

---

---

**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 7, 2012**  
(Date of earliest event reported)

---

**ENTEROMEDICS INC.**

(Exact name of registrant as specified in its charter)

---

**Commission File Number: 1-33818**

**Delaware**  
(State or other jurisdiction  
of incorporation)

**48-1293684**  
(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 7.01. Regulation FD Disclosure.**

On November 7, 2012, EnteroMedics Inc. (the "Company") issued a press release announcing that hypertension data from a subgroup analysis of the EMPOWER trial was presented at the American Heart Association's 2012 Scientific Sessions held November 3-7 in Los Angeles, California. Copies of this press release and presentation are furnished herewith as Exhibits 99.1 and 99.2 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K and in the accompanying exhibit shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Current Report on Form 8-K and in the accompanying exhibits shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u>                              |
|--------------------|---|
| 99.1               | Press release dated November 7, 2012.           |
| 99.2               | AHA 2012 Presentation made on November 7, 2012. |

**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 13, 2012

**EXHIBIT INDEX**

| <u>Exhibit No.</u> | <u>Description</u>                              |
|--------------------|---|
| 99.1               | Press release dated November 7, 2012.           |
| 99.2               | AHA 2012 Presentation made on November 7, 2012. |



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

**Enteromedics Announces EMPOWER Trial Hypertension Data  
 Presented at the American Heart Association's 2012 Scientific Sessions**

**ST. PAUL, Minn., November 7, 2012** – Enteromedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced that hypertension data from a subgroup analysis of the EMPOWER trial were presented today at the American Heart Association's 2012 Scientific Sessions, held on November 3-7, 2012 in Los Angeles, CA.

The EMPOWER trial is a randomized, double-blind, controlled pivotal study designed to evaluate the safety and efficacy of the Maestro® System using VBLOC® vagal blocking therapy in 294 obese subjects. A subgroup analysis was conducted to determine if VBLOC Therapy would improve blood pressure prior to significant weight loss in obese subjects with hypertension, as defined by elevated blood pressure at baseline by JNC-7 guidelines (n=37, Group A) or history of hypertension (n=58, Group B) at baseline. The analysis was performed in a subset of subjects who had ≥ 9 hours therapy delivered per day to 12 months.

**Subject Demographics**

|                          | <b>Group A<br/>(Elevated Blood Pressure)</b> | <b>Group B<br/>(History of Hypertension)</b> |
|--------------------------|--|--|
| # of Subjects            | 37   | 58   |
| BMI (kg/m <sup>2</sup> ) | 41±1   | 41±1   |
| Age (Years)              | 50±1   | 51±1   |
| Female/Male              | 31/6   | 47/11  |

**Change in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) from Baseline**

**Group A (Subjects with Elevated Blood Pressure) (P<.001)**

|                      | <u>Baseline</u> | <u>Week 2</u> | <u>Week 4</u> | <u>12 Months</u> |
|----------------------|-----------------|---------------|---------------|------------------|
| SBP (mmHg)           | 145±2           | -17±3         | -17±3         | -18±3            |
| DBP (mmHg)           | 89±2            | -9±2          | -8±2          | -10±2            |
| % Excess Weight Loss | N/A             | 9±2           | 12±1          | 21±4             |

**Group B (Subjects with History of Hypertension) (P<.001)**

|                      | <u>Baseline</u> | <u>Week 2</u> | <u>Week 4</u> | <u>12 Months</u> |
|----------------------|-----------------|---------------|---------------|------------------|
| SBP (mmHg)           | 134±2           | -10±2         | -9±2          | -13±2            |
| DBP (mmHg)           | 84±1            | -6±1          | -6±1          | -7±1             |
| % Excess Weight Loss | N/A             | 9±1           | 13±2          | 23±3             |

“The results of this substudy analysis are remarkable, in that VBLOC Therapy has demonstrated a clinically meaningful, non-pharmacologic, immediate and sustained reduction in blood pressure in obese subjects with hypertension,” said Robert M. Carey, M.D., Professor, Division of Endocrinology and Metabolism, University of Virginia Health System. “This effect suggests that VBLOC Therapy may offer the first, non-pharmacologic intervention for hypertension in obese subjects, a clinical outcome that, with available obesity surgical treatments, has never before been achieved.”

