# 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: June 14, 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)

ck 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 isions:
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 June 14, 2011, EnteroMedics Inc. (the "Company") issued a press release to announce that updated weight loss data from clinical studies of the Company's VBLOC® vagal blocking therapy delivered via the Maestro® Rechargeable (RC) System will be presented at the 28th Annual Meeting of the American Society of Metabolic and Bariatric Surgeons being held June 13-17 in Orlando, Florida. The Company also announced long-term, updated obesity, diabetes and hypertension clinical results from its VBLOC-DM2 ENABLE and EMPOWER Studies of the Maestro® System. 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

No. Description

99.1 Press release dated June 14, 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: June 14, 2011

# EXHIBIT INDEX

Exhibit No.

Description

99.1 Press release dated June 14, 2011.



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

# EnteroMedics Announces Maestro® RC System Updated Weight Loss Data to Be Presented at the American Society for Metabolic and Bariatric Surgery Annual Meeting

# Company Also Announces Long-term, Updated Data from VBLOC-DM2 and EMPOWER Studies

ST. PAUL, Minn., June 14, 2011 – EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, today announced that updated weight loss data from clinical studies of the Company's VBLOC® vagal blocking therapy delivered via the Maestro® Rechargeable (RC) System will be presented at the 28th Annual Meeting of the American Society of Metabolic and Bariatric Surgeons (ASMBS), being held June 13-17 in Orlando, FL. The presentation, titled "Vagal Blocking for the Treatment of Obesity Delivered Using the Fully Implantable Maestro Rechargeable System: 12 Month Results," will be delivered by Dr. Lillian Kow, BMBS, PhD, FRACS, on June 17, 2011 at 8:30 AM ET.

Dr. Kow stated: "The Maestro System is the only surgical intervention to demonstrate a prolonged effect on weight loss and obesity related co-morbidities without compromises in safety, lifestyle or anatomy. The data presented at ASMBS support our increasingly well-established understanding of how VBLOC Therapy affects the underlying physiology of obesity and undermines the feelings of hunger or lack of fullness that sustain it. I look forward to longer-term follow up in the DM2 study and to results of the ongoing, larger outcome ReCharge study."

The Company also announced long-term, updated obesity, diabetes and hypertension clinical results, including weight loss, HbA1c and blood pressure data, from its VBLOC-DM2 ENABLE and EMPOWER Studies of the Maestro® System. For all studies of the Maestro® Systems, there remain no reported therapy-related serious adverse events.

Mark B. Knudson, PhD, EnteroMedics' President and Chief Executive Officer, said: "We continue to see clinically meaningful and durable weight loss results, an excellent overall safety profile, significant effects on the co-morbidities of hypertension and diabetes and high levels of patient acceptance with the Maestro System. These outcomes, which come from a broad patient population, support our confidence in the ongoing pivotal ReCharge Trial, which remains on track for completion of enrollment by year-end. We also continue to make progress in our commercial development efforts for the Maestro System in Australia and select European markets."

#### Updated Maestro® Rechargeable System Data Presented at ASMBS

Updated data presented at ASMBS included combined excess weight loss (EWL) data from two studies of EnteroMedics' second-generation Maestro® RC System: the Company's initial feasibility study in patients with morbid obesity and the VBLOC-DM2 ENABLE study in patients with morbid obesity and Type-2 diabetes mellitus.

Percent excess weight loss (% EWL) (BMI Method from implant, Company presented data):

Visit	%EWL	N
Visit 4 Weeks	-12.3	33
12 Weeks	-19.9	30
6 Months	-23.5	30
12 Months	-25.4	30

## **Updated VBLOC-DM2 ENABLE Study Data**

• Percent excess weight loss (% EWL) (BMI Method from implant, Company updated data):

	%EWL	
	(≥ 12	
Visit (post-device activation)	hours therapy delivery per day)	N
Week 1	-9.5	25
3 Months	-20.8	26
6 Months	-25.2	24
12 Months	-27.2	24
18 Months	-24.6	22

% EWL for all patients (N=24) is -22.6 at 18 Months. Two patients are not currently receiving therapy for unrelated medical reasons.

Interim analysis. N is patients who have reached those time points and were seen for the scheduled visit.

 $H_bA1_c$  change in percentage points (Company updated data):

Visit (post-device activation)	% H <sub>b</sub> A1 <sub>c</sub> change	N	P=
Week 1 (Baseline 7.8%)	-0.3	28	0.002
Week 4 (Baseline 7.8%)	-0.7	28	< 0.001
3 Months (Baseline 7.7%)	-0.9	26	< 0.001
12 Months (Baseline 7.7%)	-1.0	26	< 0.001
18 Months (Baseline 8.1%)	-1.2	13	< 0.001

• Fasting Plasma Glucose Change (Baseline 151.4 mg/dl average)(Company updated data):

	Glucose		
	Change		
Visit (post-device activation)	(mg/dl)	N	P=
Week 1	-20.9	28	< 0.001
6 Months	-28.7	25	0.002
12 Months	-27.6	25	0.003
18 Months	-38.4	12	0.008

Change in mean arterial pressure (MAP) in hypertensive patients (baseline 99.5 mmHg, Company updated data):

Visit (post-device activation)	MAP change (mmHg)	<u>N</u>	P=
Week 1	-6.8	15	0.04
6 Months	-12.5	13	< 0.001
12 Months	-7.8	14	0.03
18 Months	-13.0	13	0.002

Change in diastolic blood pressure (DBP) in hypertensive patients (baseline 87.2 mmHg, Company updated data):

Visit (post-device activation)	DBP change (mmHg)	N	P=
Week 1	-10.1	12	< 0.001
6 Months	-13.8	10	< 0.001
12 Months	-10.2	11	0.009
18 Months	-15.9	10	< 0.001

## **Updated EMPOWER Study Results**

The EMPOWER study is a randomized, double-blind, controlled pivotal study designed to evaluate the safety and efficacy of the Company's first-generation Maestro® RF System in the treatment of obesity. Unlike the second-generation Maestro® RC System, which is powered by an internal battery recharged via an external mobile charger and transmit coil worn by the patient for a short time each week, the Maestro® RF System is powered by an external controller and transmit coil which must be worn daily by the patient for the hours prescribed to receive therapy.

The Company today announced updated 30 month data on EWL:

Visit	EWL	N
<u>Visit</u> 6 Months	-17.9%	N 271
12 Months	-16.3%	265
18 Months	-17.2%	188
24 Months	-19.2%	164
30 Months	-19.8%	107

Interim analysis. N at 18, 24 and 30 months are patients who have reached those time points and were seen for the scheduled visit.

#### **About the ReCharge Pivotal Trial**

The ReCharge Clinical Trial is a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in 234 patients at up to 12 sites testing the effectiveness and safety of VBLOC® vagal blocking therapy in EnteroMedics' second generation Maestro® Rechargeable (RC) System. All patients in the study will receive an implanted device and will be randomized in a 2:1 allocation to

treatment or control groups. The control group will receive a functional, but non-active device without lead placement on the vagus nerve that will deliver no charge to the vagus nerve during the study period. All patients are expected to participate in a weight management counseling program.

#### 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 <a href="https://www.enteromedics.com">www.enteromedics.com</a>.

#### **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 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 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.