UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report: June 17, 2014
(Date of earliest event reported)

ENTEROMEDICS INC.
(Exact name of registrant as specified in its charter)

Commission File Number: 1-33818

Delaware	**48-1293684**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

2800 Patton Road, St. Paul, Minnesota 55113
(Address of principal executive offices, including zip code)

(651) 634-3003
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On June 17, 2014, EnteroMedics Inc. (the "Company") met with the U.S. Food and Drug Administration Advisory Gastroenterology and Urology Devices Panel ("GUDP") to review the Company's premarket approval application for approval of the Company's Maestro Rechargable System. A copy of the slides accompanying this meeting is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	GUDP Meeting Slides dated June 17, 2014.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

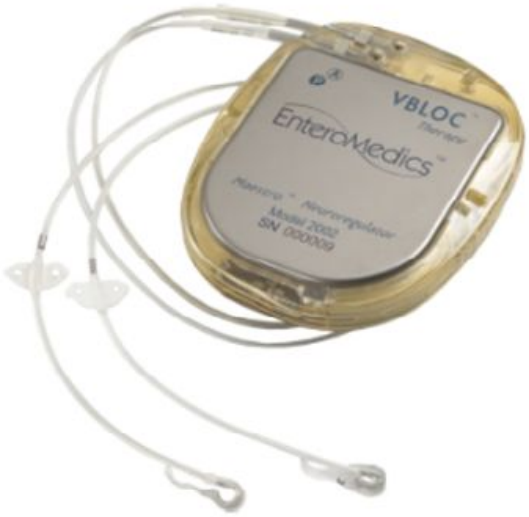
ENTEROMEDICS INC.

By: /s/ Greg S. Lea
Greg S. Lea
Senior Vice President,
Chief Financial Officer and Chief Operating Officer

Date: June 20, 2014

EXHIBIT INDEX

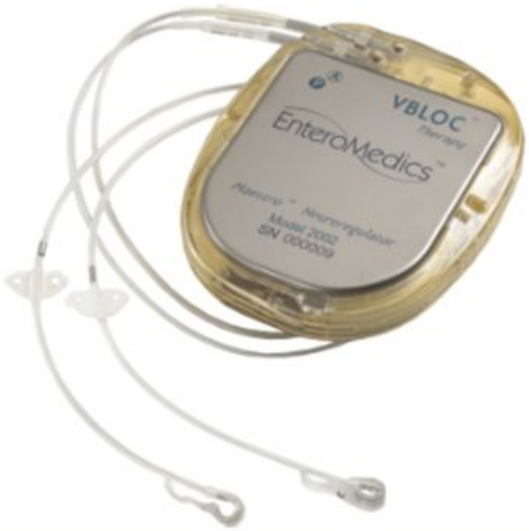
Exhibit Number	Description
99.1	GUDP Meeting Slides dated June 17, 2014.



MAESTRO Rechargeable System

EnteroMedics Inc

Gastroenterology-Urology Devices Panel
June 17, 2014



MAESTRO Rechargeable System

Mark B. Knudson, PhD

President and Chief Executive Officer

EnteroMedics Inc

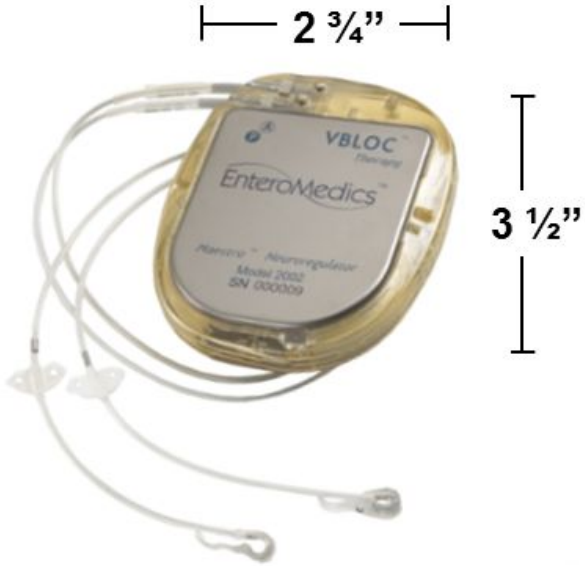
MAESTRO Rechargeable System Requested Indication

- Weight reduction in adults who have failed at least one supervised weight management program within the past 5 years
- BMI ≥40 kg/m^2

  OR
- BMI ≥35 kg/m^2 with one or more obesity related co-morbid conditions

MAESTRO Implantable Components

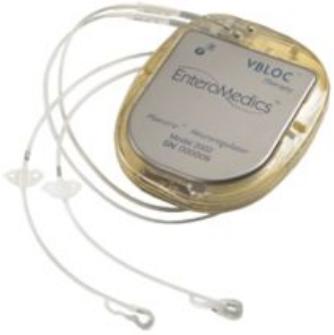
- Neuroregulator
  - Electronics based on proven technology
  - 5th generation battery technology
  - 155 grams
- Two flexible leads



External Components and Charging Process

- Mobile charger attaches to transmit coil
- Transmit coil placed over neuroregulator
- Battery level checked and recharged daily

Mobile Charger



Neuroregulator

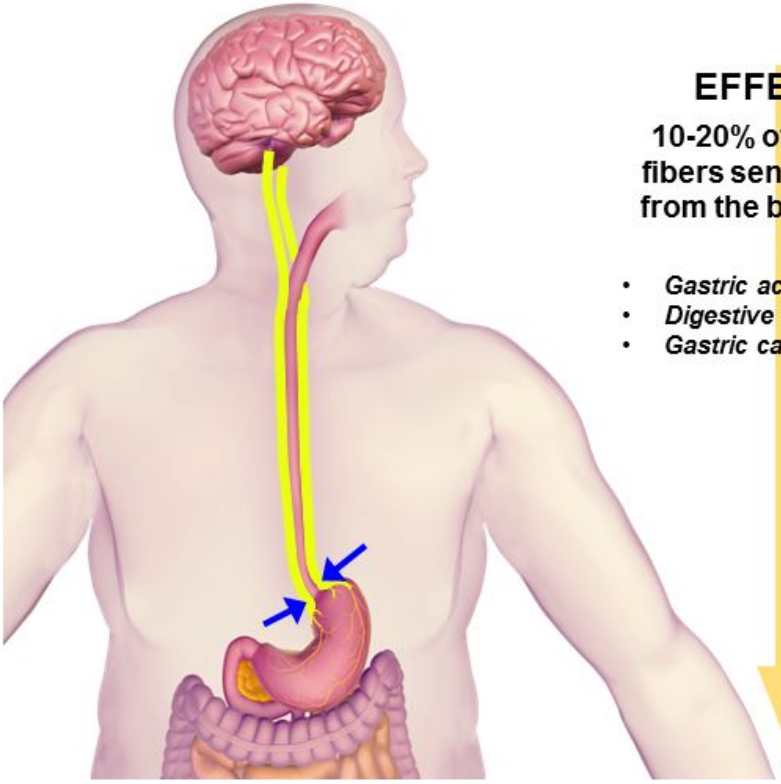
Transmit Coil

Programming the Device by a Clinician

- Laptop computer with pre-installed proprietary software
- Communicates with neuroregulator and mobile charger
- Clinician programmable parameters
  - Current amplitude (mA)
  - Hours of use
  - Ramp time

Physiological Basis for Therapeutic Effect and Proof of Concept

Science Underlying Vagal Block



EFFERENT

10-20% of vagus nerve fibers send instructions from the brain to the gut

- *Gastric acid secretion*
- *Digestive enzyme secretion*
- *Gastric capacity/motility*

AFFERENT

- *Satiety (Hunger)*
- *Satiation (Fullness)*

80-90% of vagus nerve fibers send instructions from the gut to the brain

Weight Loss Through VBLOC Therapy

- Vagus modulates multiple mechanisms involved with body weight regulation
- Vagotomy has been used to treat obesity[1,2]
- VBLOC Therapy: Intermittent, reversible electrical blocking signals to vagal nerve trunks
- Blocks, does not stimulate, naturally occurring vagus nerve signals

1. Gortz *et al.* Physiology and Behavior 1990; 48:775-781
2. Kral *et al.* World J Surgery 1993; 17:75-79

Proof-of-Concept Studies

Study Description		Key Findings	Reference
Nerve Electro-physiology	Rodent model	Application of 5000 Hz resulted in complete and reversible nerve block	Waataja *et al.* J Neural Eng 2011; 8:1-7
End-organ Function	Porcine model	Pancreatic exocrine secretion and gastric contractions significantly down-regulated with block	Tweden *et al.* *SOARD 2006; 2:301-302*
System Safety	Porcine model	Normal nerve function, Normal typical fascicle histology, No Wallerian degeneration	Tweden *et al.* *SOARD 2006; 2:301-302*

Clinical Mechanism of Action Studies

Study Description		Key Findings	Reference
Satiation	12 months 8 patients	Early fullness in maximum tolerable volume	Herrera *et al.* Gastroenterology 2009; 136:A-386
Food Intake	12 months 10 patients	Reduced calorie intake without changing dietary composition	Camilleri *et al.* Surgery. 2008; 143(6):723-31 Wray *et al.* Obesity 2011; 19:S190

Mechanism of Action Summary

- VBLOC is efficacious in blocking vagus nerve
- Effects observed across multiple mechanistic and clinical studies
- Calorie intake reduction consistent with vagus-mediated physiologic effects on hunger, fullness and food intake

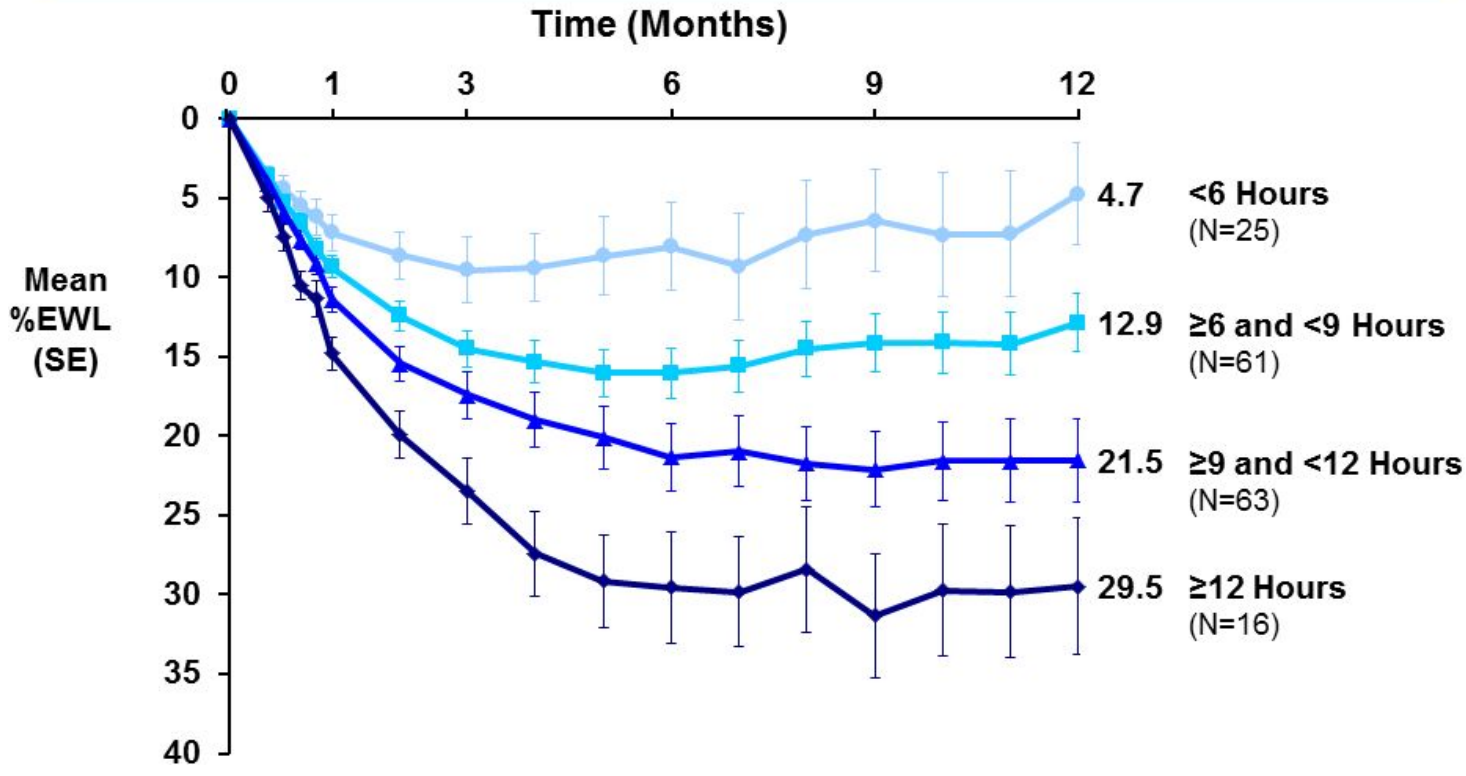
Prior Clinical Investigations EMPOWER and VBLOC-DM2

Prior Clinical Investigations EMPOWER and VBLOC-DM2

EMPOWER

- Double blind, Randomized N=294 (BMI 35-45)
- Initiated 2007
- Earlier "RF" Technology,
- ~50% did not comply with recommended 9 hours of use
- Patients >12 hours of device use achieved 25% EWL
- Demonstrated safety and tolerability of device

EMPOWER Mean %EWL (BMI method) by Average Hours of Use per Day at 12 Months in Treatment Group



Prior Clinical Investigations EMPOWER and VBLOC-DM2

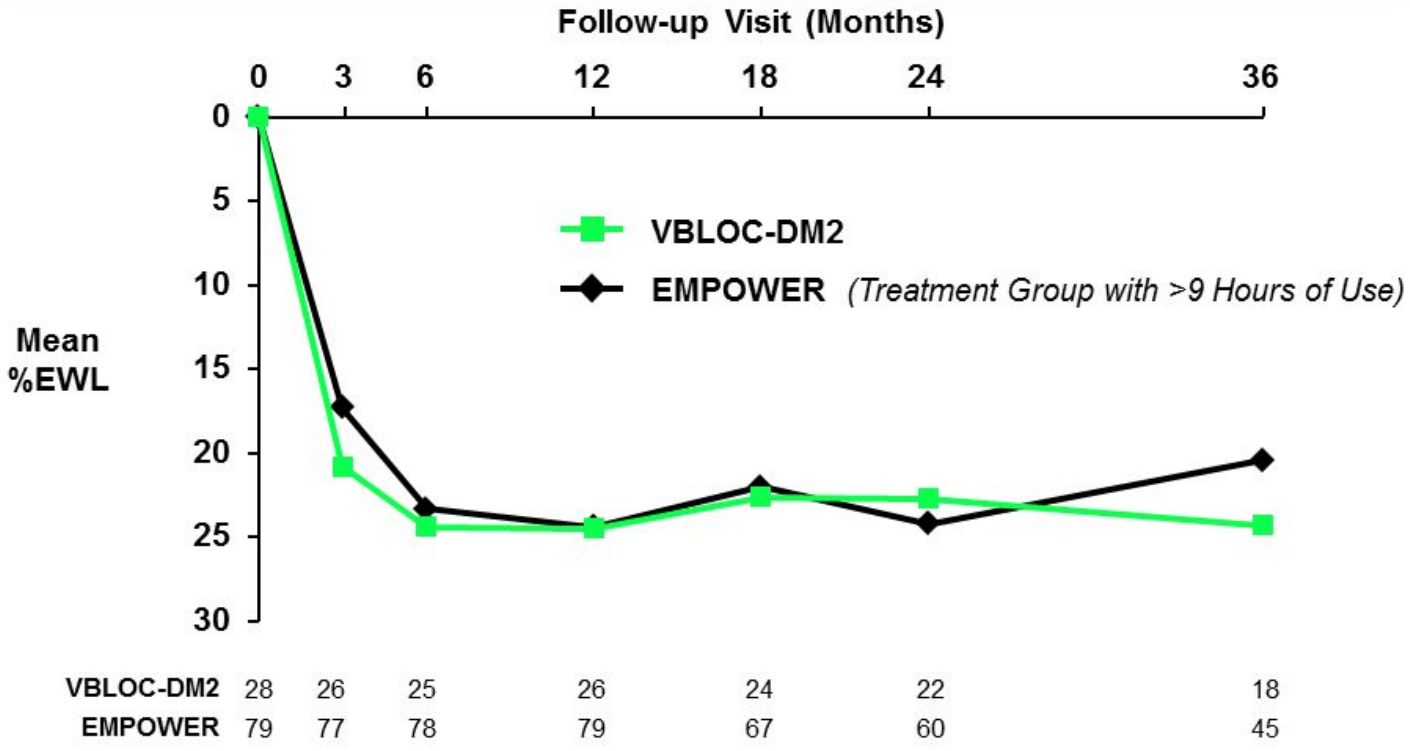
EMPOWER

- Double blind, Randomized N=294 (BMI 35-45)
- Initiated 2007
- Earlier "RF" Technology,
- ~50% did not comply with recommended 9 hours of use
- Patients >12 hours of device use lost 30% EWL
- Demonstrated safety and tolerability of device

