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: February 7, 2013
(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.

At 5:00 p.m. Eastern Time on February 7, 2013, EnteroMedics Inc. (the "Company") hosted a conference call to discuss the preliminary results of its ReCharge pivotal trial for obesity, following its issuance of a press release announcing the preliminary results. A replay of the conference call will be available on the Company's website at www.enteromedics.com for approximately 90 days. A copy of the slides accompanying this conference call and a copy of the script for this conference call are filed as Exhibit 99.1 and Exhibit 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Conference Call Slides dated February 7, 2013.
99.2	Conference Call Script dated February 7, 2013.

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 and
Chief Financial Officer

Date: February 7, 2013

EXHIBIT INDEX

Exhibit Number	Description
99.1	Conference Call Slides dated February 7, 2013.
99.2	Conference Call Script dated February 7, 2013.

Exhibit 99.1

ReCharge Pivotal Trial Results

February 7, 2013

Study Design

Prospective, double-blind, sham controlled randomized trial in 239 subjects (233 implanted)

Co-Primary Efficacy Endpoint:	At least 10% difference in %EWL by super-superiority of treatment over sham control (BMI method at 12 months, post randomization)
Co-Primary Efficacy endpoint:	55% of subjects achieve at least 20% EWL, 45% of subjects achieve at least 25% EWL in the treatment group (BMI method at 12 months, post randomization)
Primary Safety Objective:	Implant/revision procedure, device and therapy-related serious adverse events (SAE) through 12 months post-randomization is less than 15% in the treatment group
Mean BMI:	40.9 Kg/m^2
Mean Age:	47
Gender:	85% female/ 15% male

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Results Overview – ITT Population

Overall outcome:	Excellent benefit/risk ratio at 12 months
Efficacy Percent EWL:	Clinically meaningful, statistically significant superiority over Sham Control
Efficacy – Responder analysis:	Strongly in favor of VBLOC
Safety:	Primary endpoint met

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Efficacy Results: Mean %EWL in ITT Population

Excess Weight Loss (%) at 12 months (BMI)	Treated	Control	Difference
N	162	77	
Mean ±SD	**24.4** ± 23.6	**15.9** ± 17.7	8.5 ±21.9
[95% CI]	[20.8, 28.1]	[11.9, 19.9]	[3.1, 13.9]
Super-superiority P-value			0.705
Superiority P-value			0.002

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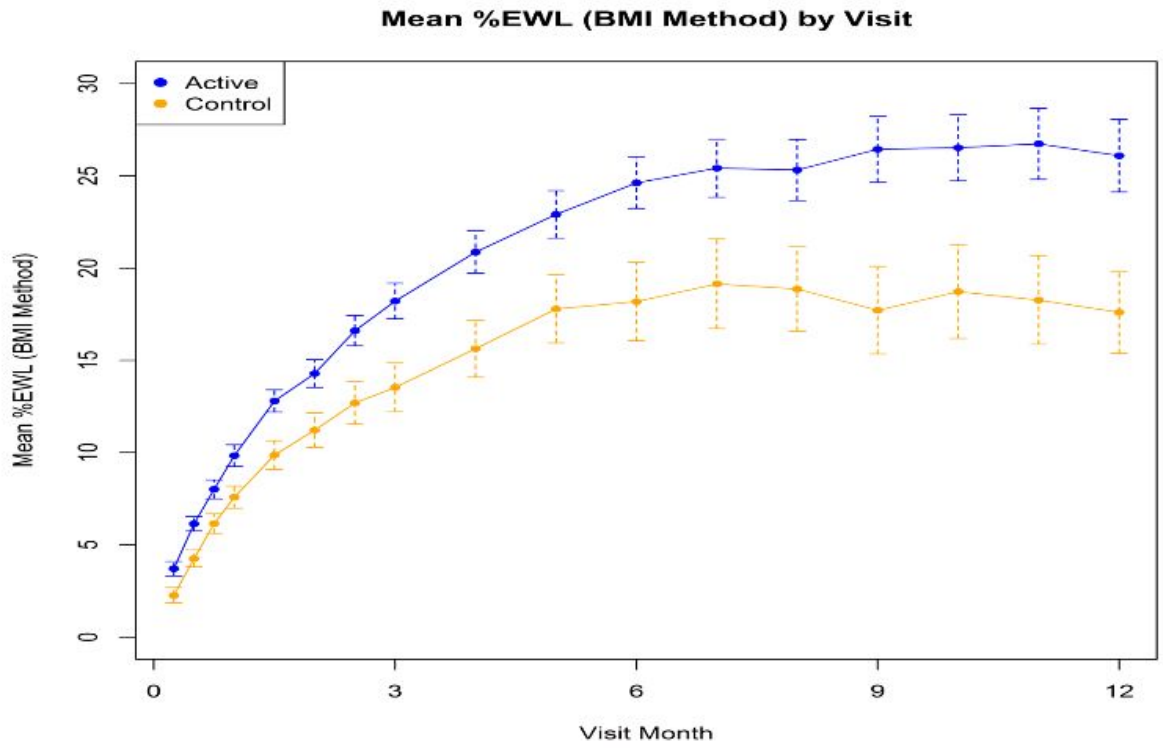
ReCharge Weight Loss



