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: November 12, 2009
(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 November 12, 2009, EnteroMedics Inc. (the "Company") issued a press release announcing preliminary results from its detailed review of the EMPOWER™ study, a randomized, double-blind, controlled pivotal study designed to evaluate the safety and efficacy of the Company's Maestro® System in the treatment of obesity. The Company will be hosting a conference call and live webcast to discuss the detailed findings of its EMPOWER study November 12, 2009 at 8:00 a.m. Eastern Standard Time. During the conference call, the Company will webcast slides containing additional details of the clinical results. The conference call may be accessed by dialing (888) 205-6702 for domestic callers and (913) 312-0665 for international callers and providing passcode 9194735. A replay of the call will be available from November 12, 2009 at 10:00 AM Eastern Time through February 12, 2010 at 11:59 PM Eastern Time by dialing (888) 203-1112 for domestic callers and (719) 457-0820 for international callers and providing passcode 9194735. A copy of the press release, conference call transcript and slide presentation are filed as Exhibit 99.1, Exhibit 99.2 and Exhibit 99.3, 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 No.	Description
99.1	Press Release dated November 12, 2009.
99.2	Conference Call Transcript dated November 12, 2009.
99.3	Slide Presentation of preliminary EMPOWER clinical results, dated November 12, 2009.

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: November 12, 2009

EXHIBIT INDEX

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Exhibit 99.1

Contact:
EnteroMedics Inc.
Greg S. Lea
(651) 789-2860
ir@enteromedics.com

ENTEROMEDICS ANNOUNCES PRELIMINARY RESULTS FROM DETAILED REVIEW OF EMPOWER STUDY

Company to Host Conference Call November 12, 2009 8:00 AM EST

ST. PAUL, Minn., November 12, 2009 – EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, today announced preliminary findings from its ongoing detailed review of its EMPOWER™ study, a randomized, double-blind, controlled pivotal study designed to evaluate the safety and efficacy of the Maestro® System in the treatment of obesity. On October 2, 2009, the Company announced that the study did not meet its primary and secondary efficacy endpoints, as results in the control and treatment arms were statistically indistinguishable, while achieving all of its safety endpoints.

The ongoing detailed review suggests that vagal blocking therapy may promote safe and effective weight loss as an adjunct to behavioral support, diet and exercise in morbidly obese patients. The review further suggests that these effects were evident in both the treatment and control arms. The Company is continuing a comprehensive analysis of all clinical, statistical, and engineering data to understand this finding. Based on the analysis to date, the control arm of the trial, which was intended to be inactive, apparently provided a low-intensity blocking signal that introduced VBLOC Therapy in human subjects.

The Company is informing patients and physicians of the following study findings:

- The EMPOWER study met all of its safety goals, including the finding that there were no therapy-related serious adverse events reported across the entire study population;
- Patients who met or exceeded the prescribed nine hours of daily device use (n=128, 51% of evaluated patients) averaged 10.9 hours of daily use and experienced an average excess weight loss (EWL) of 23.1% from implant by BMI method (18.3% from treatment initiation by Met Life method) in the treatment arm and 22.6% (BMI) from implant, (17.8% from initiation, Met Life) in the control arm at 12 months;
- Patients that did not meet the prescribed nine hours of daily device use (n=125) averaged 6.9 hours of daily use and experienced a mean EWL of 10.5% (BMI) from implant in the treatment arm (6.4% from initiation, Met Life) and 8.6% (BMI) in the control arm (4.6% from initiation, Met Life) at 12 months;

- For all patients (n=253), the average EWL at 12 months was 16.6% EWL (BMI) from implant (12.1% from initiation, MetLife) for the treatment arm and 16.4% EWL (BMI) from implant (12.0% from initiation, MetLife) for the control arm; and
- For those patients with a diagnosis of hypertension (n=110), a statistically significant reduction of systolic and diastolic blood pressure from baseline was observed, a result that will require follow-up study.