VBLOC-DM2

- Open label, single arm N=28; Type 2 Diabetes (BMI 30-45)
- Initiated 2008
- Current MAESTRO Device Successfully resolved the inconsistent therapy delivery observed in EMPOWER
- Mean weight loss of 24.5% EWL at 12 months
- Demonstrated safety and tolerability of device

Weight Loss in VBLOC-DM2 and the EMPOWER through 36 Months

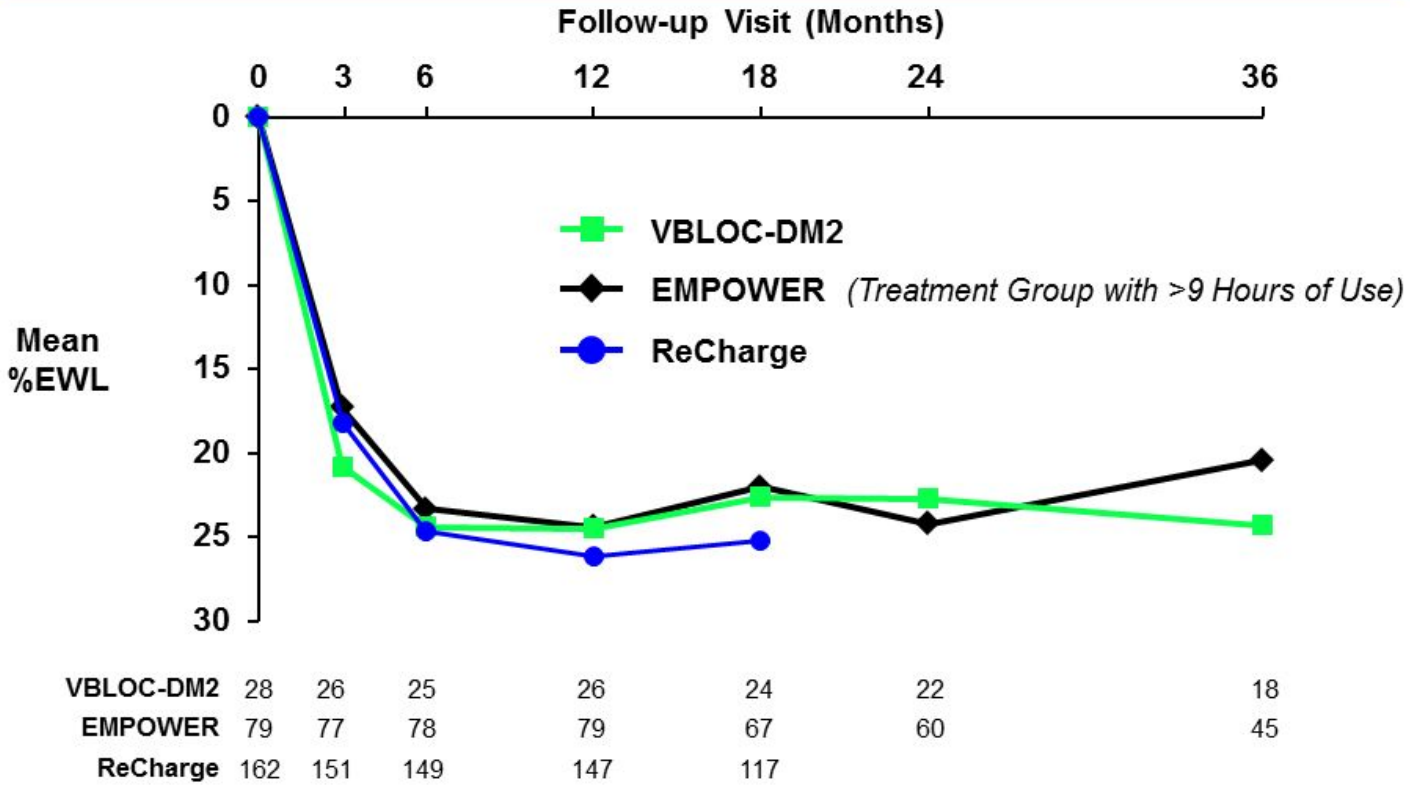


Observed Case

ReCharge Trial Overview

- Five-year randomized, double-blind, multi-center, sham-controlled study
- Effectiveness
  - Pre-specified super-superiority and responder objectives not met
  - Significantly greater weight loss compared to Sham Control was achieved
  - Improvements in comorbid conditions

Weight Loss in VBLOC-DM2 and the EMPOWER through 36 Months



VBLOC-DM2	28	26	25	26	24	22	18
EMPOWER	79	77	78	79	67	60	45
ReCharge	162	151	149	147	117		

Observed Case

EMPOWER and VBLOC DM-2: SAE Rates Related to Device, Implant/Revision or Therapy

	% Patients (N)	Kaplan-Meier Estimate % (N at risk)	
Time Point	ReCharge	EMPOWER	VBLOC DM-2
12 Months	3.7% (162)	3.1% (181)	3.6% (28)
24 Months	-	4.3% (134)	7.1% (27)
36 Months	-	6.0% (90)	7.1% (21)

- No deaths or unanticipated adverse device effects

MAESTRO: Agenda

Maesto Implant Procedure and ReCharge Trial Efficacy Results	**Scott Shikora, M.D.** Chief Consulting Medical Officer Section Chief of Bariatric Surgery Brigham and Women's Hospital
ReCharge Trial Safety Results	**Bruce Wolfe, M.D.** Professor of Surgery Oregon Health & Science University
Training **Controlled Distribution** **Post-Approval Registry**	**Mark B. Knudson, PhD** President and Chief Executive Officer EnteroMedics Inc
Closing Remarks	**Caroline M. Apovian, M.D.** Professor of Medicine, Boston University School of Medicine Director, Nutrition & Weight Management Center Boston Medical Center

ReCharge Trial
VBLOC Therapy

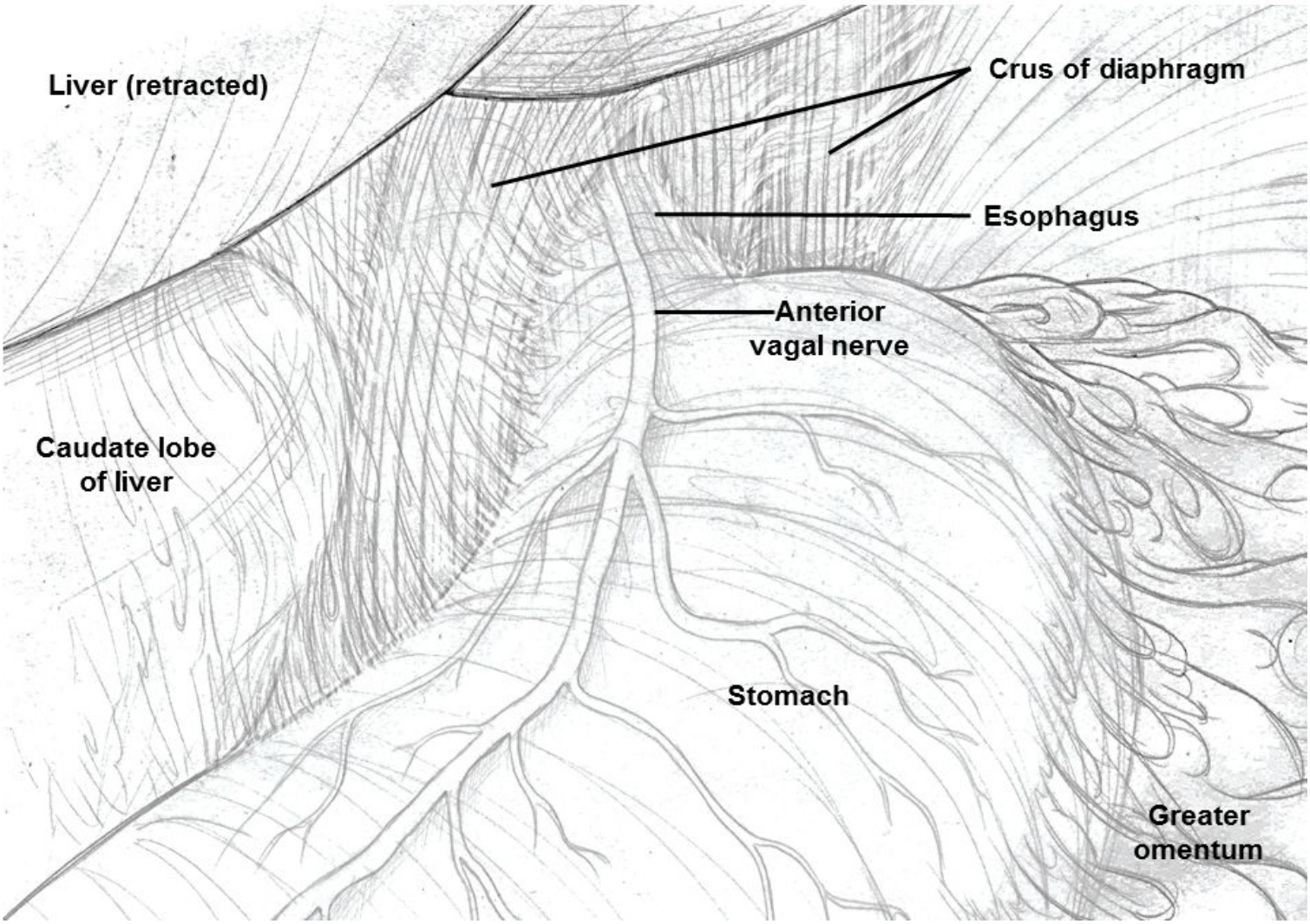
Scott Shikora, M.D.

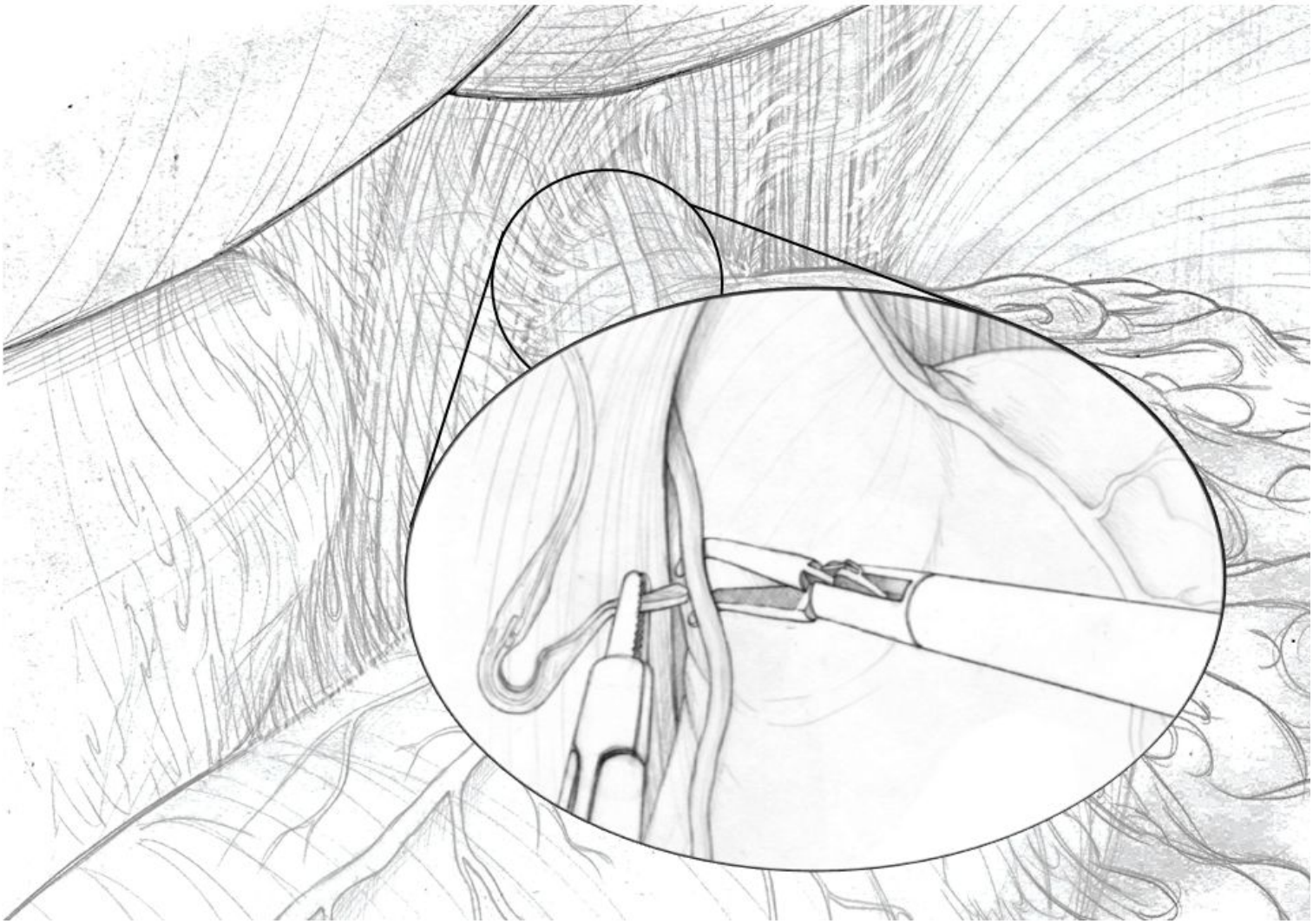
Chief Consulting Medical Officer, EnteroMedics Inc.