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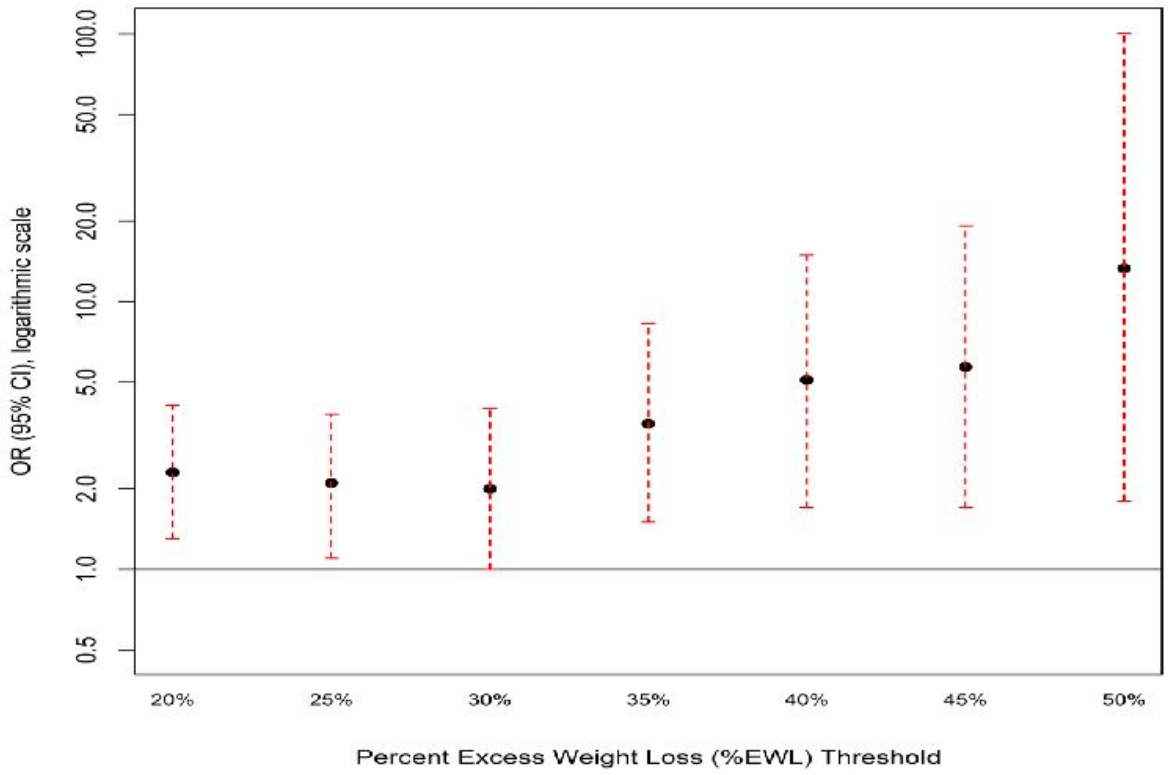
Efficacy Results: Responder Analysis in ITT Population

Percent EWL achieved (BMI)	Treated N=162	Control N=77	Odds Ratio	p-Value
≥20%	**52.5%** (85)	**32.5%** (25)	2.3 (1.3, 4.1)	.004
≥25%	**38.3%** (62)	**23.4%** (18)	2.1 (1.1, 3.8)	.02
≥30%	**30.2%** (49)	**18.2%** (14)	2.0 (1.0, 3.9)	.047
≥35%	**25.9%** (42)	**9.1%** (7)	3.5 (1.5, 8.3)	.004
≥40%	**21.6%** (35)	**5.2%** (4)	5.1 (1.7, 14.9)	.003
≥45%	**18.5%** (30)	**3.9%** (3)	5.7 (1.7, 19.2)	.005
≥50%	**14.8%** (24)	**1.3%** (1)	13.3 (1.8, 100.5)	.01