As of today, in accord with the study protocol, 252 patients remain in the EMPOWER study and are receiving VBLOC Therapy. Consistent with the study protocol, physicians are encouraging their patients to use the Maestro System for a minimum of the prescribed 9 hours per day.

“The EMPOWER study demonstrated a remarkable level of safety for an implanted medical device,” added James W. Freston, M.D., Ph.D., Professor of Medicine and Clinical Pharmacology (*emeritus*), University of Connecticut Health Center and Chairman of the EMPOWER study Data Safety Monitoring Board.

“Results from the two arms of the EMPOWER study as well as from our previous VBLOC Therapy trials were consistent with each other, suggesting a pattern of positive clinical outcome when blocking the vagus nerve,” said President and CEO Mark B. Knudson, Ph.D. “The apparent control arm effect, while unexpected, may be a scientifically important addition to our understanding of neuromodulation. We are taking steps to discuss the outcome of this study with the FDA to determine the appropriate regulatory path forward for the Maestro System as a treatment for morbid obesity.”

The Company will discuss these findings in detail in a conference call and slide presentation today at 8:00 AM Eastern Standard Time.

Conference Call, Presentation and Webcast Details

EnteroMedics management will host a conference call and live webcast to discuss the detailed findings of its EMPOWER study November 12, 2009 at 8:00 AM Eastern Standard Time. The conference call may be accessed by dialing (888) 205-6702 for domestic callers and (913) 312-0665 for international callers and providing passcode 9194735. A replay of the call will be available from November 12, 2009 at 10:00 AM Eastern Time through February 12, 2010 at 11:59 PM Eastern Time by dialing (888) 203-1112 for domestic callers and (719) 457-0820 for international callers and providing passcode 9194735.

The conference call will be accompanied by a slide presentation. The presentation and call will be webcast live and may be accessed by visiting EnteroMedics’ website at www.enteromedics.com. Investors can access the webcast under “Press Room” in the “Investors” section of EnteroMedics’ website. Please connect to EnteroMedics’ website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. A replay of the webcast will also be available immediately after the conclusion of the presentation.

About VBLOC Therapy

EnteroMedics developed VBLOC® vagal blocking therapy to offer bariatric surgeons and their patients a less invasive alternative to existing surgical weight loss procedures that may present significant risks and alter digestive system anatomy, lifestyle and food choices. VBLOC Therapy is delivered via the Maestro® System through laparoscopically implanted leads to intermittently block the vagus nerves using high-frequency, low-energy electrical impulses. VBLOC Therapy is designed to target the multiple digestive functions under control of the vagus nerves and to affect the perception of hunger and fullness.

About EnteroMedics Inc.

EnteroMedics is a development stage medical device company focused on the design and development of devices that use neuroblocking technology to treat obesity and other gastrointestinal disorders. EnteroMedics' proprietary neuroblocking technology, VBLOC® vagal blocking therapy, is designed to intermittently block the vagus nerves using high-frequency, low-energy, electrical impulses. EnteroMedics is currently conducting a feasibility study examining VBLOC Therapy's effects on blood glucose levels in diabetic patients outside of the United States. For more information, visit www.enteromedics.com.

Forward-Looking Safe Harbor Statement:

This press release contains forward-looking statements about EnteroMedics Inc. Our actual results could differ materially from those discussed due to known and unknown risks, uncertainties and other factors including our limited history of operations, our losses since inception and for the foreseeable future; our lack of regulatory approval for our Maestro® System for the treatment of obesity; our preliminary findings from our EMPOWER™ pivotal trial; our ability to commercialize our Maestro System; our dependence on third parties to initiate and perform our clinical trials; the need to obtain regulatory approval for any modifications to our Maestro System; physician adoption of our Maestro System and VBLOC® vagal blocking therapy; our ability to obtain third party coding, coverage or payment levels; ongoing regulatory compliance; our dependence on third party manufacturers and suppliers; the successful development of our sales and marketing capabilities; our ability to raise additional capital when needed; our ability to attract and retain management and other personnel and to manage our growth effectively; potential product liability claims; potential healthcare fraud and abuse claims; potential healthcare legislative reform and our ability to obtain and maintain intellectual property protection for our technology and products. These and additional 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 Form 10-K dated March 12, 2009. We are providing this information as an update to our October 2, 2009 press release and call and do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

Caution-Investigational device. Limited by U.S. Federal law to investigational use.