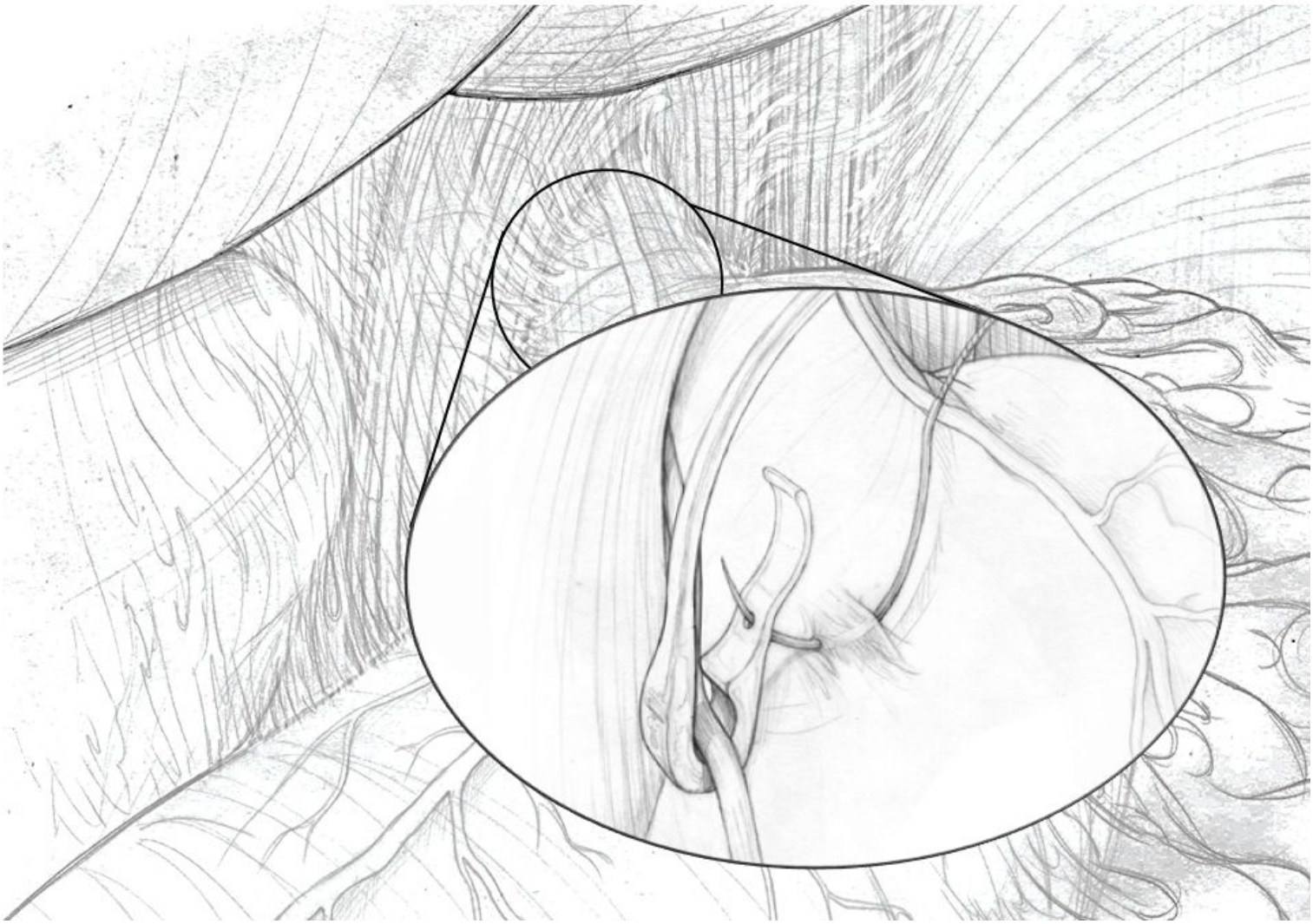
Associate Professor of Surgery, Harvard Medical School

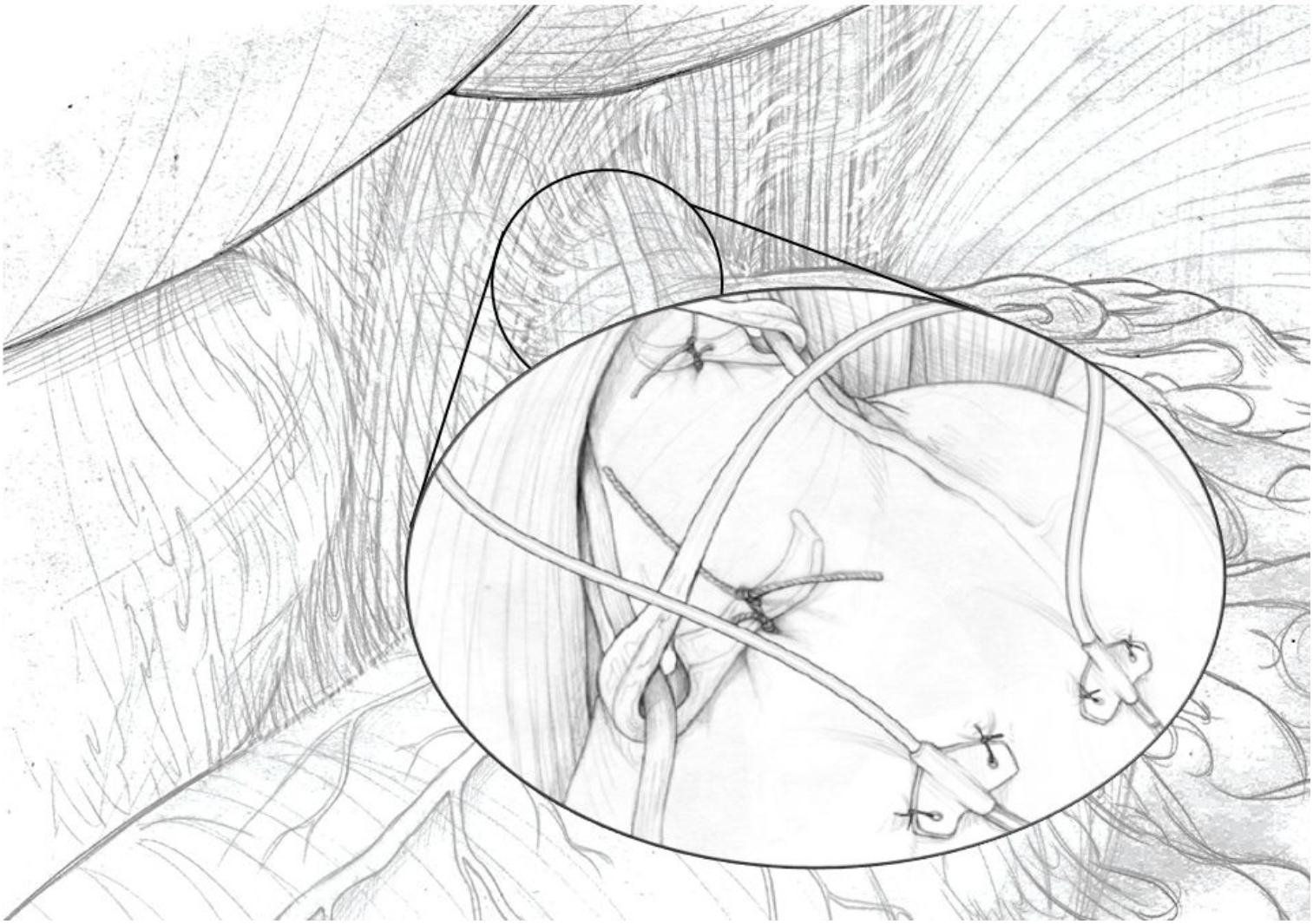
Director of Bariatric Surgery, Brigham and Women's Hospital

Past President ASMBS


Liver (retracted)
Crus of diaphragm
Esophagus
Anterior
vagal nerve
Caudate lobe
of liver
Stomach
Greater
omentum







ReCharge: 5-Year, Randomized, Double Blind, Sham-Controlled, Multicenter Trial

VBLOC Group

2:1 Randomization

Blinded	Un-blinded			
Year 1	Year 2	Year 3	Year 4	Year 5
17 visits	12 visits	6 visits	6 visits	6 visits
Primary Endpoint Assessment at Month 12 Visit				
• Weight, vital signs, adverse events, medication use at each visit • Clinical labs at screening, 6 months, annually • Patient Reported Outcomes at Screening, month 3 and every 6 months • ECGs at screening, 4, 8, 12 months				

Sham Control Group

Sham eligible to receive VBLOC

Sham Patients Received Virtually Identical Procedure and Follow-up

	VBLOC	Sham Control
Anesthesia	✓	✓
Trocar incisions	✓	✓
Leads implanted	✓	
Neuroregulator implanted	✓	✓
Battery depletion	✓	✓
Interaction with clinical programmer	✓	✓
Interaction with mobile charger	✓	✓
Follow-up visits	✓	✓

Key Inclusion Criteria

- Ages 18-65
- BMI:
  - ≥40 kg/m^2 to <45 kg/m^2 or
  - ≥35 kg/m^2 and ≥1 obesity related comorbid condition
- Patients with diabetes, limited to 10% of enrollment
- Failed supervised diet/exercise program in last 5 years

Key Exclusion Criteria

- History of bariatric surgery, gastric resection, major upper abdominal surgery
- Genetic cause of obesity
- History of Crohn's Disease and/or ulcerative colitis
- More than 10% weight loss in last 12 months
- History of psychiatric disorders
- Significant disease or other serious illness

Co-Primary Efficacy Objective #1 %EWL VBLOC vs. Sham at Month 12

- Mean %EWL in VBLOC vs. Sham groups
  - Demonstrate superiority in mean %EWL at a margin of 10% (super-superiority)
- Design assumptions
  - 25% EWL in VBLOC arm
  - 5% EWL in Sham Control arm
- Super-superiority design selected to address concern that sham arm would gain weight on average

Co-Primary Efficacy Objective #2 Responder Rate at Month 12

- Responder rates in %EWL in the VBLOC arm
  - 55% of VBLOC patients achieve ≥20% EWL
  - 45% of VBLOC patients achieve ≥25% EWL
- Design assumptions
  - Targets based on VBLOC DM-2 responder rates

Disposition of all Enrolled, Randomized, and Implanted Patients

Randomized N=239		
VBLOC		Sham Control
162	ITT Population	77
5	Withdrawals Before Implant Subject/Surgeon Decision, Operative Exclusions or Comorbid Conditions	1
157	Implanted	76
	Withdrawals After Implant	
1	Adverse Event	3
2	Lost to Follow-up	0
0	Subject Decision	3
7	Missed 12-Month Visit	4
147 (91%)	Completed 12-Month Visit	66 (86%)
1	Delayed Activation	0
0	Not Implanted as Randomized	1
146	Per Protocol Population	65

Baseline Demographics

	VBLOC	Sham Control
Age (Mean ± SD)	47.1 ± 10.3	46.6 ± 9.4
Female	87.0%	80.5%
Race		
Caucasian	92.0%	94.8%
African American	4.9%	3.9%
Other	3.1%	1.3%
Type 2 Diabetic	5.6%	7.8%
Obese before Adulthood	44%	52%

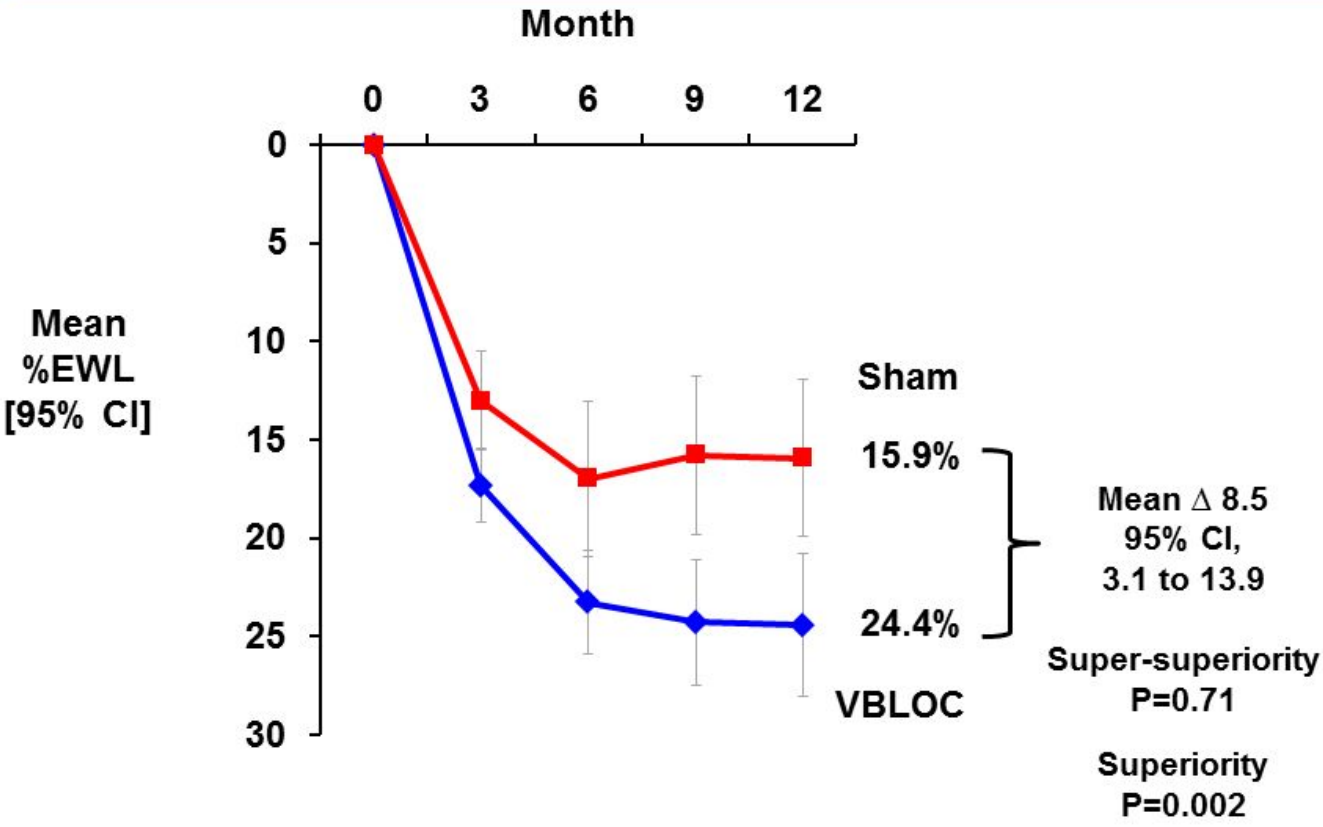
Baseline Demographics

	VBLOC Mean ± SD (Range)	**Sham Control** Mean ± SD (Range)
BMI (kg/m^2)	**41 ± 3** (34-46)	**41 ± 3** (35-48)
Weight (lbs)	**247 ± 29** (175-349)	**254 ± 31** (196-352)
Excess weight, BMI method (lbs)	**96 ± 19** (51-161)	**99 ± 21** (59-145)
Waist circumference (in)	**48 ± 5** (36-60)	**48 ± 4** (39-58)