Odds Ratio for Various Response Rates Treated vs. Sham Control



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Per Protocol Population Efficacy Results

Excess Weight Loss (%) at 12 months (BMI)	Treated	Control	Difference
N	146	65	
Mean ±SD	**26.3**± 23.8	**17.3**± 18.1	8.9 ±22.2
[95% CI]	[22.4, 30.2]	[12.9, 21.8]	[3.0, 14.8]
P-value (Delta = 10%)			0.640
P-value (Delta = 0%)			0.003

Percent EWL achieved (BMI)	Treated N=146	Control N=65
20%	**56.8% (83)**	**35.4%**(23)
25%	**41.8% (61)**	**26.2%**(17)

Safety Results

- No deaths, no unanticipated adverse device effects
- Implant/revision procedure, device, therapy-related SAEs in treated subjects (primary safety endpoint): 3.1% vs. 15% pre-specified limit, CI (1.0, 7.1%); $p<0.0001$
- 93% of subjects were active in the blinded trial at 12 months

Cardiovascular Safety

Measure Visit Type	Treated		
	N	Mean	SD
Systolic Blood Pressure (mmHg)			
6 months	149	-6.6	12.7
12 months	147	**-5.5**	14.2
Diastolic Blood Pressure (mmHg)			
6 months	149	-3.4	8.9
12 months	147	**-2.8**	9.6
Heart Rate (bpm)			
6 months	149	-4.4	11.9
12 months	147	**-3.6**	10.3

Overview of Results
ReCharge Pivotal Trial
By: Robert D. Gibbons, Ph.D.

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Conclusions

- Excellent safety profile met pre-specified target
- Statistical superiority achieved in favor of treated group based on percent EWL
- Statistically significant responder analyses based on pre-specified (20% and 25%) and "super-responder" (50%) thresholds
- ITT and per protocol analyses are in agreement
- Highly clinically meaningful EWL of 24.4%
- Although the pre-defined "super-superiority" efficacy endpoint was not met, the risk/benefit ratio for Maestro RC2 device is clearly positive and supports FDA PMA submission

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Thank you

Exhibit 99.2

EnteroMedics Conference Call

ReCharge Conference Call Script

Speaker Dial-in Number:	***Speakers, US/Canada: (877) 291-1297***
	Speakers, International: (707) 287-9374
Speaker Passcode:	88748024
Online Q&A Manager:	***http://www.leader-view.com***
	Conference ID number: 88748024
	Web PIN: 1170
Participants:	Greg Lea
	Mark B. Knudson, Ph.D.
	Katherine Tweden, Ph.D.
	Robert D. Gibbons, Ph.D.

3:50 PM CST: Dial into the conference line; line will remain mute until the operator connects you

3:59 PM CST: Operator will ask for a moment of silence as he/she connects the call

4:00 PM CST: Call commences

[Operator Introduction] I will now turn the call over to Greg Lea, Chief Financial Officer, to start the call. Mr. Lea?

Greg Lea:

Thank you for joining us this morning to discuss results from our pivotal ReCharge Trial of VBLOC Therapy in obesity.

As a reminder, this conference call, as well as EnteroMedics' SEC filings and website at enteromedics.com, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those discussed due to known and unknown risks, uncertainties and other factors. These risks and uncertainties are described more fully in the Company's filings with the Securities and Exchange Commission, particularly those factors identified as "risk factors" in the Company's 10-K filed March 15, 2012.

With me on the call from EnteroMedics are Dr. Mark Knudson, our President and CEO, and Dr. Katherine Tweden, Vice President, Clinical and Regulatory. We are also joined today by Dr. Robert Gibbons, Professor of Biostatistics at the University of Chicago, who has completed an overview of the results from our ReCharge study. We will begin with prepared remarks, which are accompanied by a slide presentation available at enteromedics.com. This will be followed by a review of the results from Dr. Gibbons. When these are concluded, we will open the call for questions.

I will now turn the call over to Dr. Knudson. Mark?

Mark Knudson:

Thank you, Greg.