The implantation procedure and usage of the Maestro® System carry some risks, such as the risk generally associated with laparoscopic procedures and those related to treatment as described in the EMPOWER clinical trial informed consent.

# # #

Exhibit 99.2

EnteroMedics Conference Call

EMPOWER Study Analysis

Speaker Dial-in Number: 888.218.8164

Speaker Passcode: 9194735

Participants:

Greg Lea

Mark B. Knudson, Ph.D.

Katherine Tweden, Ph.D.

6:50 AM CST: Dial into the conference line; line will remain mute until the operator connects you

6:59 AM CST: Operator will ask for a moment of silence as he/she connects the call

7:00 AM CST: Call commences

SLIDE 1

[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 the preliminary results from our detailed review of the EMPOWER study.

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 12, 2009. The Company is providing this information as an update to our October 2 call and does not undertake any obligation to update any forward-looking statements contained in this call as a result of new information, future events or otherwise.

With me today on the call are Dr. Mark Knudson, our President and CEO, and Dr. Katherine Tweden, our Vice President of Research and Clinical. We will begin with prepared remarks and an accompanying presentation, which is available online at www.enteromedics.com. When these remarks are concluded, we will open the call for questions.

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

Mark Knudson:

Thank you Greg, and good morning.

This morning, we announced the preliminary analysis of a detailed review of the EMPOWER study. The ongoing review suggests that vagal blocking therapy may promote safe and effective weight loss as an adjunct to behavioral support, diet and exercise in morbidly obese patients. Because of this, we feel it is important to inform the over 264 patients still enrolled in the study, including 252 study data patients, of our clinical results to date, and to encourage these individuals to continue participating in the trial as prescribed in the protocol.

Our review of data to date suggests that the weight loss effects seen in the trial were evident in both the treatment and control arms. In an effort to understand this finding, we are conducting a comprehensive analysis of clinical, statistical, and engineering data, both from the EMPOWER study and from a recently conducted pre-clinical study. Based on our analysis to date, the control arm of the trial, which was intended to be inactive, apparently provided a low-intensity blocking signal that introduced VBLOC Therapy in human subjects.

SLIDE 2

As we announced on October 2nd, the EMPOWER study did not meet its efficacy endpoints. There was no difference at 12 months between

treatment and control, both of which showed a statistically indistinguishable EWL from implant. That said, the level of weight loss in the control arm was unusually high for inactive therapy. We further noted that results in both arms correlated with average hours of daily use. At an average daily use of over 9 hours, the recommended amount per protocol and a threshold met by 51% of the study subjects, patients in the treatment arm saw an average excess weight loss of 23.1% from implant by BMI method and patients in the control arm saw 22.6% EWL from implant by BMI method.

We also found that for subjects with a diagnosis of hypertension, the study demonstrated a statistically significant average decrease in systolic and diastolic blood pressure that was similar in both the treatment and control groups. This effect was noticeable at one week after activation and was sustained through 12 months.

These results led us to believe that the “placebo mode”, as used in the control group, may not have been neutral. As Dr. Tweden will present to you in a moment, data from a recently completed pre-clinical study show that the “placebo mode,” which delivered low intensity electrical signals as impedance measures and associated system measurements, appears to have delivered enough energy to the nerve to maintain vagal block. This finding expands our understanding of neuroblocking, and we now believe that its effect on vagal block may have been sufficient to lead to weight loss in the control group.

I will now pass the call over to Dr. Tweden who will discuss results of the work we undertook to characterize and understand the control arm effect.

Katherine Tweden:

Thank you Dr. Knudson.