Mark B. Knudson, Ph.D., EnteroMedics’ President and Chief Executive Officer, added: “These data suggest that VBLOC Therapy may significantly reduce blood pressure in obese subjects with hypertension, an effect which appears to be independent of weight loss and achieves a greater magnitude of reduction at higher baseline blood pressure values. These data add to our extensive clinical experience with VBLOC Therapy and the Maestro System in obesity and its related co-morbidities of hypertension and diabetes. We have begun the process of amending our CE Mark certification to include these effects on hypertension and diabetes, adding to our obesity certification.”

#### **About Maestro® System**

The Maestro System delivers VBLOC® vagal blocking therapy via two small electrodes that are laparoscopically implanted and placed in contact with the trunks of the vagus nerve just above the junction between the esophagus and the stomach. The Maestro RF System, used in the EMPOWER trial reported here, is powered by an external battery, contained in a mobile controller, via a transmit coil. The newer Maestro RC System is powered by an internal, rechargeable battery. The battery is recharged as needed via an external mobile charger and transmit coil.

#### **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 medical device company focused on the development and commercialization of its neuroscience based technology to treat obesity and metabolic diseases.

EnteroMedics’ proprietary technology, VBLOC® vagal blocking therapy, delivered by a pacemaker-like device called the Maestro® Rechargeable System, is designed to intermittently block the vagus nerves using high-frequency, low-energy, electrical impulses. VBLOC allows people with obesity to take a positive

path towards weight loss, addressing the lifelong challenge of obesity and its comorbidities without sacrificing wellbeing or comfort. EnteroMedics' Maestro Rechargeable System has received CE Mark and is listed on the Australian Register of Therapeutic Goods.

**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 commercial regulatory approval for our Maestro® System for the treatment of obesity in the United States or in any foreign market other than Australia and the European Community; our preliminary findings from our EMPOWER™ pivotal trial; our ability to comply with the Nasdaq continued listing requirements; 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; international commercialization and operation; 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; 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 annual report on Form 10-K filed March 15, 2012. We are providing this information as of the date of this press release 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 Federal (United States) law to investigational use.

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

# Intermittent Neural Transmission Block Of The Intra-abdominal Vagus Induces Sustained Blood Pressure Reduction In Obese Subjects

Katherine S Tweden, PhD<sup>a</sup>, Mark B Knudson, PhD<sup>a</sup>,  
Scott A Shikora, MD<sup>b</sup>, Robert M Carey, MD<sup>c</sup>

<sup>a</sup>EnteroMedics, Inc, St. Paul, MN; <sup>b</sup>Brigham and Women's Hospital, Boston, MA;  
<sup>c</sup>University of Virginia Health System, Charlottesville, VA

Abstract

13195

SCIENTIFIC 2012  
SESSIONS 0|12

# Financial Disclosures

This clinical trial was completely funded  
by *EnteroMedics Inc.*, St. Paul, MN, USA

# Background

- Intermittent block of the intra-abdominal vagus (VBLOC) using an implantable device has been shown to cause significant EWL in obese subjects.
- We tested the hypothesis that VBLOC would improve blood pressure (BP) prior to significant WL in obese subjects with a diagnosis of hypertension (HT) or elevated BP at baseline.

# Methods

- BP was measured at baseline, weekly to 4 wk and monthly to 12 mo during a randomized, controlled trial to evaluate weight loss in 294 obese subjects.
- HT was defined by JNC-7 guidelines (group A) or if subjects had HT history (group B); the analysis was performed in a subset of subjects who had  $\geq 9$  hrs therapy delivered per day to 12 mo.

# Demographics

|                               | <b>Group A</b>                   | <b>Group B</b>                     |
|-------------------------------|----------------------------------|------------------------------------|
|                               | <b>Subjects with elevated BP</b> | <b>Subjects with history of HT</b> |
| <b>n</b>                      | <b>37</b>                        | <b>58</b>                          |
| <b>BMI (kg/m<sup>2</sup>)</b> | <b>41±1</b>                      | <b>41±1</b>                        |
| <b>Age (years)</b>            | <b>50±1</b>                      | <b>51±1</b>                        |
| <b>Female/Male Ratio</b>      | <b>31/6</b>                      | <b>47/11</b>                       |