Co-Primary Endpoint 1

Difference Between Groups in Mean Percent Excess Weight Loss at 12 Months

Co-Primary Endpoint: Mean % EWL Between Groups at 12 Months

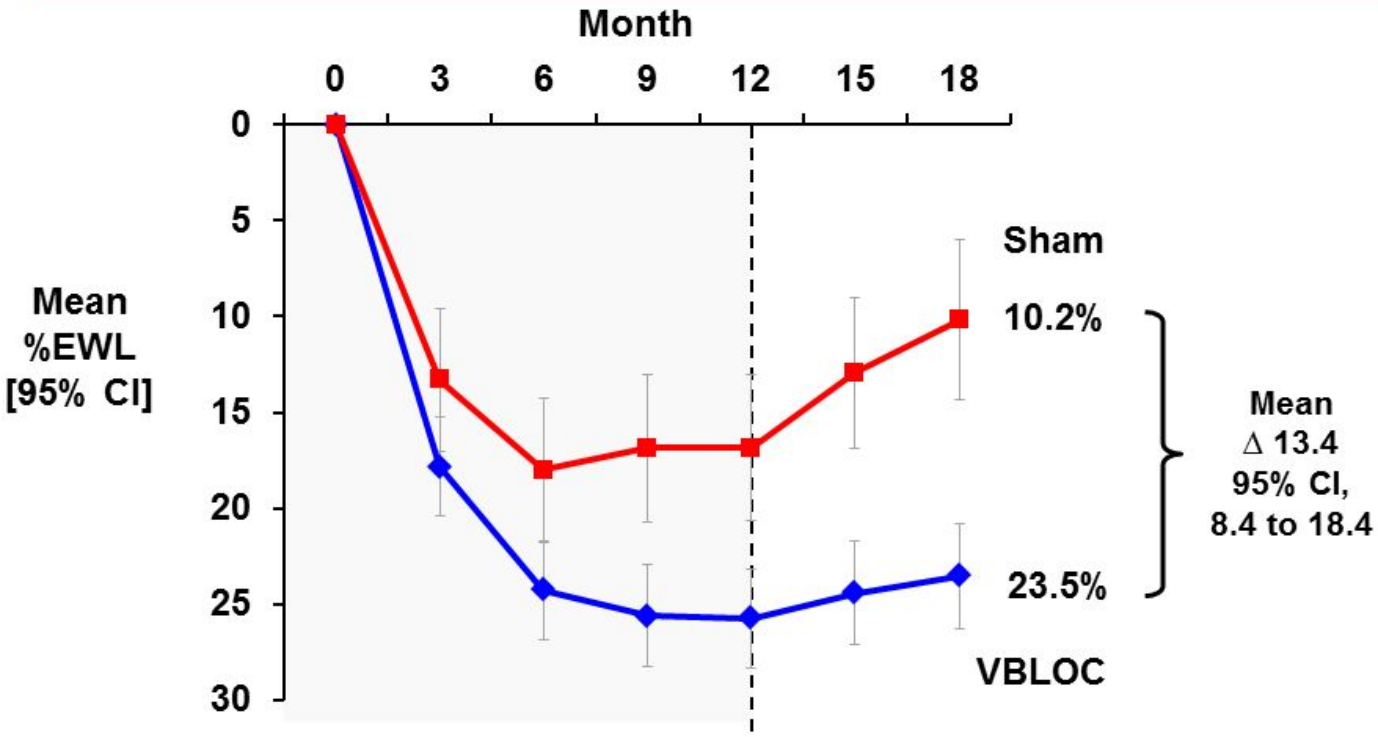


ITT Population LOCF; Error bars represent 95% confidence intervals

Durability of Effect

- 18-month results
- Most patients unblinded 16 months or later
- No cross-overs from Sham to VBLOC occurred prior to 18 months

Results at 18 Months Demonstrate Durability of VBLOC Therapy



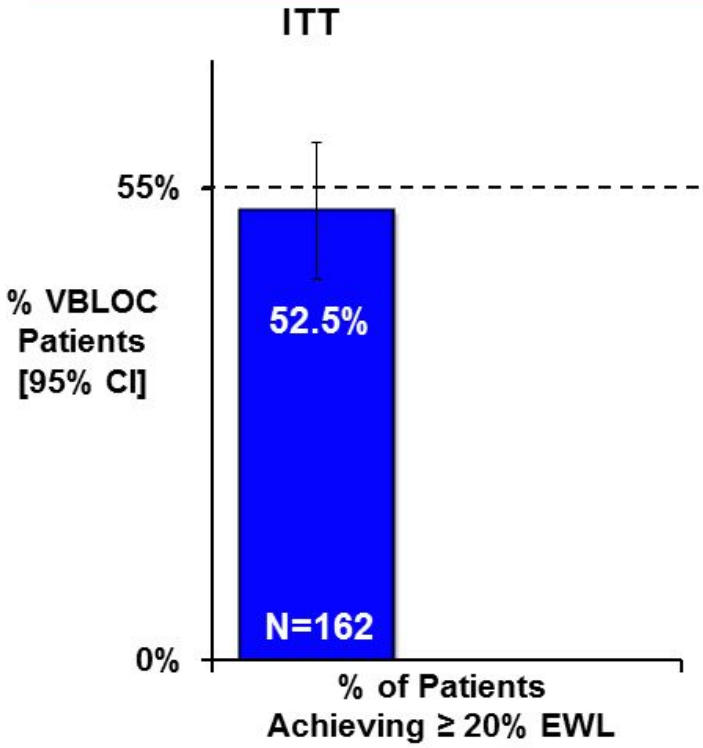
ITT – Mixed Effects Model; Median Time to Unblinding: 16 Months

