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

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**FORM 8-K**

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

**Date of Report: May 14, 2013  
(Date of earliest event reported)**

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**ENTEROMEDICS INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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))
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**Item 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.**

On May 14, 2013, EnteroMedics Inc. (the "Company") received a written notice (the "Notice") from the Listing Qualifications department of The Nasdaq Stock Market ("Nasdaq") indicating that the Company is not in compliance with the \$1.00 Minimum Bid Price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on the Nasdaq Capital Market.

The Nasdaq Listing Rules require listed securities to maintain a minimum bid price of \$1.00 per share and, based upon the closing bid price for the last 30 consecutive business days, the Company no longer meets this requirement. The Notice indicated that the Company will be provided 180 calendar days in which to regain compliance. If at any time during this period the bid price of the Company's common stock closes at or above \$1.00 per share for a minimum of ten consecutive business days, the Nasdaq Staff will provide the Company with a written confirmation of compliance and the matter will be closed.

In the event the Company does not regain compliance with Rule 5550(a)(2) prior to the expiration of the 180 calendar day period, the Nasdaq Staff will provide the Company with written notification that its securities are subject to delisting from The Nasdaq Capital Market. At that time, the Company may appeal the delisting determination to a Hearings Panel.

Alternatively, if the Company fails to regain compliance with Rule 5550(a)(2) prior to the expiration of the 180 calendar day period, but meets the continued listing requirement for market value of publicly held shares and all of the other applicable standards for initial listing on The Nasdaq Capital Market, with the exception of the minimum bid price, and provides written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary, then the Company may be granted an additional 180 calendar days to regain compliance with Rule 5550(a)(2).

The Company intends to actively monitor its performance with respect to the listing standards and will consider available options to resolve the deficiency and regain compliance with the Nasdaq rules.

**Item 8.01. Other Events.**

On May 17, 2013, the Company issued a press release announcing it had completed a pre-PMA (Premarket Approval) application meeting with the U.S. Food and Drug Administration (FDA) on May 15, 2013 regarding the Maestro® Rechargeable System's VBLOC® vagal blocking therapy as a treatment for obesity. In the meeting, the FDA indicated that, subject to acceptance of the application and validation and detailed review of the submitted data by the FDA, the Company can anticipate presenting the PMA before a future FDA Advisory Committee panel. The Company expects to submit a PMA for the Maestro Rechargeable System, based on the ReCharge Pivotal Trial, in the second quarter of 2013. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Information and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 17, 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,

Chief Financial Officer and Chief Operating Officer

Date: May 17, 2013

**EXHIBIT INDEX**

Exhibit  
Number

Description

99.1

Press Release dated May 17, 2013.



## **EnteroMedics Completes VBLOC Therapy Pre-PMA Meeting with FDA**

***-Company Expects to Submit PMA in Second Quarter 2013  
- Prepares for Subsequent Advisory Panel Review***

**ST. PAUL, Minnesota, May 17, 2013** – EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced that the Company completed a pre-PMA (Premarket Approval) application meeting with the U.S. Food and Drug Administration (FDA) on May 15, 2013 regarding the Maestro® Rechargeable System’s VBLOC® vagal blocking therapy as a treatment for obesity. In the meeting, the FDA indicated that, subject to acceptance of the application and validation and detailed review of the submitted data by the FDA, the Company can anticipate presenting the PMA before a future FDA Advisory Committee panel. The Company expects to submit a PMA for the Maestro Rechargeable System, based on the ReCharge Pivotal Trial, in the second quarter of 2013.

“We had a very open and productive meeting with the FDA and look forward to submitting our PMA, as anticipated, this quarter,” said Mark B. Knudson, Ph.D., EnteroMedics’ President and Chief Executive Officer. “We are confident that the Maestro System holds the unique potential to fill a significant gap that currently exists in the treatment options for people with obesity.”

### **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 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. In February, EnteroMedics announced that its ReCharge Trial demonstrated a statistically significant and clinically meaningful excess weight loss (EWL) outcome and excellent safety profile. This included an average EWL of approximately 25% for VBLOC Therapy-treated patients, with over 50% of those patients achieving at least a 20% EWL. While the results demonstrated an excellent safety profile that met the pre-specified trial measures, with both a positive benefit-to-risk equation and a medically meaningful and clinically significant effect over the control group, the results did not meet the study’s predefined efficacy measures.

## **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 7, 2013. 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.

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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.

Company Contact:

EnteroMedics Inc.

Greg S. Lea

(651) 789-2860

ir@enteromedics.com

Media Contact:

Sam Brown Inc.

Mike Beyer

(312) 961-2502

beyer@sambrown.com