that the enrollment hold had a significant effect on our cash flows from operations for the three month's ended March 31, 2015.
  - The enrollment hold's impact on the costs of the ENDO Trial is uncertain at this time. It is possible that in the short-term we may realize savings in patient recruiting expenses; however, the long-term costs associated with the risk mitigation strategies we implement are unknown at this time.

Operating Goals Through 2016

- Achieve awareness of our mission, vision and value proposition among 100% of our stakeholders.
- Establish a quality organization, culture and systems that exceed global regulatory requirements.
- Develop and implement business models for market development by geography that are reproducible, scalable and based on return on investment.
- Generate clinical evidence in support of our value proposition with clinical trials, publications and geographically-specific patient registries.
- Restart and complete ENDO Trial in a manner that ensures the best possible chance of clinical and regulatory success.
- Pursue research and development focused on improving and expanding the EndoBarrier platform.
- Obtain a NASDAQ company listing in 2015.