Before we began EMPOWER, existing literature and research led us to believe that signal blocking was related directly to the amount of energy delivered to the nerve. We tested a variety of signal intensities and found that high frequency, low amplitude signaling was the optimal means of achieving a rapid, near-complete block of the vagal nerve. Our pre-clinical research led us to believe that low intensity signals, including the control arm signals, had only a brief and minimal effect on the nerve.

We designed the control arm of EMPOWER to turn off the treatment arm signal, but maintained the low intensity treatment arm impedance and associated system measurement signals to help maintain the study blind. The result was that the treatment arm delivered exponentially more energy than the control arm.

As part of our continuing next-generation research efforts, we recently developed technology and techniques that allow us to test nerve function during high-frequency VBLOC Therapy.

Based on the preliminary EMPOWER results, we applied this technology to conduct a test to measure the effect of the low-intensity signals produced under the control arm conditions on nerve impulses. Using this model, we observed that the nerve impulse decreased by up to approximately 28%. While the response does not occur as rapidly as the treatment arm blocking signal, which achieves a 90 plus percent decrease in nerve impulse in seconds, the cumulative effect of the control arm signal may have been sufficient, due to length of exposure, to cause similar conditions as the treatment arm when used in humans.

Mark Knudson

Thank you Dr. Tweden.

With the possibility of both arms receiving active therapy, we began to look at the data and clinical outcomes of EMPOWER. The results were consistent between the two arms.

SLIDE 3

As you can see from the chart entitled “Optimal Hours of Usage”, average hours of use, or the period of time in which the patient is exposed to therapy, directly corresponds to their level of excess weight loss, with the low energy, partial blocking of the vagal nerve in the control arm producing an almost identical result to the high energy of the treatment arm. We found that optimal hours of use is between 10 and 12 hours a day.

SLIDE 4

In the next slide, entitled “EWL Through 12 Months,” we see both arms combined in a completer analysis. Patients demonstrated a significantly greater EWL benefit when using the device for greater than 9 hours average per day, as prescribed in the protocol. Those exposed to optimal therapy saw sustained weight loss, as seen in the red line, and those who did not, began to see weight gain past 6 months, the blue line. There was no overlap in standard error past activation of the device.

SLIDE 5

In the next slide, entitled “Safety Outcomes,” we see that the EMPOWER study met all of its safety endpoints. The Maestro System was designed to be a safe surgical treatment for obesity, in that it does not require the anatomy to be altered and it does not forcibly constrict a patient’s stomach. As this figure demonstrates, no serious adverse events related to therapy were reported in the EMPOWER study. This data contributes to what is now over 400 patient years of safety data.

SLIDE 6

In the final safety slide, we see very encouraging study participation results, as the chart illustrates. As I noted in my opening remarks, 264 patients, including 252 of the 253 study patients, remain on study. The difference in these numbers relates to the 12 roll-in patients who were not part of the 12 month endpoint but who are now part of the study. All of these patients are now receiving the treatment arm algorithm, but remain blinded as to

their original therapy. In light of our new findings, it is important for us and our participating study centers to support patients in using their Maestro System for 9 or more hours per day.

PAUSE

SLIDE 7

With preliminary results of our detailed review of the EMPOWER study in place:

- We believe that an unanticipated control arm signal may have been sufficient to cause therapeutic vagal down-regulation in human subjects;
- We believe that the EMPOWER study demonstrated a clinically meaningful impact on weight loss and hypertension, results that were achieved with an excellent safety profile;
- We believe that daily hours of therapy use relates directly to weight loss response; and
- We know that over 91 percent of subjects remain on study, receiving VBLOC therapy and are being instructed by their physicians to continue using their Maestro System per protocol.

We are taking steps to discuss the EMPOWER Study with the FDA to determine the appropriate regulatory path forward for the Maestro System as a treatment for morbid obesity.

Before we open the call to questions, I would again like to thank all the investigators and patients who are participating in this trial. We greatly appreciate their time and dedication and will continue working closely with both as we explore the full potential of VBLOC Therapy.