Co-Primary Efficacy Objective #2

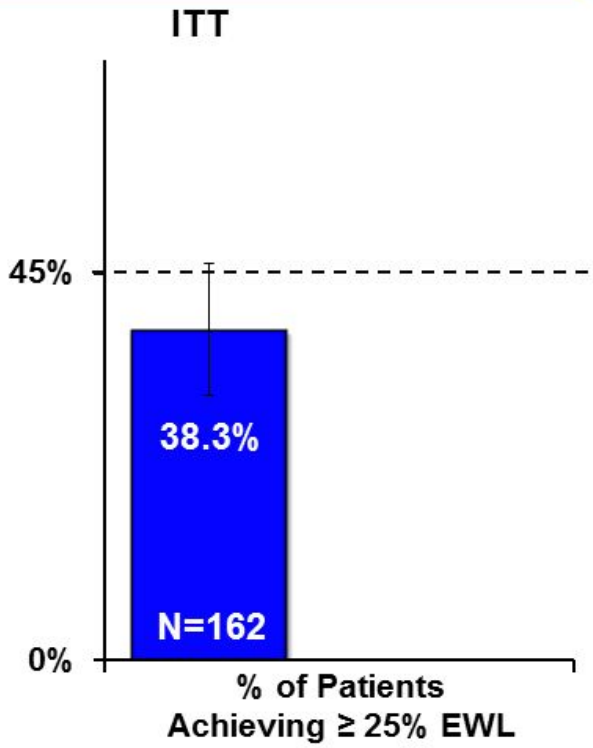
VBLOC group responder rates

- 55% of patients achieve ≥20% EWL
- 45% of patients achieve ≥25% EWL

Percent of VBLOC Patients Achieving 20% and 25% EWL at 12 Months

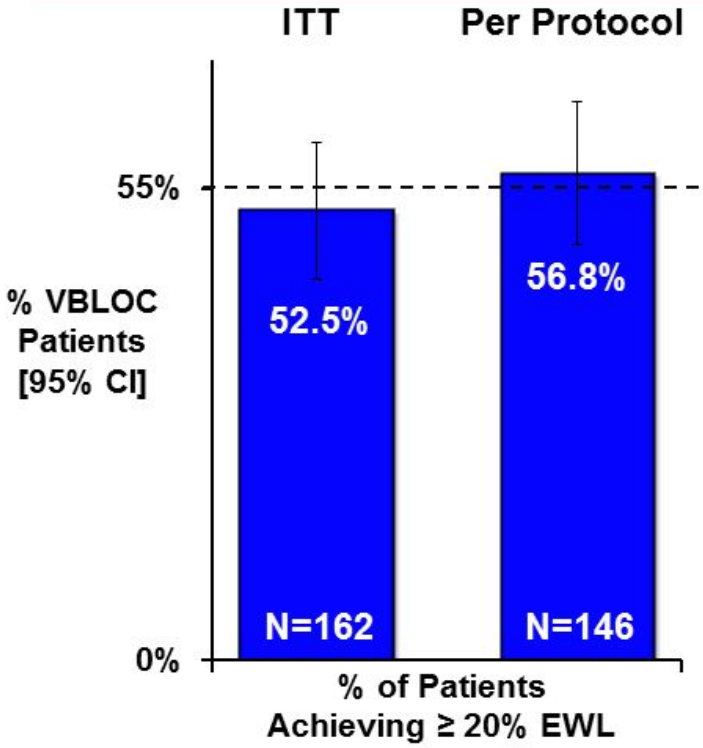


Note: 20% EWL ≈ 7.5% TBL

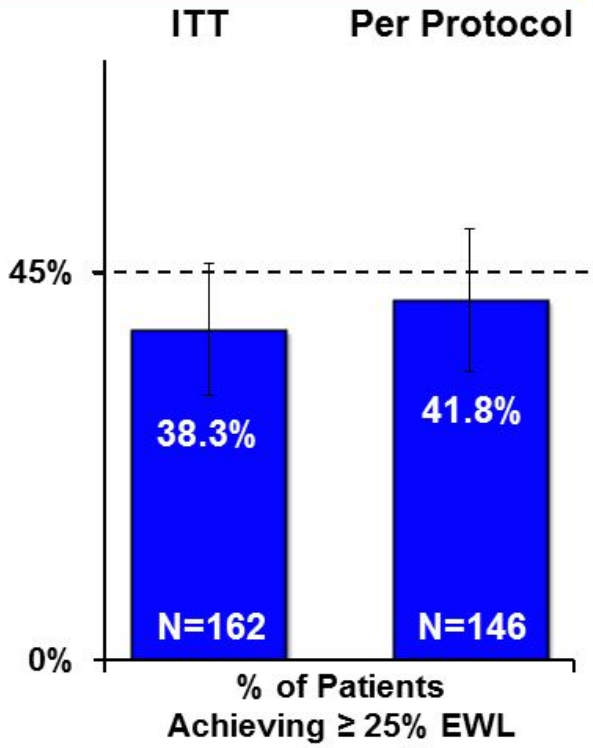


Note: 25% EWL ≈ 9.4% TBL

Percent of VBLOC Patients Achieving 20% and 25% EWL at 12 Months

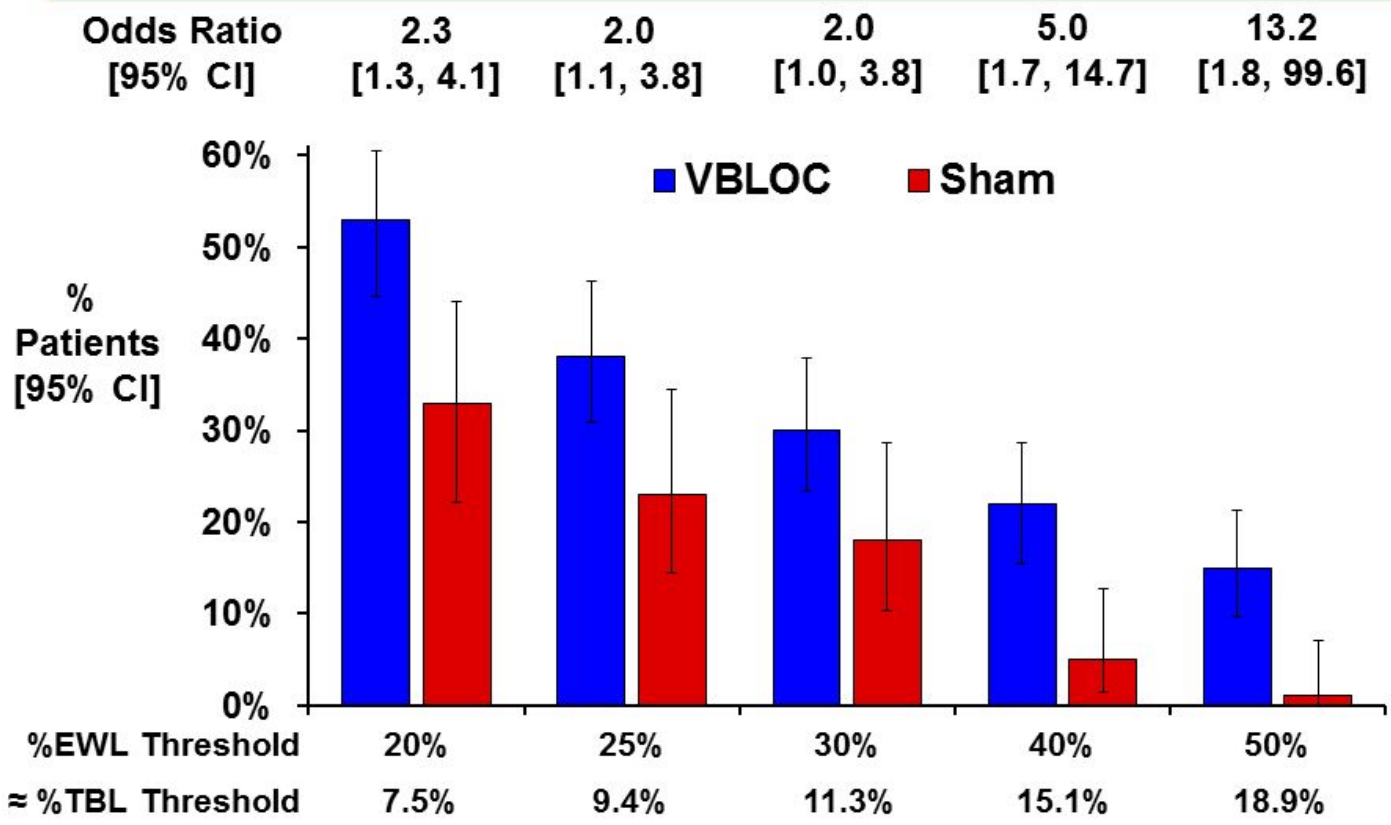


Note: 20% EWL ≈ 7.5% TBL



Note: 25% EWL ≈ 9.4% TBL

Magnitude of VBLOC Beneficial Effect Over Sham Increases at Higher Thresholds



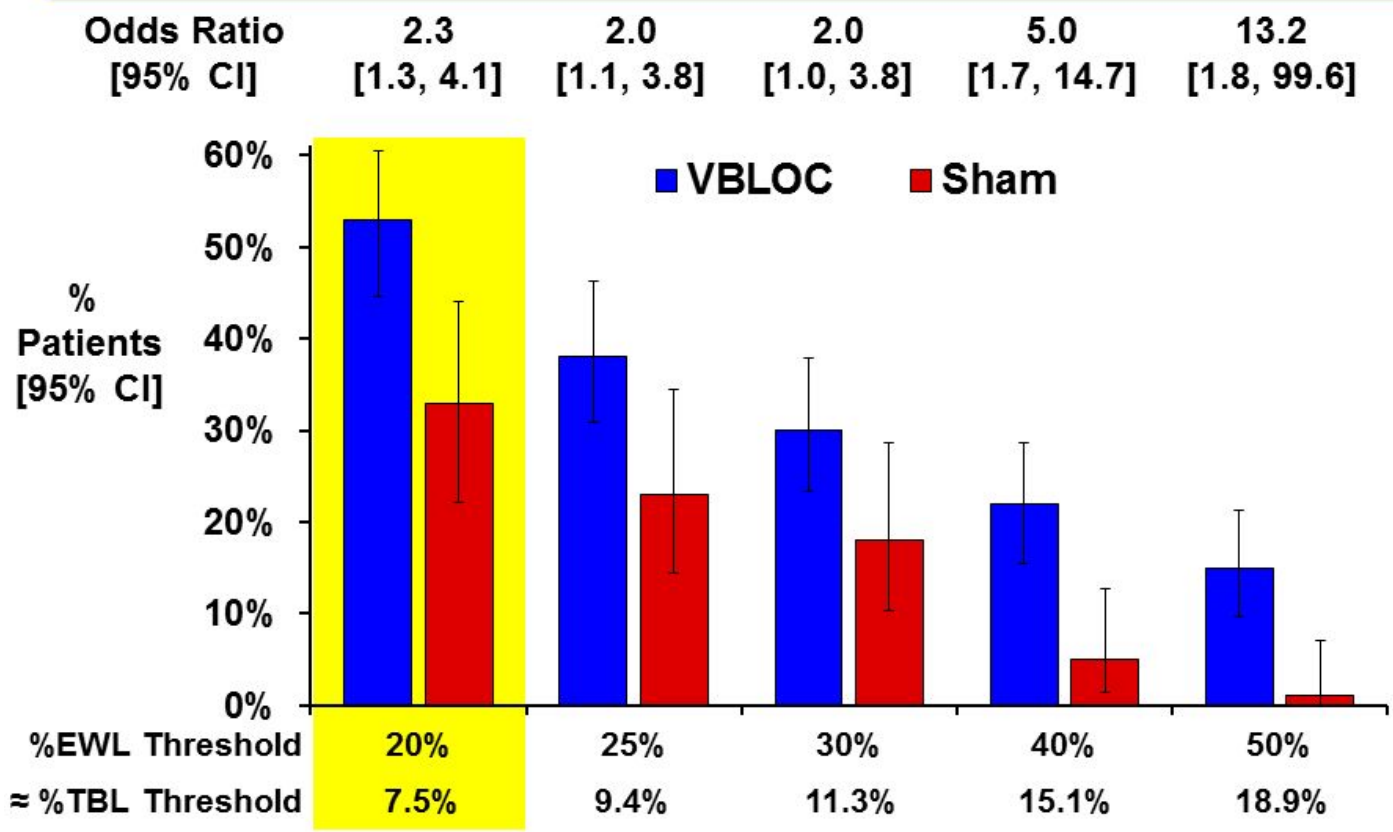
ITT Population, LOCF

Clinical Relevance

Current Practice Guidelines Endorses Beneficial Effects of 5% Total Body Weight Loss

- 2013 AHA/ACC/TOS Guidelines for the Management of Overweight and Obesity in Adults (November 2013)
- >5% total body weight loss leads to:
  - Improvements in blood pressure
  - Increases in HDL-C
  - Reduction in triglycerides and LDL-C
  - Reduction in hypertensive medications

VBLOC Patients Achieved Higher %EWL at 12 Months



ITT Population, LOCF

Clinically Relevant Changes in Risk Factors for VBLOC Patients Achieved

Risk Factor	VBLOC Mean Change		
	All Patients	7.5% TBL	10% TBL
Systolic BP (mmHg)	-5	-8	-9
Diastolic BP (mmHg)	-3	-5	-6
Heart Rate (bpm)	-4	-4	-6
Total Cholesterol (mg/dL)	-9	-12	-15
LDL (mg/dL)	-5	-8	-9
Triglycerides (mg/dL)	-21	-32	-41
HDL (mg/dL)	1	2	3
Waist circumference (inches)	-4	-6	-7
HbA1c (%)	-0.3	-0.5	-0.5

Post Hoc Analysis, As-Observed

VBLOC Patients: Measures of Pre-Diabetes Improves with Weight Loss

Pre-Diabetic: FPG ≥ 100 mg/dL, OR HbA1c ≥ 5.7% Normal: FPG <100 mg/dL AND HbA1c <5.7%	VBLOC at 12 months
Pre-diabetic at Baseline (N=55)	
Pre-diabetic	42%
Normal	58%
Normal at Baseline (N=55)	
Pre-diabetic	13%
Normal	87%

Medication Changes at 12 Months for VBLOC Patients

- Hypertension Medications (N=58)
  - 22% discontinued or decreased
  - 10% increased
- Diabetes Medications (N=8)
  - 50% decreased
  - 0% increased

Summary of Efficacy Data

- Rigorous, double-blind, sham-controlled trial
- Super-superiority of 10% not achieved
- Superiority over Sham achieved (P=0.002)
- Majority of VBLOC patients achieved clinically significant weight loss
- VBLOC patients maintained weight loss through 18 months
- VBLOC therapy led to sustained, significant improvements in many patients:
  - Reduction in obesity risk factors
  - 58% of pre-diabetic patients improved to normal

ReCharge Safety

Bruce Wolfe, M.D.

Professor of Surgery, Oregon Health & Science University

Steering Committee Chair, Longitudinal Assessment of Bariatric Surgery Consortium

Past President, ASMBS

Safety Summary

- Primary safety endpoint achieved:
  - Primary SAE rate of 3.7%
  - Significantly below pre-specified 15% performance goal ($p<0.0001$)
- 98% of AEs related to VBLOC were mild or moderate in severity
- 79% of AEs related to VBLOC resolved
- All AEs not resolved at 18 months were mild or moderate

Review of SAEs

Definition and Determination of Serious Adverse Events (SAEs)

- Protocol used FDA SAE definition
  - Death or serious deterioration resulting in:
    - In-patient hospitalization or prolongation of existing hospitalization
    - Life-threatening illness or injury
    - Permanent impairment of body structure or function
    - Medical or surgical intervention to prevent permanent impairment to body structure or function
- Clinical Events Committee adjudicated origin of all SAEs

SAEs Adjudicated by Clinical Events Committee (CEC)

- Origin of event
  - Device
  - Therapy algorithm
  - Implant/revision procedure
  - General surgical procedure
  - Pre-existing condition
  - Not related/other

All SAEs in VBLOC through 12 Months

- Nausea (6)
- Gallbladder disease (2)
- RNR malfunction (2)
- Pain, other (2)
- Abdominal Pain (1)
- Atelectasis (1)
- Chest pain (1)
- Cirrhosis (1)
- Colitis (1)
- Emesis / vomiting (1)
- Generalized ileus (1)
- Gastroenteritis (1)
- Intra-operative oozing (1)
- Osteoarthritis (1)
- Pain, neuroregulator site (1)
- Palpitations (1)
- Pericarditis (1)

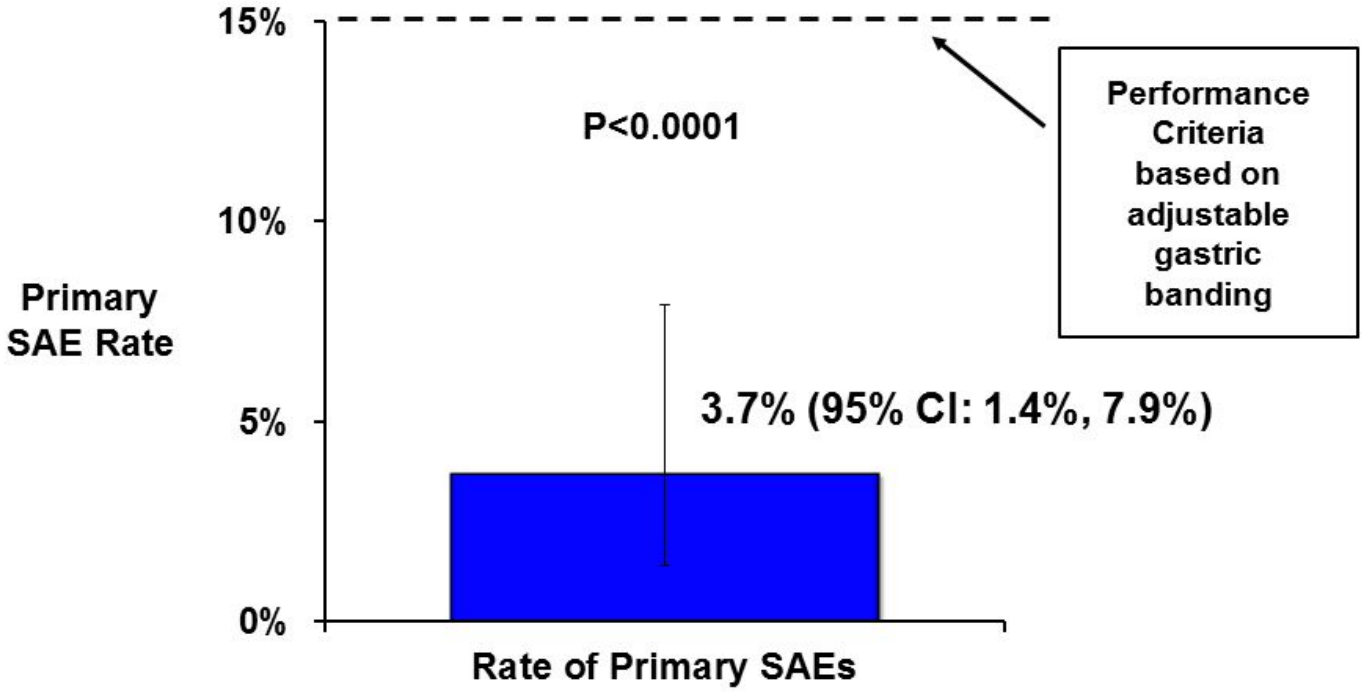
ReCharge Trial: Primary Safety Objective at 12 Months

- Implant/revision procedure, device, or therapy-related SAE rate <15% among VBLOC patients
- 15% performance goal based on FDA labeling for adjustable gastric band devices

SAEs for Primary Safety Endpoint

Subject ID	SAE Description	Treatment	Notes
301-303	Neuroregulator Malfunction	Neuroregulator replaced	Patient hospitalized overnight
311-319	Neuroregulator Malfunction	Neuroregulator replaced	Patient hospitalized overnight
301-325	Pain Neuroregulator Site	Neuroregulator repositioned	80% EWL, resulting in pain at neuroregulator, site Patient hospitalized overnight
311-309	Atelectasis	Pain and anti-emetic medications	Discharged Day 3
317-309	Emesis (Vomiting)	Hernia repair 1 day post-implant	Discharged Day 2 after repair
313-323	Gallbladder Disease	Cholecystectomy	20% EWL, possibly related to therapy

Prespecified Safety Objective Met



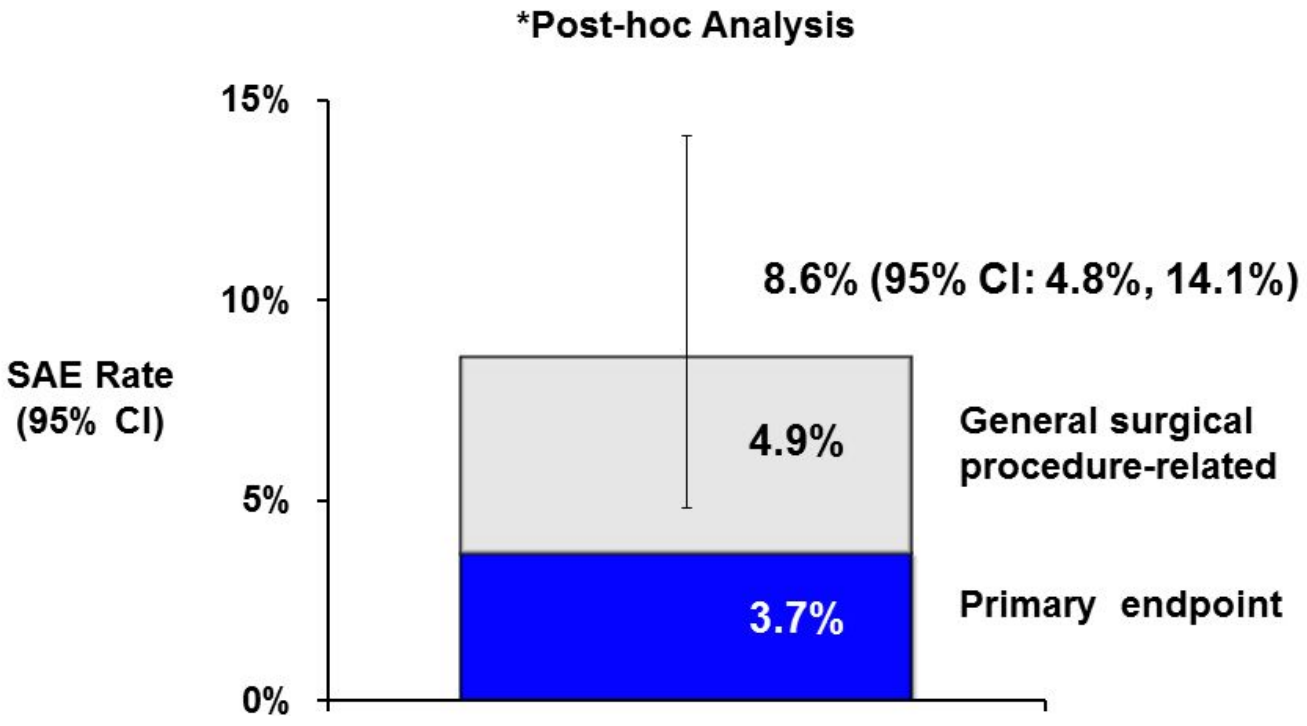
Error bar represent 95% confidence interval

Serious Adverse Events Related to General Surgical Procedure

- Nausea (6)
- Intra-operative oozing (1)
- Generalized ileus (1)
- Events resolved within 14 days post procedure without further sequelae

- Cirrhosis (1)
  - Not implanted, delayed discharge

SAE Safety Endpoint + General Surgical Procedures SAEs



Surgical Revisions and Explants

Surgical Revisions Through Month 12

	VBLOC	Sham Control
	N patients (%)	N patients (%)
Revision rate	8 (4.9%)	0 (0.0%)

	VBLOC	Sham Control
Reasons for revision	N events	N events
Neuroregulator malfunction	4	0
Pain at neuroregulator site	3	0
Neuroregulator tilt	2	0

Note: One patient had two revisions

Device Explants Through Month 12

	VBLOC	Sham Control
	N patients (%)	N patients (%)
Explant rate	5 (3.1%)	8 (10.4%)

	VBLOC	Sham Control
Reason for explant	N events	N events
Patient decision	3	4
Pain at the neuroregulator site	1	1
Heartburn	1	0
MRI for shoulder pain	0	1
Worsening IBS symptoms	0	1
Cancer diagnosis	0	1

Adverse Events

Related AEs Attributed Primarily to Implant/Revision Procedure or Device

AE Type	VBLOC			Sham Control		
	Patients with Event through 12 Months	Events Mild to Moderate	Events Resolved through 18 Months	Patients with Event through 12 Months	Events Mild to Moderate	Events Resolved through 18 Months
Pain, neuroregulator site	38%	96%	84%	42%	100%	83%
Nausea	7%	86%	100%	1%	100%	100%
Dysphagia	8%	100%	77%	0%	-	-
Incision pain	7%	100%	100%	9%	100%	100%

Note: events reported by ≥5% of patients in VBLOC group. % resolved is based on those AEs resolved before 18m data lock.

