UNITED STATE
SSECURITIES 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.

On February 7, 2013, EnteroMedics Inc. (the "Company") issued a press release announcing the preliminary results of its ReCharge pivotal trial for obesity. The Company will host a conference call to discuss the preliminary ReCharge results at 5:00 p.m. Eastern Time on February 7, 2013. The information needed to access the conference call is provided in the press release. A copy of the press release 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	Press release 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	Press release dated February 7, 2013.

EnteroMedics' ReCharge Trial Demonstrates Statistically Significant Weight Loss in Obesity But Does Not Meet Predefined Efficacy Endpoints

-Based on Compelling Data, Company Plans Pre-Market Approval (PMA) Application

-Company to Host Conference Call Today, February 7, 2013, at 5:00 PM ET

ST. PAUL, Minnesota, February 7, 2013 – EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced results from its randomized ReCharge Pivotal Trial of VBLOC® vagal blocking therapy for the treatment of obesity. The trial demonstrated a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% for VBLOC Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. The trial met its primary safety endpoint, though it did not meet its predefined primary efficacy measures.

As a result of the excellent safety and efficacy profile of VBLOC Therapy, EnteroMedics plans to move forward with a Pre-Market Approval (PMA) application with the U.S. Food and Drug Administration (FDA) in the second quarter of 2013.

"Even though we did not reach the predefined efficacy thresholds, data from the ReCharge trial clearly demonstrate VBLOC Therapy's positive effect on weight loss, while adding to an excellent safety record," said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. "Based on these compelling results, and the totality of our clinical experience with the Maestro System, which now includes more than 600 patients worldwide, we believe EnteroMedics is well positioned to deliver this novel therapy to people with obesity in the U.S. We are moving forward with a PMA application to the FDA, in addition to advancing our plans for pursuing other indications, including obesity-related diabetes and hypertension, outside the U.S."

"Coupled with excellent safety results, the weight loss results for individuals getting VBLOC Therapy in the ReCharge trial demonstrate an excellent benefit-to-risk equation," said Robin Blackstone, MD, FACS, FASMBS, surgeon and Medical Director of Scottsdale Healthcare Bariatric Center at Scottsdale Healthcare in Arizona and Clinical Associate Professor of Surgery at the University Of Arizona College Of Medicine and investigator for the ReCharge trial. "If approved, VBLOC will fill a significant gap in the treatment spectrum, offering a unique approach that supports a healthy lifestyle and addresses the lifelong challenges associated with obesity and its co-morbidities."

Results in Detail

The ReCharge Pivotal Trial of VBLOC Therapy is a prospective double-blind, sham-controlled clinical trial involving 239 randomized patients (233 implanted) at ten sites in the United States and Australia.

Patients were surgically implanted with either a fully functional device with leads to the vagus nerve (treated) or a device without leads to the vagus nerve (sham control).

In the primary analysis (intent-to-treat) population (n=239), treatment patients achieved a 24.4% average EWL compared to 15.9% for sham control patients. This 8.5% difference demonstrated statistical superiority over sham control (p=0.002), but not super-superiority at the pre-specified 10% margin (p=0.705). In total, 52.5% of treatment patients had 20% or more EWL compared to 32.5% in the control group (p=0.004), and 38.3% of treatment patients had 25% or more EWL compared to 23.4% in the sham control group (p=0.02). 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.

In the per protocol group, which included only those patients who received therapy per the trial design (n=211), the treatment patients had an average 26.3% EWL compared to 17.3% for the sham control group (p=0.003). In total, 56.8% of treated patients achieved at least 20% EWL, which was above the pre-defined threshold of 55% compared to 35.4% in the sham control group (p=0.004). 41.8% of patients also achieved at least 25% EWL in this population, which is slightly less than the predefined threshold of 45%, compared to 26.2% in the sham control group (p=0.03).

The rate of device-related serious adverse events was 3.1% for the treatment arm, significantly lower than the threshold of 15% ($p<0.0001$). The safety results also confirmed VBLOC Therapy had no adverse cardiovascular effect. An overall reduction in blood pressure and heart rate was also observed in the treatment arm. Approximately 93% of patients reached the 12 month assessment in the trial, consistent with a rigorously executed trial.

Conference Call and Webcast

EnteroMedics will host a conference call and live webcast to discuss the detailed findings of its ReCharge Pivotal Trial today, February 7, 2013, at 5:00 PM ET. The conference call will be accompanied by a slide presentation available at www.enteromedics.com. The conference call may be accessed by dialing (877) 280-7473 for domestic callers and (707) 287-9370 for international callers and providing conference ID number 88748024. A replay of the call will be available beginning February 7, 2013 through May 6, 2013, and may be accessed by dialing (855) 859-2056 for domestic callers and (404) 537-3406 for international callers.

The call will be webcast live and may be accessed by visiting EnteroMedics' website at www.enteromedics.com. Investors can access the webcast under "Events" 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 the ReCharge Pivotal Trial

The ReCharge Pivotal Trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial in 239 randomized patients (233 implanted) at 10 sites testing the effectiveness and safety of VBLOC® vagal blocking therapy utilizing EnteroMedics' second generation Maestro® Rechargeable (RC) System. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or control groups. The control group received a non-functional device during the trial period. All patients are expected to participate in a weight management counseling program.

About Maestro Rechargeable (RC) System

The Maestro RC 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 RC System is powered by an internal, rechargeable battery. The battery is recharged via an external mobile charger and transmit coil that the patient uses for a short time each week. The Maestro RC System has received CE Mark and has been listed on the Australian Register of Therapeutic Goods.

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™ and ReCharge pivotal trials; 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.

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