Earlier this afternoon, we announced the outcome of our ReCharge study of VBLOC Therapy in the treatment of obesity. We believe, based on this study, that VBLOC Therapy is a very exciting, new and novel treatment for obesity that fills a significant gap in the treatment spectrum for this epidemic disease.

As previously announced, while the ReCharge Study achieved its safety endpoint, it did not achieve its two pre-specified efficacy endpoints in the intent to treat population; however, this was not because the treatment was ineffective. In fact, the study demonstrated a clinically meaningful and statistically significant average excess weight loss of 24.4% for VBLOC Therapy patients, with 52.5% of treatment patients achieving at least 20% excess weight loss, and 38.3% achieving at least 25% excess weight loss.

In the per protocol group, which included only those patients who received therapy per the trial design, treated patients had an average 26.3% excess weight loss, with 56.8% achieving at least 20% excess weight loss, which was above our pre-defined threshold of 55%. 41.8% of treated patients also achieved at least 25% excess weight loss in this population, which was slightly less than our predefined threshold of 45%.

Again, we easily met our safety endpoint. Dr. Gibbons will address the significance of these data in greater detail during his remarks. As a result of these compelling safety and efficacy data, which demonstrate an excellent benefit-to-risk ratio, we plan to move forward with a Pre-Market Approval application with the FDA in the second quarter of 2013.

Before I hand it over to Dr. Tweden to review the results in detail, I would like to reinforce what makes VBLOC Therapy, delivered via the Maestro System, such an important and potentially revolutionary treatment option for obesity and its comorbidities. VBLOC Therapy offers a unique neuroblocking approach to weight loss that directly addresses the physiology of obesity. It consists of an active implantable, pacemaker-like device designed to block the signals between the brain and the stomach that control many aspects of the digestive system – including hunger, fullness and energy expenditure.

The data show that impacting these three areas over time provides a unique benefit to patients, one that shows an excellent balance of risk and reward, and one that leads to healthy, long-term weight loss.

If approved, VBLOC Therapy will fill a significant gap in the treatment spectrum for U.S. patients. It does not share the side effects or compliance shortfalls of systemic pharmaceutical treatments. It involves no surgical alteration of the digestive system or barriers to prevent absorption of nutrients. With VBLOC Therapy, patients are able to eat normal, healthy meals, without food restrictions, as they learn to make choices that are tolerable for their lifestyle and support a healthier relationship with food.

We view current weight loss options as a continuum of treatment, from diet and exercise, to pharmaceuticals, to existing surgical procedures. VBLOC provides what may be an important step between early options and anatomy altering options, offering meaningful weight loss and fewer side effects, and lifestyle altering decisions and less risk of nutritional deficiency.

With that, I would like to turn to the data, which our vice president of Clinical and Regulatory, Dr. Katherine Tweden, will summarize. Katherine?

Katherine Tweden:

Thank you Mark.

[Slide 1]

[Slide 2]

Before I go into the results, I'd like to briefly discuss the design of the ReCharge study. As you see in slide 2, the ReCharge study is a prospective, double blind, sham controlled, randomized trial in 239 patients, of which 233 were implanted. The first Co-Primary efficacy endpoint is to demonstrate at least 10 percent difference in EWL by super-superiority margin of treated over sham control at 12 months post-randomization. The second Co-primary efficacy endpoint is a responder analysis in the treated arm, where 55% of subjects are to achieve at least 20% EWL and 45% of subjects are to achieve at least 25% EWL, all by BMI method at 12 months, post randomization.

The Primary Safety Objective is for the composite rate of implant/revision procedure, device and therapy-related serious adverse events through 12 months post-randomization to be less than 15% in the treatment group.

Key baseline demographics are as follows:

Mean BMI was 40.9 Kg/m2 and Mean Age was 47; with 85% of the population female, 15% male.

[Slide 3]

Our key takeaways from the ReCharge trial results, as seen on slide 3, are as follows: the overall outcome of the trial in the Intent-to-treat population defined as all 239 randomized patients, demonstrated an excellent benefit to risk ratio at 12 months. With regard to efficacy in terms of % EWL, a clinically meaningful, statistically significant superiority over surgical sham control was demonstrated.

With regard to efficacy in the responder analysis, clinically meaningful weight loss in favor of VBLOC therapy treated patients was observed at all EWL thresholds.

And importantly, the primary safety endpoint was met.

[Slide 4]

Next, I will transition to our detailed discussion of the efficacy and safety data.