Details of Related AEs in VBLOC Patients Attributed Primarily to Implant/Revision Procedure or Device

AE Type	Patients with Event through 12 Months	Events			
		Mild to Moderate	Resolved through 18 Months	Median days to Onset	Median duration (days)
Pain, neuroregulator site	38%	96%	84%	21	23
Nausea	7%	86%	100%	1	5
Dysphagia	8%	100%	77%	7	25
Incision pain	7%	100%	100%	0	22

Note: events reported by ≥5% of patients in VBLOC group

Related AEs Attributed Primarily to Therapy

AE Type	VBLOC			Sham Control		
	Patients with Event through 12 Months	Events Mild to Moderate	Events Resolved through 18 Months	Patients with Event through 12 Months	Events Mild to Moderate	Events Resolved through 18 Months
Heartburn/dyspepsia	24%	100%	55%	4%	100%	100%
Pain, other	23%	100%	69%	0%	-	-
Pain, abdominal	12%	100%	89%	3%	100%	100%
Eructation/belching	8%	100%	69%	0%	-	-
Chest pain	6%	100%	67%	3%	100%	100%

Note: events reported by ≥5% of patients in VBLOC group

Details of Related AEs in VBLOC Patients Attributed Primarily to Therapy

AE Type	Patients with Event through 12 Months	Events			
		Mild to Moderate	Resolved through 18 Months	Median days to Onset	Median duration (days)
Heartburn/dyspepsia	24%	100%	55%	124	51
Pain, other	23%	100%	69%	24	26
Pain, abdominal	12%	100%	89%	78	22
Eructation/belching	8%	100%	69%	11	88
Chest pain	6%	100%	67%	32	4

Note: events reported by ≥5% of patients in VBLOC group

Non-Gastrointestinal AEs

Preferred Term Investigator Assessment	Comment	Severity	Resolved?	Medical Treatment Required?
Cardiac Abnormality Not-related	Sinus arrhythmia related to pre-existing condition	Mild	Yes	No
Lightheadedness Possibly related	Pulse rate 81; no ECG	Mild	Yes	No
Lightheadedness Not related	Pulse rate 73; no ECG	Mild	Yes	No
Bradycardia Possibly related	Pulse rate 71; ECG 59 bpm	Mod	Yes	No
Bradycardia Unknown	Pulse rate 80; ECG 50 bpm	Mild	Ongoing at explant	No
Bradycardia Possibly related	Pulse rate 64; ECG 54 bpm	Mild	Ongoing	No

Safety Data through 18 Months

- Safety profile through 18 months is similar to what was observed through 12 months
- 6 additional SAEs related to pre-existing conditions: chest pain (3), infection (1), bladder cancer (1), respiratory abnormality (1)
- One additional related SAE
  - Gastric perforation during explant
    - Root cause identified
    - Corrective action implemented

Safety Summary

- Primary safety endpoint achieved:
  - SAE Rate of 3.7%, significantly below 15% performance goal ($P<0.0001$)
- 98% of AEs related to VBLOC were mild or moderate in severity
- 79% of AEs related to VBLOC through 12 months were resolved
- All related AEs not resolved at 18 months were mild or moderate

Training
Controlled Distribution
Post-Approval Studies

Mark B. Knudson, PhD

President and Chief Executive Officer

EnteroMedics Inc

Center Certification Criteria

- Trained / experienced staff
  - Project Manager
  - Clinical Coordinator
  - Follow-up Nurse
- Experienced laparoscopic surgeon(s)
- Patient follow-up program
- Quality control program

Surgeon Certification Process

- Didactic
  - Review of procedures and clinical data
  - Interactive training with components, device and leads
  - Video review of example procedures – including explants
- Operating room
  - Implant training
    - Live or recorded
    - Proctored cases
  - Explant procedure training
- Provisional certification following this training

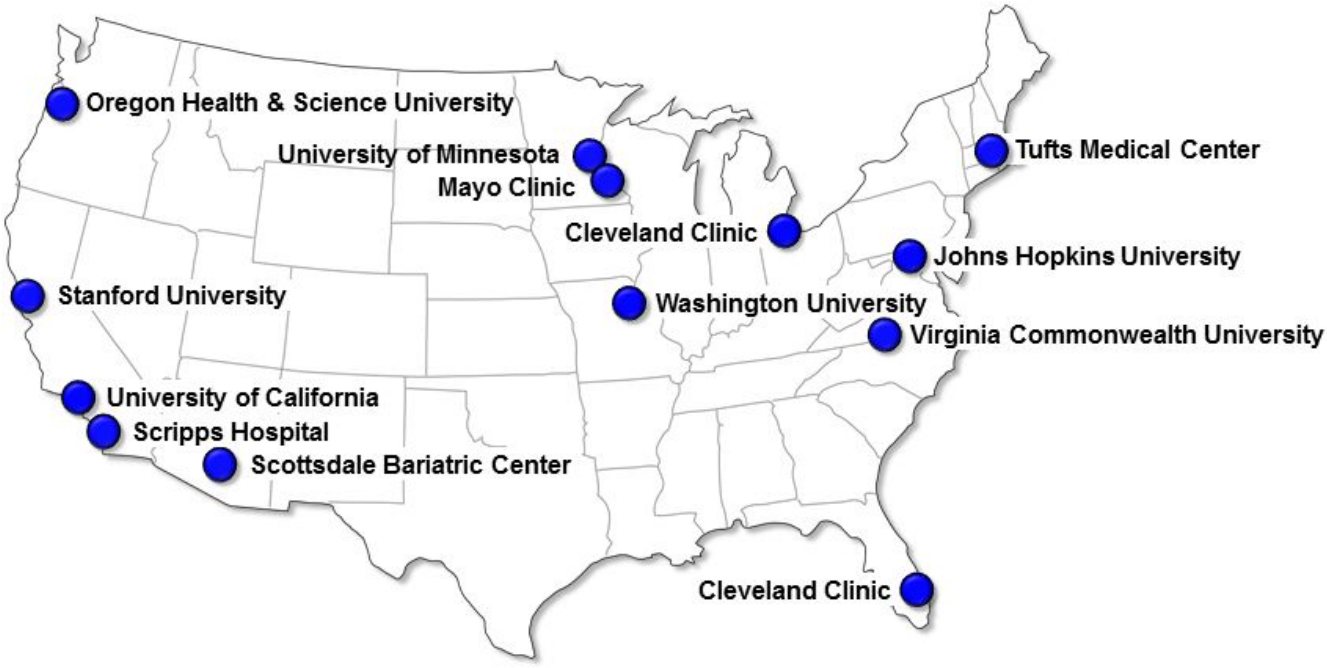
Surgeon Certification Process

- Required Final Certifications
  - Implant
    - Video review of implants by surgeon trainer
    - Outcomes database in place
  - Explant
    - Proctored removal procedure (explant)
    - Record of any explant required for maintenance of certification

Magnetic Resonance Imaging (MR) Maestro System Safety

- Patient and physician training program are part of Instructions for Use
- Patients given an Identification Card with MR warning
  - Registration with the MedicAlert Foundation or an equivalent organization is recommended
- Representation from the American College of Radiology MR Safety Committee has agreed that a question addressing the neuroregulator and leads (including remnants) will be included in their MR Safety Screening Worksheet

Controlled US Distribution to Current VBLOC Centers



Post-Approval Study ReCharge Continued Through 5 years

- Follow-up:
  - Monthly during Year 2
  - Bi-monthly during Years 3-5
- Weight, vital signs, adverse events, medication use, IWQoL, TFEQ, VAS, BDI
- Weight management sessions continued

Post Approval Registry

- Prospective, 5-year, multicenter, single-arm registry
- 500 patients at up to 25 centers in the United States
- 50% enrollment from new sites

Post Approval Registry

- Safety objectives
  - Evaluate 5-year related SAE rate
  - Evaluate 5-year therapy-related AE rate
  - Evaluate 5-year device malfunction rate
- Training objectives
  - Evaluate surgical revision rates
  - Evaluate implant procedure time
- Efficacy objectives
  - Evaluate mean %EWL through 5 years
  - Evaluate 20% and 25% EWL responder rates through 5 years
- Annual updates to the FDA

Concluding Remarks
Safety, Efficacy and Benefit / Risk

Caroline M. Apovian, M.D.

Professor of Medicine, Boston Univ. School of Medicine
Director, Nutrition & Weight Management Center
Section of Endocrinology, Diabetes and Nutrition,
Department of Medicine, Boston Medical Center

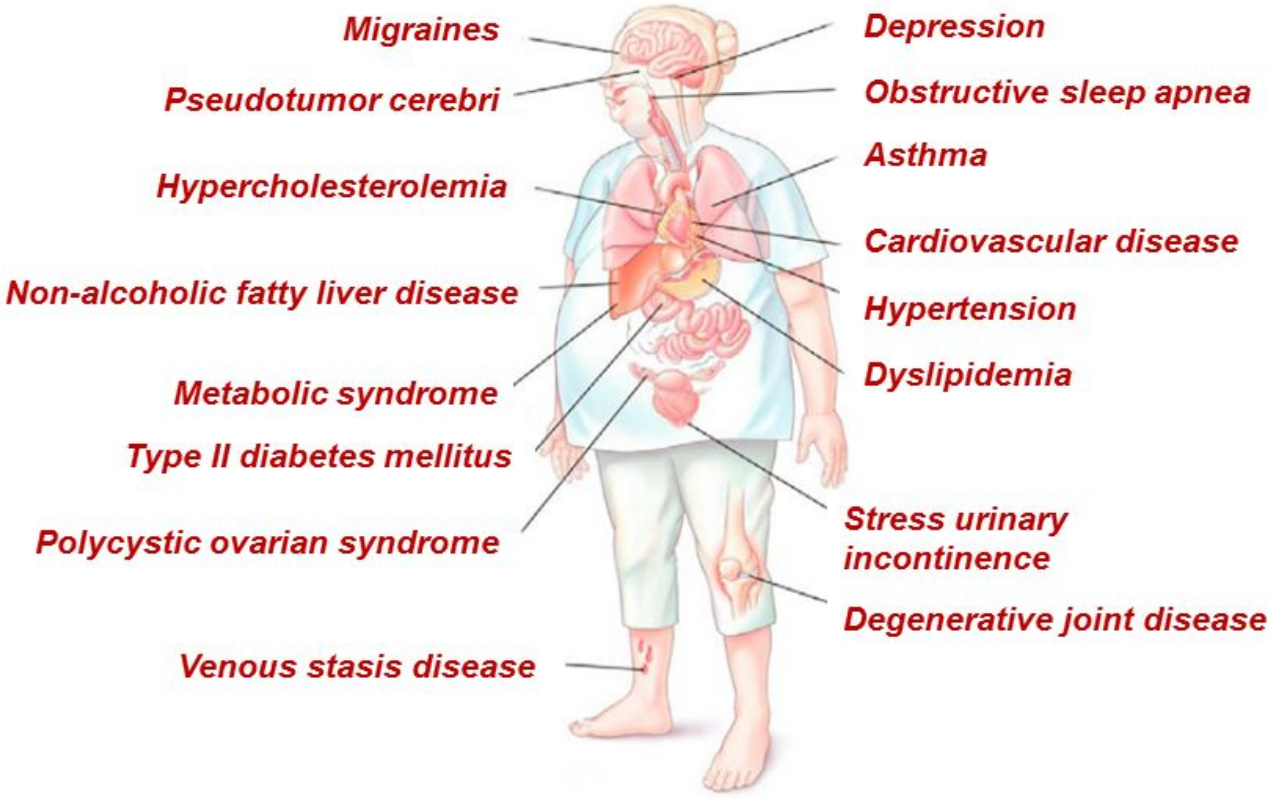
Obesity – The Defining Health Challenge of our Age

Obesity is a Disease

Obesity is a Disease

"…doctors should consider obesity a disease and more actively treat obese patients for weight loss. The guidelines reflect the latest information that scientists have about weight loss to prevent heart disease and stroke, the nation's No. 1 and No. 4 killers."

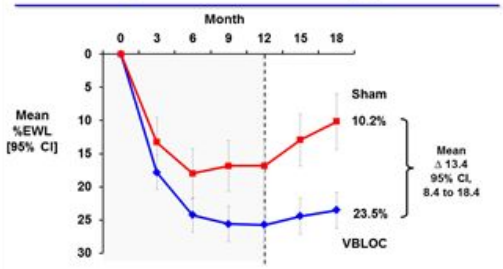
Numerous Comorbidities Are Associated With Obesity



Clinically Significant Weight Loss Achieved by the Majority of Patients Treated With VBLOC

CO-40

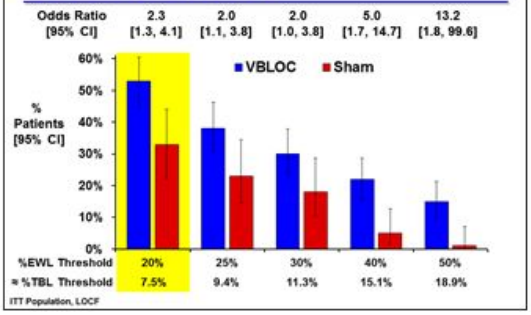
Results at 18 Months Demonstrate Durability of VBLOC Therapy



ITT – Mixed Effects Model, Median Time to Unblinding: 16 Months

CO-47

VBLOC Patients Achieved Higher %EWL at 12 Months



ITT Population, LOCF

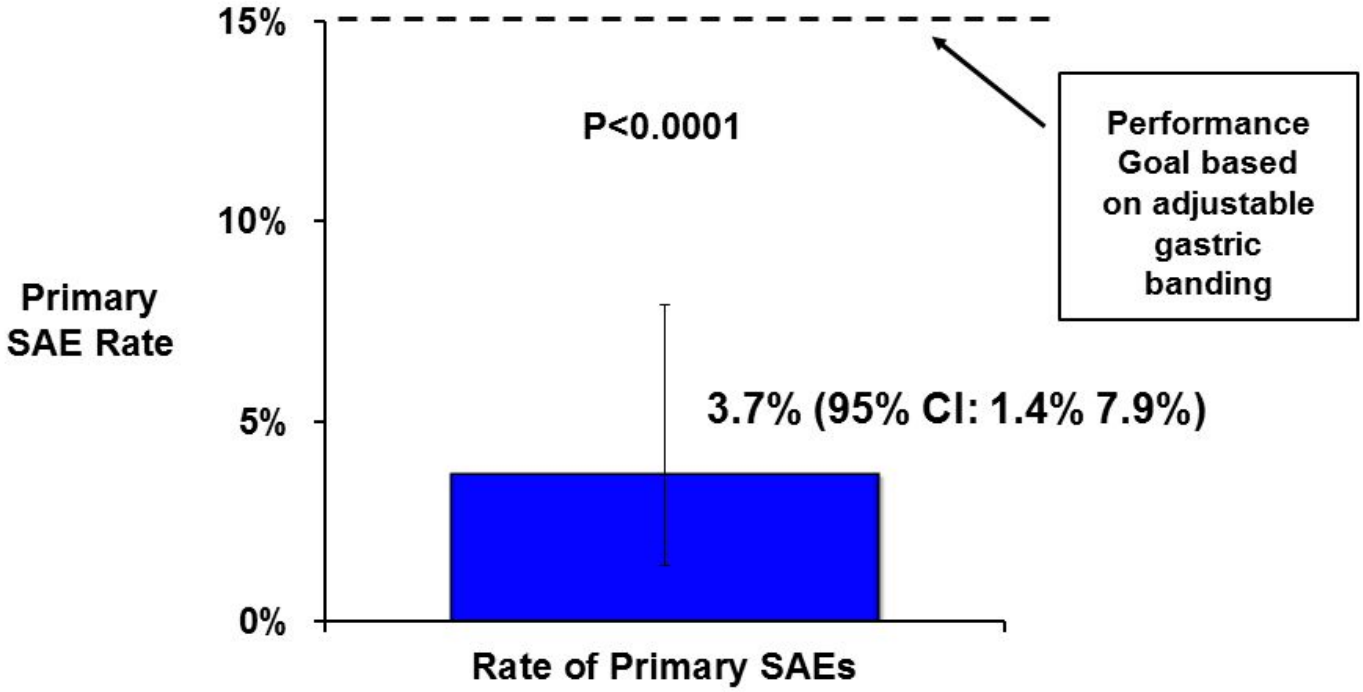
CO-48

Clinically Relevant Changes in Risk Factors for VBLOC Patients Achieved

Risk Factor	VBLOC Mean Change		
	All Patients	7.5% TBL	10% TBL
Systolic BP (mmHg)	-5	-8	-9
Diastolic BP (mmHg)	-3	-5	-6
Heart Rate (bpm)	-4	-4	-6
Total Cholesterol (mg/dL)	-9	-12	-15
LDL (mg/dL)	-5	-8	-9
Triglycerides (mg/dL)	-21	-32	-41
HDL (mg/dL)	1	2	3
Waist circumference (inches)	-4	-6	-7
HbA1c (%)	-0.3	-0.5	-0.5