With that, let me now open the call for questions.

Operator?

EMPOWER Study

Summary of Ongoing Review

November 2009

EMPOWER Efficacy Outcomes

Group	EWL from Initiation (primary efficacy endpoint, MetLife)	EWL from Implant (BMI)
VBLOC Therapy	12.1%	16.6%
Control	12.0%	16.4%
By >= 9 hours use/day (prescribed): 128 of 253 subjects (51%) Average hours of use: 10.9 hours/day		
VBLOC Therapy	18.3%	23.1%
Control	17.8%	22.6%
By <9 hours use/day: 125 of 253 subjects (49%) Average hours of use: 6.9 hours/day		
VBLOC Therapy	6.4%	10.5%
Control	4.6%	8.6%

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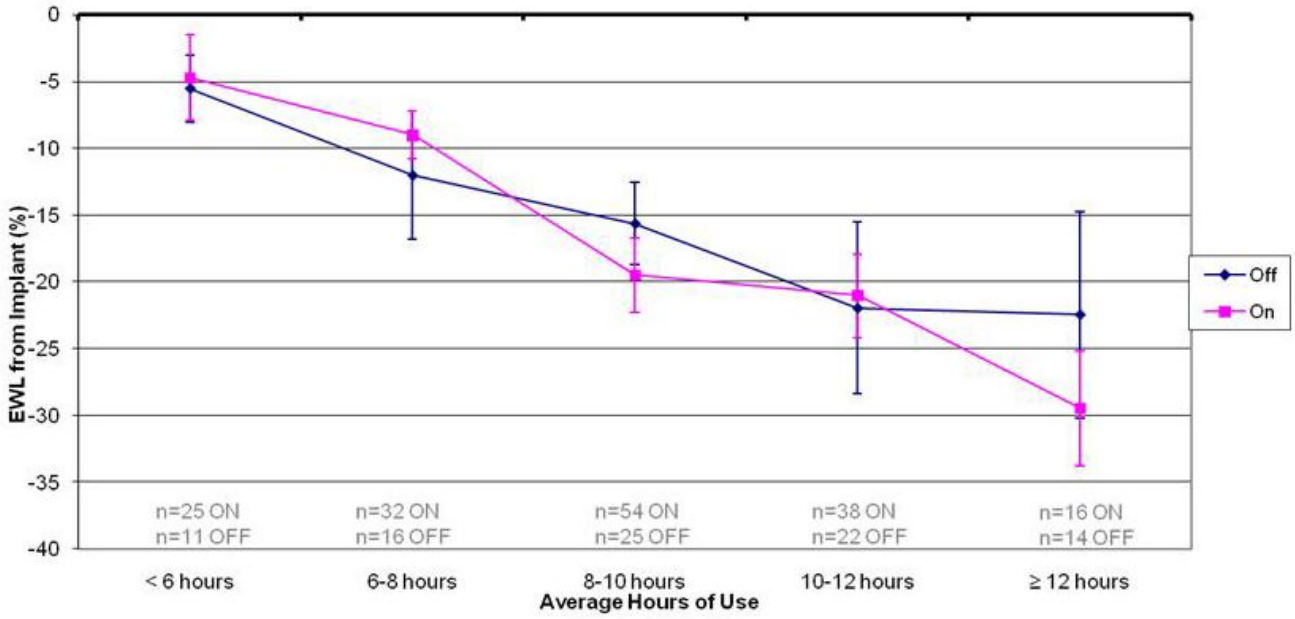
Optimal Hours of Usage