The first co-primary efficacy measure, mean %EWL at 12 months in the intent to treat population is shown in slide 4.

Of the 239 subjects, 162 subjects were randomized to the treated arm and 77 subjects were randomized to the control arm, and 233 were implanted.

What we observed at 12 months was a mean weight loss of 24.4% in the treated group and 15.9% in the sham control group, for a difference of 8.5 percentage points.

This difference was statistically significant with a p value of .002, however we did not meet the primary efficacy endpoint of a 10% super-superiority margin over sham control.

[Slide 5]

On this slide 5, mean percent EWL over the first 12 months of the Recharge study in the control and treated group, as observed, is shown.

The treated group is shown in blue and the control group in orange.

These data clearly show superiority of weight loss with VBLOC therapy over sham control throughout the study's first 12 months. Separation between the groups occurs early and is sustained throughout the study.

The ongoing trend of these differences is sustained for the two months where we have sufficient data past 12 months, with weight loss continuing in the treated group.

[Slide 6]

The responder analysis in the ITT population is summarized on slide 6.

Again, the results show a clear treatment benefit over sham control at all percent EWL thresholds.

Specifically, the first two thresholds, which are, together, the study's co-primary endpoint, demonstrate that 52.5 percent of treated subjects achieve 20% EWL compared to 32.5% of sham subjects, for a difference of 20%. This difference is significant, with a p value of .004.

This effect continues at the 25% threshold, with 38.3% of treated subjects achieving 25% EWL compared to 23.4% for sham, which is also significant with a p value of .02.

These differences carry through to the highest thresholds, where the relative odds of attaining greater weight loss increase dramatically, and where these differences are significant. A clear, consistent and clinically relevant treatment effect is observed.

While the respective co-primary endpoint targets of 55% and 45% were not met, the endpoint targets were within the 95% confidence intervals for the observed rates and therefore the observed rates were not significantly lower than these pre-specified rates. These efficacy data demonstrate VBLOC Therapy's positive effect on weight loss.

[Slide 7]

On slide 7, we see the odds ratio reflected in graphic form. The black dots represent the estimated odds ratio and the red dashed lines represent the 95% confidence limits. As you can see, the treatment patients have significantly higher odds of achieving higher EWLs over sham control at every threshold 20% and above. In fact, the odds ratio for achieving a 50% EWL is 13 for treatment over sham, which means that they had 13 times greater chance of achieving at least 50% EWL if they are in the treatment group compared to if they are in the sham control.

[Slide 8]

Let’s turn our attention now to the active participants in the study, shown here in the per protocol analysis on slide 8.

These data are especially compelling and relevant.

Specifically, this population excludes patients who had a missing 12-month value – which includes 6 patients who were never implanted, 5 in the treatment group – patients who received the incorrect treatment per randomization or patients who were not initiated 45 days after implant. This group still includes about 88 percent of the total randomized population.

You can see here that EWL at 12 months in the treatment arm was 26.3 percent, and that we observed that 56.8% of the treated subjects achieved 20% EWL, which was above our pre-defined threshold of 55%, and 41.8% of treated subjects achieved 25% EWL in the responder analysis, which was slightly less than our predefined threshold of 45%.

One other analysis worthy of note is what we call the “complier group” which is the per protocol population that had at least 12 hours of therapy per day over 12 months. This group consisted of 121 treated subjects and they achieved an average 27.8% EWL.

[Slide 9]

Let’s transition to our safety results, which are summarized on slide 9.

In the study, we observed no deaths and no unanticipated adverse device effects.

With regard to our primary safety outcome, our composite of implant/revision procedure, device and therapy related serious adverse events in the treatment arm was 3.1% post randomization. This easily beat our pre-specified threshold of a 15% limit. The outcome was significant with a p value of <0.0001.

Lastly, 93% of subjects were active in the blinded trial at 12 months, which is consistent with a rigorous, well managed study and suggests a well accepted therapy.

[Slide 10]

The last data set I will review is the cardiovascular safety data with regard to blood pressure and heart rate changes in the treated group which are shown on slide 10.

On average, we had a 5.5 millimeter mercury drop in systolic BP and a 2.8 mmHg drop in diastolic BP at 12 months.

Lastly, heart rate was reduced by 3.6 beats per minute at 12 months.

These data confirm that no adverse cardiovascular signal was observed with VBLOC Therapy over the first 12 months of the study, consistent with our previously reported experience.