Post Hoc Analysis, As-Observed

Prespecified Safety Endpoint Met



Error bar represent 95% confidence interval

Acceptable Adverse Event Profile

- 98% of AEs related to VBLOC were mild or moderate in severity
- All related AEs not resolved at 18 months were mild or moderate
- No dietary restrictions

Treatment Gap

Diet, Exercise, & Lifestyle Modification	Drug Therapy		Bariatric Surgery
Difficult to achieve significant weight loss Difficult to maintain weight loss	Lack of compliance Difficult to maintain weight loss Risks: • Serotonin syndrome • Pulmonary hypertension • Cognitive effects • Birth defects • Drug-drug interactions	**LARGE TREATMENT GAP** **MOST PATIENTS RECEIVE SUB OPTIMAL TREATMENT**	Significant dietary restrictions Risks: • Vomiting • Leaks • Bleeding • Bowel obstruction • Band erosion • Malabsorption • Constipation • Dumping syndrome

Benefits Outweigh Risks

- Risks/Limitations
  - Requires a surgical procedure
  - MRI incompatible
  - Current battery life ~ 8 years
  - Some patients can feel therapy
- Benefits
  - Clinically significant weight loss
  - Reduction in hunger leads to weight loss that can be maintained
  - No dietary restrictions
  - Lower risk than other surgical options

Questions from the Committee

Scott Shikora, M.D.

Chief Consulting Medical Officer, EnteroMedics Inc

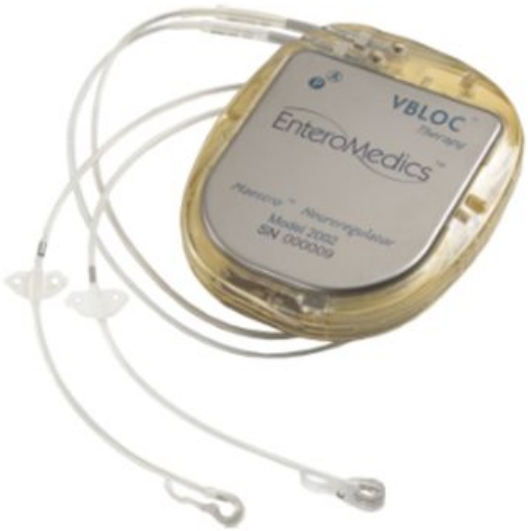
Associate Professor of Surgery, Harvard Medical School

Director of Bariatric Surgery, Brigham and Women's Hospital

Past President ASMBS

Invited Experts Available to Answer Questions from the Committee

Cardiovascular Safety	**Edward Pritchett, M.D.** Consulting Professor, Duke University Medical Center
Biostatistics	**Robert D. Gibbons, Ph.D.** Professor of Biostatistics, Departments of Medicine and Health Studies, University of Chicago **Christopher J. Miller, M.S.** Senior Medical Research Biostatistician, NAMSA
Metabolic Disease	**Ken Fujioka, M.D.** Director, Nutrition and Metabolic Research Center, Scripps Clinic
Neuroscience	**Christopher N. Honda, Ph.D.** Professor of Neuroscience, University of Minnesota
Psychosocial and Behavioral Outcomes	**David Sarwer, Ph.D.** Professor of Psychology, Perelman School of Medicine, University of Pennsylvania
Vagus Function	**Mehran Anvari, M.D., Ph.D.** Professor of Surgery, McMaster University
Clinical Studies	**Katherine Tweden, Ph.D.** Vice President - Clinical and Regulatory, EnteroMedics Inc



MAESTRO Rechargeable System

EnteroMedics Inc

Gastroenterology-Urology Devices Panel

June 17, 2014

Improvement in Obesity Risk Factors: VBLOC and Sham at 12 months

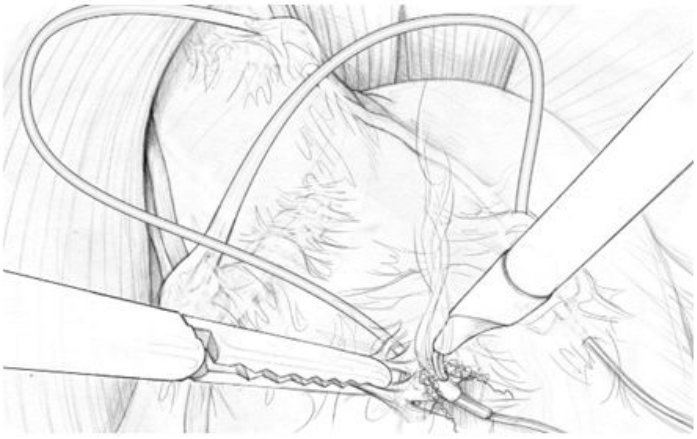
Risk Factor	VBLOC Mean Change [95% CI]	Sham Control Mean Change [95% CI]
Metabolic		
Total Cholesterol (mg/dL)	-8.7 [-13.5, -3.8]	-9.7 [-16.9, -2.6]
LDL Cholesterol (mg/dL)	-5.2 [-9.6, -0.9]	-4.3 [-10.2, 1.7]
HDL Cholesterol (mg/dL)	1.0 [-0.5, 2.5]	-0.4 [-3.0, 2.3]
Triglycerides (mg/dL)	-21 [-31, -12]	-33 [-48, -18]
Fasting Glucose (mg/dL)	-1.5 [-4.1, 1.0]	-0.7 [-3.5, 2.2]
Hemoglobin A1c (%)	-0.33 [-0.40, -0.26]	-0.31 [-0.43, -0.20]
Cardiovascular		
Systolic Blood Pressure (mmHg)	-5.5 [-7.8, -3.2]	-4.0 [-7.3, -0.7]
Diastolic Blood Pressure (mmHg)	-2.8 [-4.3, -1.2]	-4.5 [-6.5, -2.4]
Heart Rate (bpm)	-3.6 [-5.3, -1.9]	-3.5 [-6.3, -0.7]
Anthropometric		
Waist Circumference (cm)	-10 [-12, -8]	-8 [-10, -6]

Example Calculation of %EWL

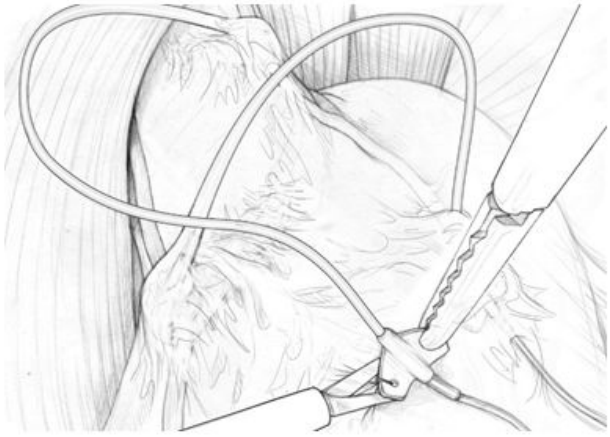
- 5’ 7, BMI 39 kg/m^2

Baseline Weight			248 lbs
Ideal Weight (BMI 25)			–158 lbs
Excess Weight			= 90 lbs
Weight loss at 12 month visit			= 22 lbs
Weight loss	÷	Excess Weight	**=%EWL**
22 lbs	÷	90 lbs	= 24.4%
Weight loss	÷	Baseline Weight	**=%TBL**
22 lbs	÷	248 lbs	= 8.9%

Explant Procedure

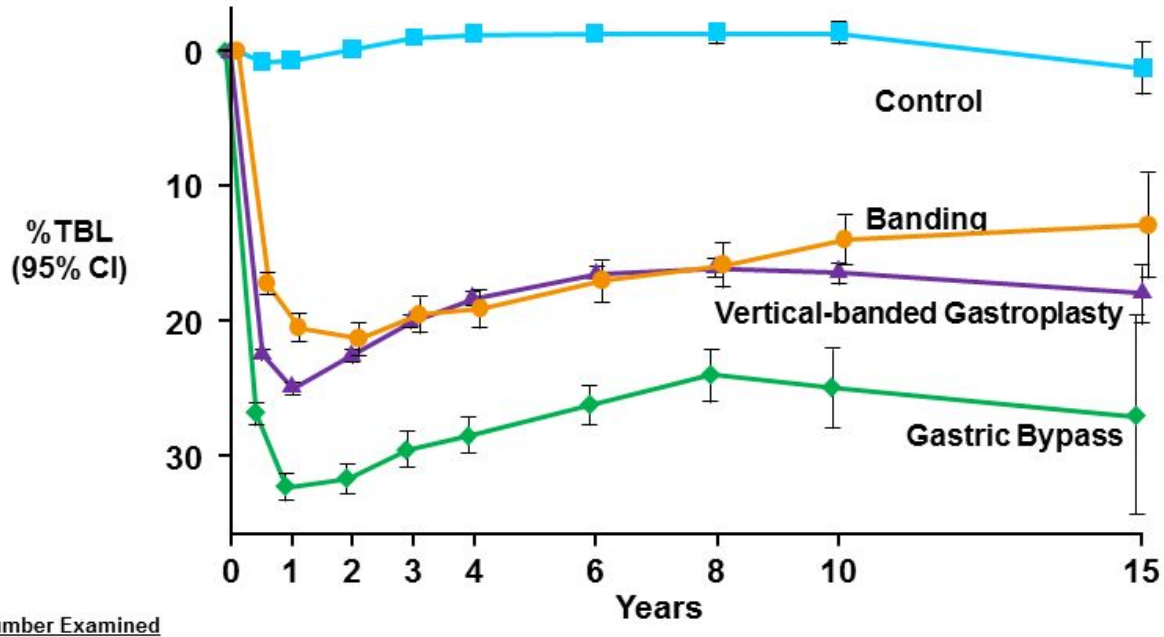


Retracted Liver to Expose GEJ and Lead Implantation Sites to Dissect Fibrotic Tissue and Free Suture Wings



Cutting Suture to Free Suture Wing

Modest Weight Regain Seen in Every Surgical Intervention



Number Examined									
Control	2037	1768	1660	1553	1490	1281	982	886	190
Banding	376	363	357	328	333	298	267	237	52
Vertical-banded Gastroplasty	1369	1298	1244	1121	1086	1004	899	746	108
Gastric Bypass	265	245	245	211	209	166	92	58	10

Sjostrom L et al. N Engl J Med 2007;357:741-752

Related SAEs for LAGBs vs VBLOC

- Related SAEs for LAGB devices include:
  - Gastric dilatation, gastric outlet obstruction, abdominal hernia, band slippage, band erosion, port displacement, band erosion, pulmonary emboli, and death*
- Related SAEs for VBLOC:
  - Nausea, pain, neuroregulator malfunction, generalized ileus, atelectasis, emesis/vomiting, intraoperative oozing, gastric perforation

* http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070009c.pdf

Device Explants through 18 Months

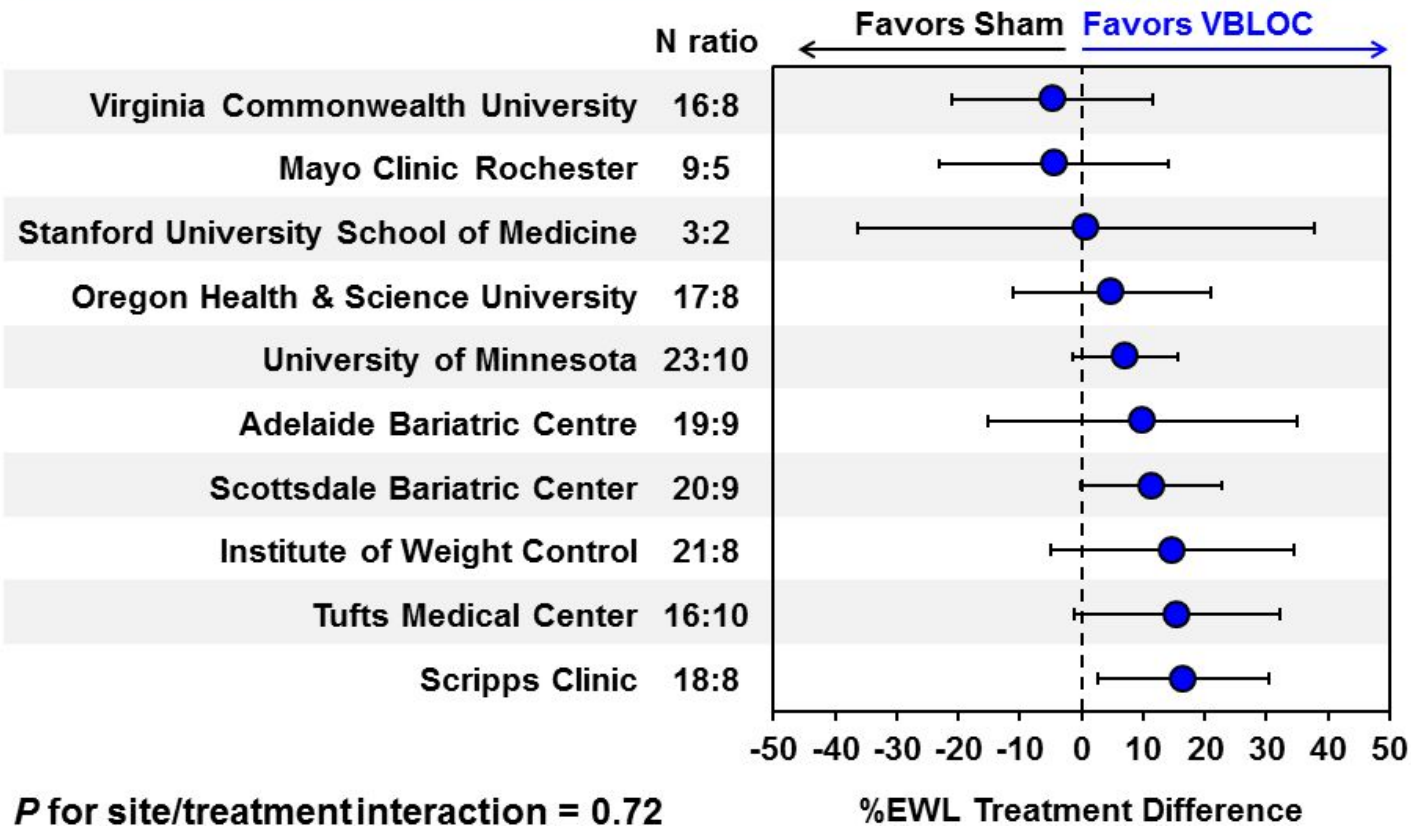
	VBLOC	Sham Control
	N subjects (%)	N subjects (%)
Explant rate	19 (11.7%)	17 (22.1%)