# Change in SBP and DBP and %EWL Over 12 months

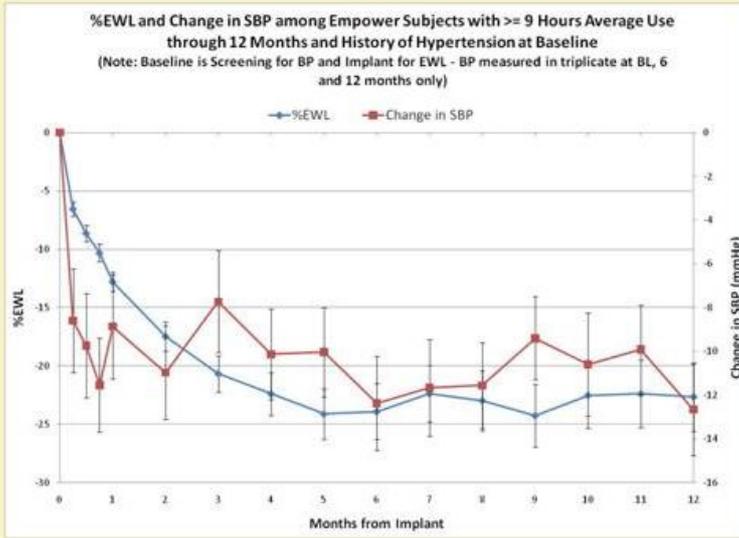


Figure 2: Relationship of Change in SBP (mmHg) to 12 Months Compared to %EWL (Group B)

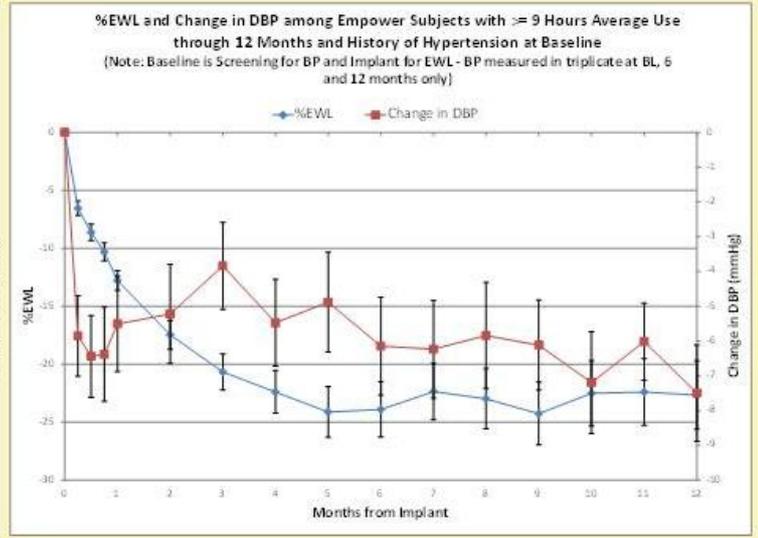


Figure 3: Relationship of Change in DBP (mmHg) to 12 Months Compared to %EWL (Group B)

# SBP and DBP Reduction Compared to %EWL at 6 months

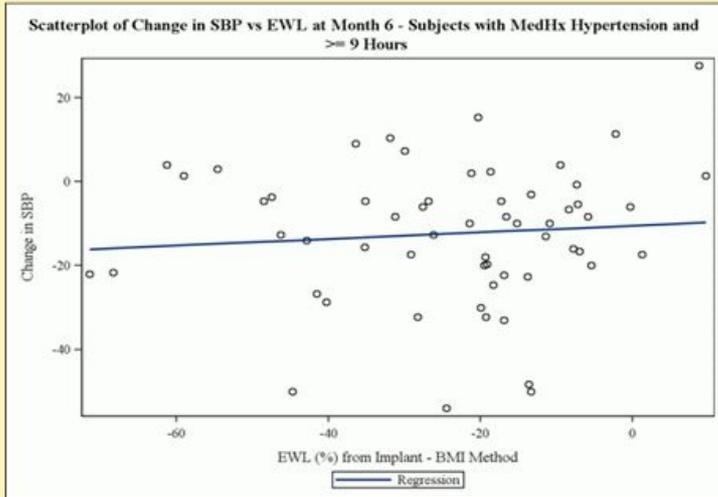


Fig 4: Relationship of Change in SBP (mmHg) at 6 Months Compared to %EWL (Group B),  $p=0.52$ ,  $r=0.09$