[Slide 11]

With that, I will turn the call over to Dr. Robert Gibbons, Professor of Biostatistics at the University of Chicago. Dr. Gibbons frequently serves on high-profile FDA advisory panels and has analyzed many drug and device trials, which is why we have asked him to review the ReCharge data. Dr. Gibbons is a member on the Institute of Medicine of the National Academy of Sciences and one of the authors of the IOM report on The Future of Drug Safety. Dr. Gibbons?

Robert Gibbons:

Thank you Dr. Tweden.

My review considers all patients randomized to treatment, the primary endpoints and the corresponding efficacy of treatment in terms of those endpoints. My review looked at data from only the complete intent to treat population – that is, all patients who were randomized, including patients who were randomized but not implanted as well as patients who did not complete the full study at 12 months. Unlike many such reviews, in which a study fails to meet its primary endpoints overall but an "important" subgroup is fortuitously discovered in post-hoc analyses of the data, that is not the case here.

Referring to the data that Dr. Tweden just reviewed with you, while it is clear neither of the two primary endpoints of this study were met from a simple regulatory standpoint, from a statistical point of view this trial did demonstrate excellent benefit for patients with minimal risk.

First, the average %EWL in treated patients is nearly 25%. Relative to traditional therapies, this is a huge and clinically important advantage. Further, we would expect increased compliance and benefit from a sham control over a non-surgical control, and indeed we found one. The sham controls demonstrated an average %EWL of 15.9%, which was higher than anticipated in the study design and is approximately four times greater than what has been routinely observed for non-surgical control conditions in randomized clinical trials in this area.

Second, the results of the trial in terms of a responders analysis are both statistically significant and pass the commonly used 20-20 criterion – that is, that the difference between response rates defined as a 20% benefit exhibit at least a 20% difference between treated and control groups. 52.5% of treated patients achieved a 20% EWL at 12 months following implant, whereas 32.5% of the controls achieved this difference at 12 months. As such the difference between the treated and control groups in the proportion of patients who had achieved at least 20% EWL is 20%, meeting the 20-20 criterion. Furthermore, this difference is statistically significant and has an associated odds ratio of 2.3, indicating that treated patients had 2.3 times greater odds than control patients of achieving at least 20% EWL.

To this point, I have described results for the co-primary endpoints of %EWL and response defined in terms of achieving a pre-specified 20% EWL. All of the analyses are based on the intent to treat sample. I extend these analyses one step further by examining “super-response” of 50% or greater EWL. This threshold was achieved by 14.8% of treated patients and 1.3% of sham controls. This difference was significant at the $p< 0.01$ level. The associated odds ratio of 13.2, indicates that treated patients had 13.2 times greater odds of achieving 50% or greater EWL compared to sham controls.

In summary, we know that the treatment works in that it is statistically differentiable from a sham control condition, and that the absolute benefit is clinically significant and of a magnitude that has critically important public health implications. Given the safety profile, these data reveal an excellent benefit to risk equation.

Mark Knudson:

Thank you Dr. Gibbons.

An excellent safety profile together with (1) a statistically significant superiority analysis based on percent excess weight loss, (2) a statistically significant responder analysis based on both 20% excess weight loss and 50% excess weight loss thresholds, and (3) an overall average of 24.4% excess weight loss for the treated patients, make it clear that the Maestro RC2 device has a positive benefit to risk ratio in all randomized patients.

In light of the data we have discussed, I want to close with a quote from a paper titled, “Benefit-risk paradigm for clinical trial design of obesity devices: FDA proposal”, written by Dr. Herb Lerner, Deputy Division Director in the Office of Device Evaluation at the FDA, and colleagues addressing the evolution of the FDA’s views on benefit-risk paradigms for obesity devices, from Surgical Endoscopy, December 18, 2012:

“... we do not want this process to be overly burdensome; nor do we intend for this tool to be a substitute for our detailed assessment of a device’s overall safety and effectiveness during the review of a marketing application. For example, if a device fails to meet the predetermined primary end points of the trial but has a good safety profile, the agency will review the submission in its entirety and make a final determination based on both benefit and risk.”

It is based on this evolving view at the FDA as well as the significant weight loss advantages of VBLOC therapy, in both absolute and comparative terms, and an excellent benefit to risk profile, that we will move ahead confidently into the Pre-Market Approval Application process with the US FDA, as planned, in the second quarter of 2013.

This concludes our prepared remarks. I will now open the line for questions. Operator?