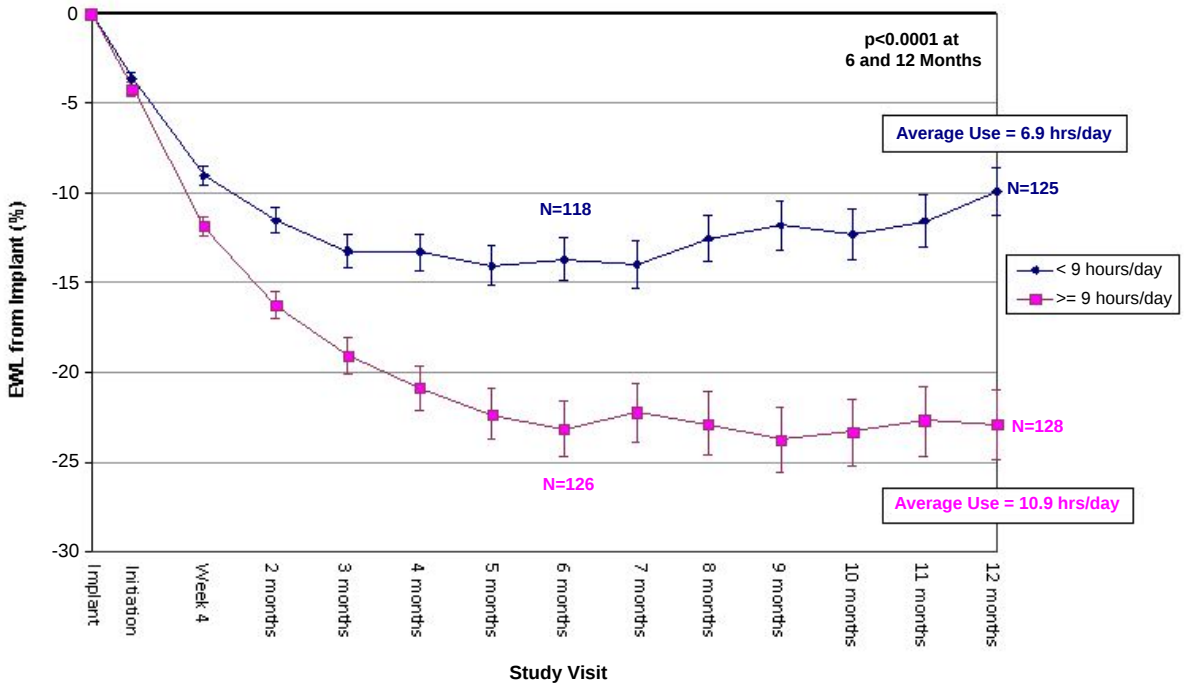
Mean EWL from Implant (BMI Method) with Standard Error at 12 Months by Categories of Average Hours of Use per Day through 12 Months



EnteroMedics

EWL Through 12 Months

Mean EWL from Implant (BMI Method) by Average Hours of Use per Day with Standard Error for 12 Month Completer Cohort



Safety Outcomes: Serious Adverse Events (SAEs)

- No deaths
- No Unanticipated Adverse Device Effects (UADEs)
- 30 SAEs (see table below)
- No therapy-related SAEs

Clinical Events Committee-Adjudicated Relatedness of SAE (Event Origin)	VBLOC Therapy N=192	Control N=102	Overall N=294
Device	3 (1.6%)	1 (1.0%)	4 (1.4%)
General surgical procedure	4 (2.1%)	0 (0.0%)	4 (1.4%)
Implant/revision procedure	3 (1.6%)	2 (2.0%)	5 (1.7%)
Pre-existing condition	9 (4.7%)	8 (7.8%)	17 (5.8%)
Therapy algorithm	0 (0.0%)	0 (0.0%)	0 (0.0%)

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Safety Outcomes: Study Withdrawals

- 8.5% of patients withdrew in the first 12 Months

Reason for Study Withdrawal	VBLOC Therapy N=192	Control N=102	Overall N=294
Adverse Event	7 (3.6%)	1 (1.0%)	8 (2.7%)
Lost to follow-up	2 (1.0%)	1 (1.0%)	3 (1.0%)
Subject decision	11 (5.7%)	3 (2.9%)	14 (4.8%)
Total	20 (10.4%)	5 (4.9%)	25 (8.5%)

EnteroMedics

EMPOWER Study

Summary of Ongoing Review

November 2009

EnteroMedics™