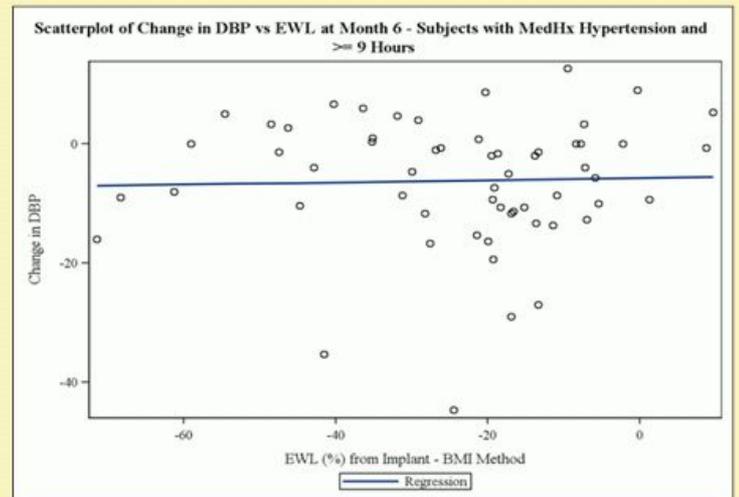


Fig 5: Relationship of Change in DBP (mmHg) at 6 Months Compared to %EWL (Group B),  $p=0.82$ ,  $r=0.03$

# SBP and DBP Reduction Compared to Baseline BP at 12 mo

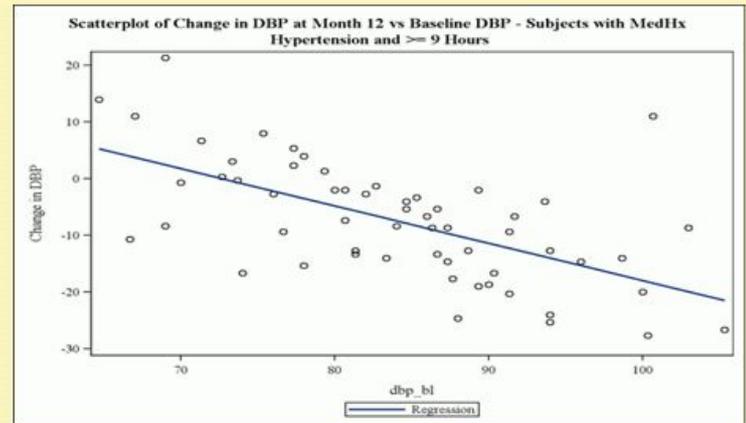
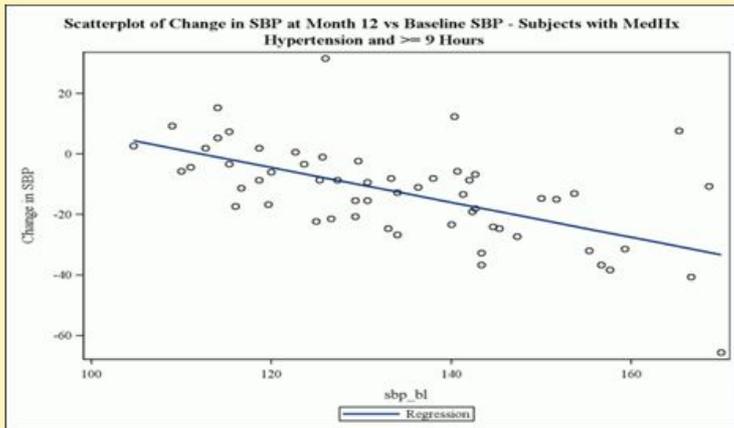


Figure 6: Relationship of Change in SBP (mmHg) at 12 Months Compared to Baseline (Group B),  $p < 0.0001$ ,  $r = -0.6$

Figure 7: Relationship of Change in DBP (mmHg) at 12 Months Compared to Baseline (Group B),  $p < 0.0001$ ,  $r = -0.61$

# Discussion

- Change in BP in hypertensive subjects and subjects with elevated BP occurred prior to weight loss and was sustained to 12 months
- BP reduction was independent of weight loss magnitude
- Higher baseline values of BP were associated with larger reductions in BP levels

# Conclusions

- VBLOC induced clinically significant, sustained BP reduction at 1 year in obese subjects with a history of HT or elevated BP prior to therapy.
- These data suggest that VBLOC therapy may offer major non-pharmacologic BP reduction for obese subjects with HT.
- These findings will need to be confirmed in a prospective, randomized, controlled trial to clarify the role of this therapy in hypertension treatment.