# 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: May 18, 2011

(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 May 18, 2011, EnteroMedics Inc. (the "Company") issued a press release to announce that the first patient has been implanted in the Company's ReCharge pivotal trial for obesity. A copy of this press release is furnished herewith as Exhibit 99.1 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 exhibit 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.

Exhibit No. Description

99.1 Press release dated May 18, 2011.

# 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: May 18, 2011

# EXHIBIT INDEX

Exhibit No. Description

99.1 Press release dated May 18, 2011.

# **Contact:**

EnteroMedics Inc.

Greg S. Lea

(651) 789-2860

ir@enteromedics.com

### EnteroMedics Announces First Implant in ReCharge Pivotal Trial for Obesity

**ST. PAUL, Minnesota, May 18, 2011** - EnteroMedics Inc., (NASDAQ: ETRM), the only developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, today announced that the first patient has been implanted in the Company's ReCharge pivotal trial for obesity. The ReCharge trial is a randomized, double-blind, parallel-group, multicenter pivotal study testing the effectiveness and safety of VBLOC Therapy, delivered via EnteroMedics' second generation Maestro Rechargeable (RC) System, in the treatment of obesity. The study is expected to enroll 234 patients at up to 12 sites in the U.S. and Australia. The Maestro RC System is the first obesity treatment to use neuroblocking technology and represents a less invasive alternative to existing surgical weight loss procedures, which alter digestive system anatomy, lifestyle and food choices and may present significant risks.

All patients in the ReCharge trial will receive an implanted device and be randomized in a 2:1 allocation to treatment or control groups. The control group will receive a functional, but non-active device that will deliver no charge to the vagus nerve during the blinded study period. All patients are expected to participate in a weight management counseling program.

"The Maestro System is the only surgical weight loss option to affect the physiology of hunger and fullness. With this device, the patient can achieve weight loss without imposing the compromises in safety, diet and lifestyle that are associated with existing surgical procedures for obesity," said Michael Sarr, M.D., Vice Chair of Research in the Department of Surgery at Mayo Clinic, and national principal investigator of the ReCharge trial. "The ReCharge study will be an important measure of the safety and efficacy of the Maestro RC System in a large study population, and builds off of clinically meaningful results seen in earlier feasibility studies."

"First implant in our pivotal ReCharge study is an important milestone for EnteroMedics as we work to deliver the first-ever patient-oriented surgical obesity treatment to markets where obesity has become an epidemic," said President and Chief Executive Officer Mark B. Knudson, Ph.D. "At this early stage, our projections to have the trial completely enrolled and implanted by yearend remain on track. EnteroMedics also continues to make substantial progress in our effort to commercialize the Maestro System in Australia, where we plan to file an application for approval and listing with the Australian Therapeutic Goods Administration. Our exploration of potential commercialization opportunities in select markets in Europe also continues to be encouraging."

For additional information on the ReCharge study, please visit www.RechargeStudy.com.

## **About Maestro RC System**

The Maestro® Rechargeable (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 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.

## 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. These electrical impulses are delivered by a neuroregulator, EnteroMedics' Maestro RC System, which is powered by an integrated rechargeable battery. 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<sup>™</sup> 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<sup>®</sup> 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 with the Securities and Exchange Commission on March 7, 2011. 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 - U.S. Investigational device. Limited within the United States 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 ReCharge clinical trial informed consent.

Mayo Clinic has a financial interest in EnteroMedics resulting from equity received for technologies licensed to EnteroMedics that are not related to this research. Mayo Clinic and Dr. M. Sarr also receive fees through a know-how agreement with EnteroMedics for his counsel related to this research.