	VBLOC	Sham Control
Reason for explant	N events	N events
Subject decision	15	11
Pain at the neuroregulator site	2	2
Heartburn	1	0
MRI required	1	2
Cancer diagnosis	0	1
Worsening IBS symptoms	0	1

Sham Control Crossovers

- 12 sham patients in Australia crossed over through 18-month data lock, but took place after their 18-month visit
  - No US subjects crossed over before 18 month lock
- No SAEs reported
- AE profile similar to VBLOC subjects
- Mean %EWL from crossover at 8 weeks is 11% (95% CI, 6 to 15)

%EWL Treatment Difference by Site

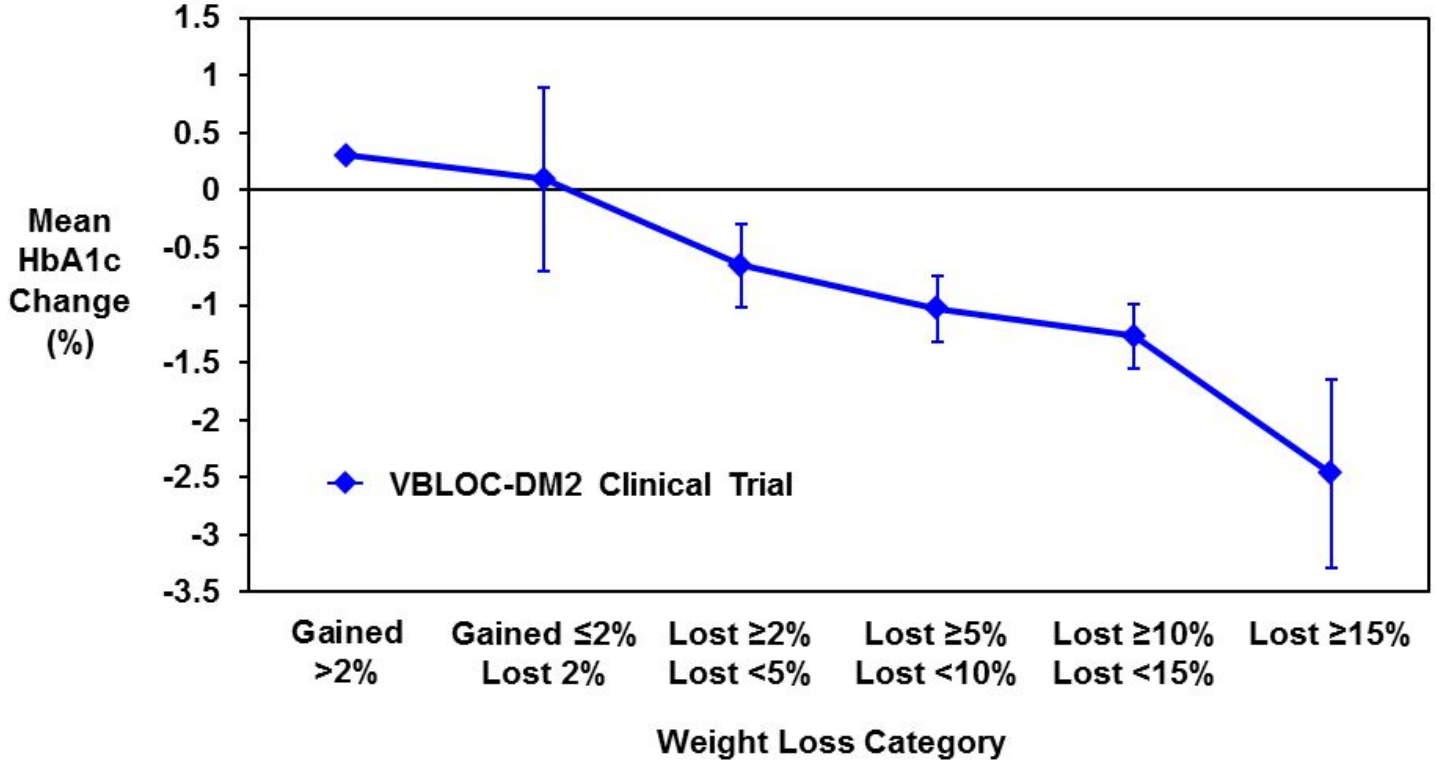


P for site/treatment interaction = 0.72

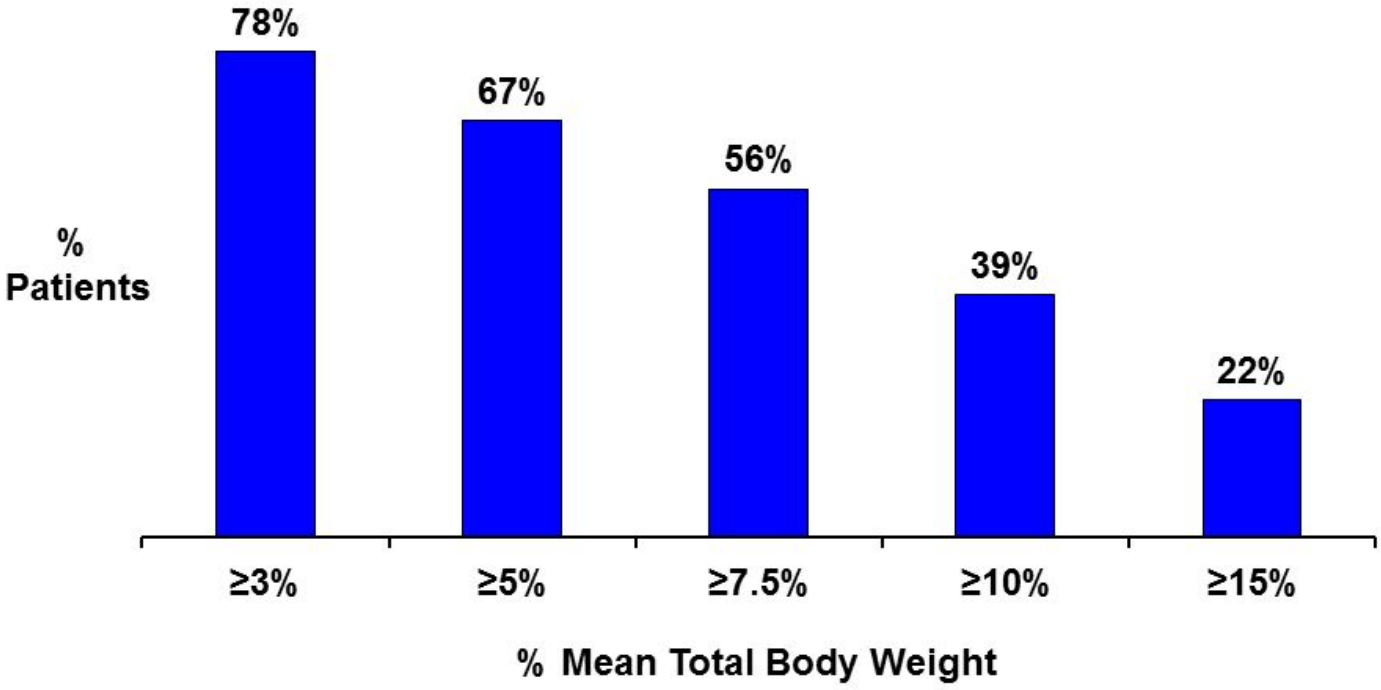
Medication Changes at 12 Months for VBLOC and Sham Patients

	VBLOC			Sham Control		
	N	Discontinued or Decreased	Increased	N	Discontinued or Decreased	Increased
Hypertension Medications	58	22%	10%	28	29%	11%
Diabetes Medications	8	50%	0%	6	0%	33%

Reduction in HbA1c Observed in VBLOC-DM2 by Weight Loss Thresholds at 12 Months



% of VBLOC Patients Achieving 3% to 15% Total Body Weight Loss at 12 Months



Observed Case

Clinically Relevant Changes in Risk Factors for VBLOC Patients Achieved

Risk Factor	VBLOC Mean Change				
	3% TBL	5% TBL	7.5% TBL	10% TBL	15% TBL
Systolic BP (mmHg)	-6	-7	-8	-9	-11
Diastolic BP (mmHg)	-3	-4	-5	-6	-8
Heart Rate (bpm)	-5	-5	-4	-6	-6
Total Cholesterol (mg/dL)	-11	-10	-12	-15	-22
LDL (mg/dL)	-6	-5	-8	-9	-16
Triglycerides (mg/dL)	-32	-33	-32	-41	-49
HDL (mg/dL)	1	2	2	3	4
Waist circumference (inches)	-5	-5	-6	-7	-7
HbA1c (%)	-0.4	-0.5	-0.5	-0.5	-0.6

Post Hoc Analysis, As-Observed

Neuroregulator Charging

- Patients with a fully charged Neuroregulator receive therapy for 3-5 days
- We advise patients to check the neuroregulator every day, if the mobile charger indicates that charging is needed, patients were instructed to charge the device which takes approximately 30 minutes

VBLOC Explants at 18 Months

- 15 Explants
  - Gained Weight (N=5)
  - Loss <10% EWL (N=3)
  - Loss >10% EWL (N=7)

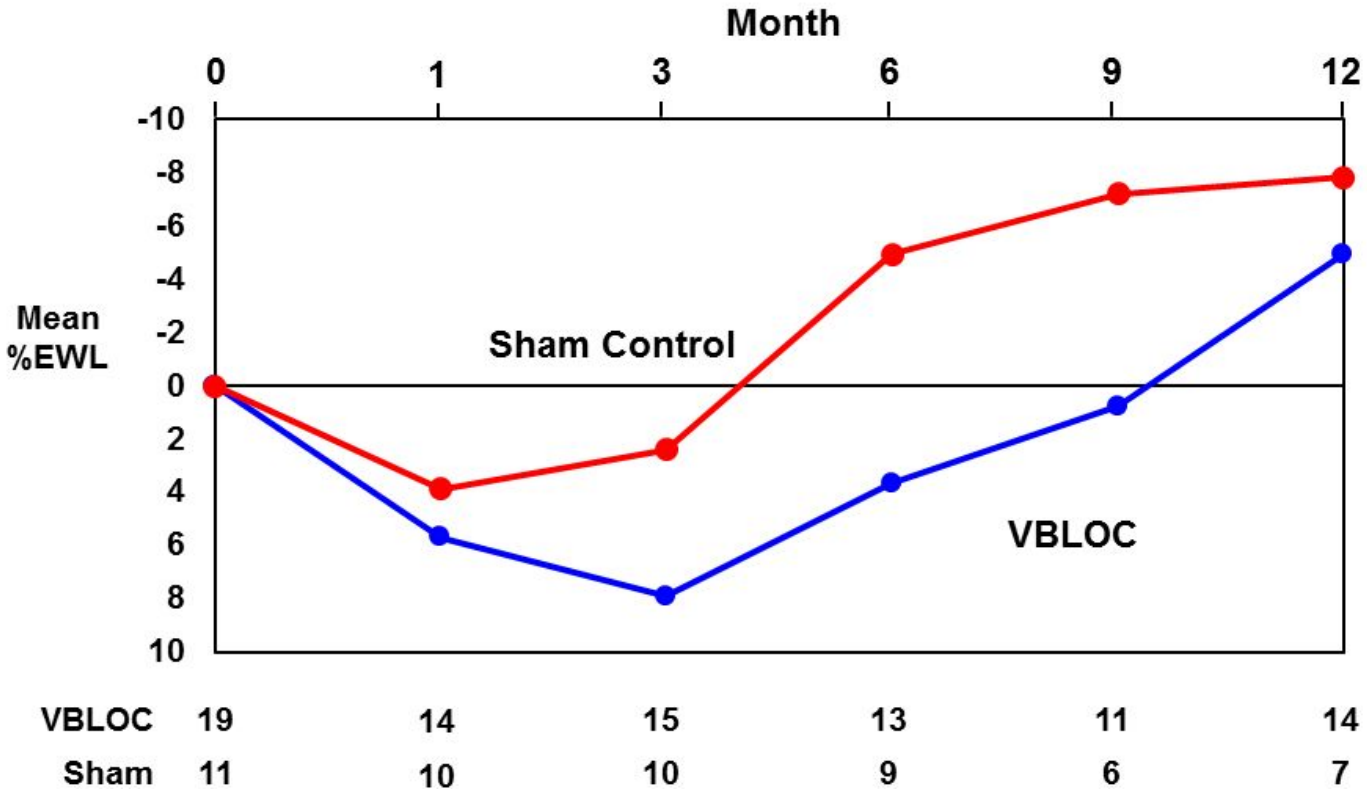
Reasons for Explant in VBLOC Patients with >10 %EWL

	Reasons for Explant
313-307-RC	Moved to Dubai
313-311-RC	Relocation
311-309-RC	Study Fatigue
310-304-RC	Study Fatigue
307-313-RC	Lack of Efficacy
304-324-RC	Family Emergency
311-310-RC	Reason Unknown

Position on Lerner Analysis

- The Lerner analysis is a thoughtful attempt to create a broad tool for assessing risk benefit
- Any tool of this nature should be used as guidance and not a hard and fast rule
- Depending on how one interprets the data from the ReCharge Trial, the Maestro System could be placed at Level 1, 2, or 3
  - For most (8 of 12) of the 12 safety categories Maestro would be a Level 1 or 2
- The VBLOC %TBL exceeded the Level 3 threshold

Patients ≤0% EWL at 12 Months or Last Visit



VBLOC	19	14	15	13	11	14
Sham	11	10	10	9	6	7

No Relationship between Therapy-Related AEs and %EWL

- 96 VBLOC patients had a therapy-related AE
- Mean %EWL among those with and without a therapy-related AE:
  - With (n=96): 26% [95% CI, 21 to 31]
  - Without (n=66): 22% [95% CI, 16 to 28]
  - Mean difference: -4% [95% CI, -11 to 4], P=0.31
- Linear regression of the number of therapy-related AEs and %EWL in VBLOC group
- Coefficient estimate for therapy-related AEs
  - 1.3% EWL (95% CI: -1.8 to 4.5)
  - *P*=0.40

Related Heartburn/Dyspepsia AEs through 12 Months

- 38 VBLOC patients (23.5%) reported 42 events
  - Reported as symptoms typical of reflux; often intermittent and/or not present when therapy was off
- 100% were mild or moderate
  - 36 mild (86%), 6 moderate (14%), 0 severe
  - Resolved in 55% by 18 months; 1 explant; no SAEs
- Median time to onset 124 (IQR, 28 to 268)
- Median time to resolution 51 days (IQR, 19 to 151)

%EWL at 24 Months – Completer Population

Statistic	VBLOC N=103	Sham Control N=23	Difference
Mean ± SD	21.0 ± 25.1	3.9 ± 14.3	17.0 ± 23.6
(95% CI)	[16.1, 25.9]	[-2.3, 10.1]	[9.3, 24.8]
Superiority P-value			<0.001

Note: 24-Month Data Not Reviewed by FDA

Pregnancy

- 3 pregnancies during first 12 months of ReCharge (1 sham, 2 VBLOC)
- All VBLOC patients had device de-activated
- All patients had non-eventful pregnancies and births.