# 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: October 20, 2010 (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 October 20, 2010, EnteroMedics Inc. issued a press release to announce updated clinical results, including weight loss, HbA1c and hypertension control data, from the Company's VBLOC-DM2 ENABLE, EMPOWER and VBLOC RF2 Studies of VBLOC® vagal blocking therapy delivered via the Maestro® System. The Company also announced that it has received unconditional approval for its Investigational Device Exemption application with the U.S. Food and Drug Administration. 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 EnteroMedics Inc., 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 October 20, 2010.

### 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: October 20, 2010

#### **EXHIBIT INDEX**

Exhibit No. Description

99.1 Press release dated October 20, 2010.



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

## EnteroMedics Announces Updated Data from VBLOC-DM2, EMPOWER and VBLOC RF2 Studies

#### Company Receives Unconditional Approval of Investigational Device Exemption

ST. PAUL, Minn., October 20, 2010 – EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, today announced updated clinical results, including weight loss, HbA1c and hypertension control data, from the Company's VBLOC-DM2 ENABLE, EMPOWER and VBLOC RF2 Studies of VBLOC® vagal blocking therapy delivered via the Maestro® System. The Maestro 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. For all studies of the Maestro RF and RC Systems, there remain no reported therapy-related serious adverse events.

The Company also announced today that it has received unconditional approval for its Investigational Device Exemption (IDE) application with the U.S. Food and Drug Administration (FDA). The IDE outlines plans for conducting a pivotal trial, the ReCharge Trial, evaluating the safety and efficacy of VBLOC Therapy delivered via the Company's next-generation Maestro RC System in the treatment of obesity. The Company announced on August 2, 2010 that it had received conditional IDE approval from the FDA.

"The Maestro System continues to demonstrate clinically meaningful weight loss results, as well as an significant effect on hypertension and diabetes, two major co-morbidities of obesity," said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. "As our ongoing studies mature past one or more years of follow up, the Maestro System clinical findings indicate that the weight loss results are durable. We continue our efforts to bring this safe and effective treatment option to major global markets where obesity has become an epidemic, while looking ahead to the ReCharge study as part of our U.S. commercialization strategy."

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

The DM2 study is an ongoing feasibility study of the Maestro System in obese patients with Type-2 diabetes mellitus. The study was designed to evaluate the safety and efficacy of the Company's next-generation Maestro RC System. The Maestro RC System 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. Patients in this trial are averaging approximately 14 hours per day of therapy.

• H<sub>b</sub>A1<sub>c</sub> change (Company updated data):

Visit (post-device activation)	H <sub>b</sub> A1 <sub>c</sub> change	Percent HbA1c	N	p
Week 1 (Baseline 7.8%)	-0.3	7.5	28	0.002
Week 4 (Baseline 7.8%)	-0.7	7.1	28	<.001
Week 12 (Baseline 7.7%)	-0.9	6.8	26	<.001
6 Months (Baseline 7.8%)	-0.9	6.8	25	<.001
12 Months (Baseline 7.6%)	-1.0	6.6	25	<.001

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

Visit (post-device activation)	EWL	N	P
Week 1	-8.9	28	<.001
Week 4	-13.7	28	<.001
Week 12	-20.8	26	<.001
6 Months	-24.4	25	<.001
12 Months	-25.3	25	<.001

• Change in diastolic blood pressure in hypertensive patients (baseline 87.2 mmHg, average) in mmHg:

Visit (post-device activation)	DBP change	N	<u> </u>
Week 1	-10.1	12	<.001
Week 4	-10.2	12	0.005
Week 12	-8.9	11	<.001
6 Months	-13.8	10	<.001
12 Months	-10.2	11	0.009

• Change in mean arterial pressure in hypertensive patients (baseline 99.5 mmHg, average) in mmHg:

Visit (post-device activation)	MAP change	N	p
Week 1	-6.8	15	0.04
Week 4	-8.6	15	0.02
Week 12	-8.9	14	<.001
6 Months	-12.5	13	<.001
12 Months	-7.8	14	0.03

#### **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. The Maestro RF System is powered by an external controller and transmit coil worn by the patient to receive therapy.

The Company today announced updated 24 month data on EWL:

<u>Visit</u>	EWL	N
<u>Visit</u> 6 Months	-17.9%	N 271
12 Months	-16.3%	265
18 Months	-17.3%	187
24 Months	-19.4%	159

Interim analysis. N at 18 and 24 months are patients who have reached those time points.

At 24 months, 71 patients using the device for  $\geq$  9 hours daily have an average EWL of 22.7%.

#### **Updated VBLOC RF2 Study Results**

The VBLOC RF2 study is a feasibility study designed to evaluate the safety and efficacy of the Company's first-generation Maestro RF System in the treatment of obesity. The Company today announced updated 24 month data on EWL, which demonstrates continued maintenance of weight-loss out to two years in this ongoing trial:

Visit	EWL	N
<u>Visit</u> 6 Months	-17.9%	35
12 Months	-22.6%	26
18 Months	-28.3%	18
24 Months	-23.0%	18

#### About the ReCharge Pivotal Trial

EnteroMedics' IDE approval outlines plans for conducting a randomized, double-blind, parallel-group, multicenter pivotal clinical trial of its Maestro RC System in 234 morbidly obese patients enrolled at up to 12 U.S. centers. All patients in the study would receive an implanted device and would 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 study period. All patients are expected to participate in a weight management program. The Company expects to conduct such a study as its U.S. commercialization strategy evolves.

#### **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 which is powered either by an external controller (Maestro RF System) or an integrated rechargeable battery (EnteroMedics' next-generation Maestro RC System). EnteroMedics is currently conducting a feasibility study examining VBLOC Therapy's effects on blood glucose levels in diabetic patients outside of the United States. 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(R) System for the treatment of obesity; our preliminary findings from our EMPOWER(TM) 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(R) 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; 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 Company's Form 10-K dated March 29, 2010. 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 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 EMPOWER clinical trial informed consent.