

---

---

**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: January 26, 2012  
(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 2.02 Results of Operations and Financial Condition.**

On January 26, 2012, EnteroMedics Inc. (the “Company”) issued a press release announcing its financial results for the three months and full year ended December 31, 2011. 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.

The information furnished herewith pursuant to Item 2.02 of this Current Report and in Exhibit 99.1 hereto is being “furnished” in accordance with General Instruction B.2 of Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 8.01 Other Events.**

On January 26, 2012, the Company announced that it has received approvals for the final Maestro System components from the Australian Therapeutic Goods Administration (the “TGA”) for listing on the Australian Register of Therapeutic Goods (the “ARTG”). The listing of these remaining components by the TGA on the ARTG completes the approval for listing of all components of the Maestro System in Australia. The approvals for the listing of the other components of the Maestro System on the ARTG were previously disclosed by the Company on a Current Report on Form 8-K filed on December 13, 2011.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 26, 2012.

**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: January 26, 2012

**EXHIBIT INDEX**

**Exhibit  
Number**

**Description**

---

99.1

Press Release dated January 26, 2012.



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

### **EnteroMedics Reports Fourth Quarter 2011 Financial Results**

#### **Announces Approval by Australia's Therapeutic Goods Administration for Listing on the Australian Register of Therapeutic Goods of All Components of the Maestro® System**

**ST. PAUL, Minnesota, January 26, 2012** – EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced financial results for the three months and full year ended December 31, 2011.

For the full year ended December 31, 2011, the Company reported a net loss of \$26.0 million, or \$0.86 per share. For the three months ended December 31, 2011, the Company reported a net loss of \$8.1 million, or \$0.22 per share, including research and development expenses of \$5.8 million and general and administrative expenses of \$2.1 million. Operating expenses were primarily associated with the cost of supporting the Company's multiple, ongoing clinical trials, including the ReCharge Study, international commercialization efforts and the continued development of VBLOC® vagal blocking therapy delivered through the Company's Maestro® System. On December 31, 2011, the Company's cash, cash equivalents, restricted cash and short-term investments totaled \$29.7 million.

The Company also announced today that it has received approvals for the final Maestro® System components from the Therapeutic Goods Administration (TGA) for listing on the Australian Register of Therapeutic Goods (ARTG). The Company previously announced approvals for a majority of the components of the Maestro System. The listing of these remaining components by the TGA on the ARTG completes the approval for listing of all components of the Maestro System in Australia.

“Full approval by the TGA for listing on the ARTG enables EnteroMedics to aggressively move forward with commercialization of the Maestro System in Australia, a country where more than 60% of the population is overweight or obese. We are excited to begin offering this safe, effective and sustainable weight loss treatment to the many patients in Australia who are seeking a less punitive, longer-term strategy for addressing their obesity,” said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. Additionally, Dr. Knudson added that “EnteroMedics achieved two critical milestones in the fourth quarter, full implantation of the ReCharge Study and approval of key components of the Maestro System by the TGA for ARTG listing. These efforts set up 2012 to be an exciting year, as we look forward to the first commercial sales of the Maestro System, progress in our commercialization efforts in other key international markets and unblinding of the Recharge Study at the end of the year.”

Greg S. Lea, Senior Vice President and Chief Financial Officer, added, "Research and development expenditures in the fourth quarter were increased as a result of the completion of enrollment and implantation of the ReCharge Study. Our cash and investments at year-end of \$29.7 million give us the required capital to continue to execute on our key clinical and commercial milestones into 2013."

#### **About Obesity in Australia**

According to the Australian Bureau of Statistics, in 2008 sixty-two percent of all adults in Australia were either overweight (BMI > 25) or obese (BMI > 30). It is estimated that by 2025, 7.2 million Australians could be obese. The Australian Federal Minister has declared obesity a national priority, with obesity related costs exceeding \$21 billion annually. Approximately 13,900 bariatric surgeries were performed in Australia in 2008.

#### **About the ReCharge Study**

The ReCharge Pivotal Trial is a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in 233 patients at 10 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 non-functional device during the study period. All patients are expected to participate in a weight management counseling program.

#### **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, metabolic diseases 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® System, which is powered by an integrated rechargeable battery. For more information, visit [www.enteromedics.com](http://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 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™ 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 current report on Form 8-K filed September 28, 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—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.

(See attached tables)

**ENTEROMEDICS INC.**  
(A Development Stage Company)

Condensed Consolidated Statements of Operations (unaudited)  
(in thousands, except per share data)

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2011	2010	2011	2010
Operating expenses:				
Research and development	\$ 5,791	\$ 1,438	\$ 16,673	\$ 8,499
Selling, general and administrative	2,095	2,182	8,583	7,678
Total operating expenses	7,885	3,620	25,257	16,177
Loss from operations	(7,885)	(3,620)	(25,257)	(16,177)
Other income (expense), net	(171)	(335)	(741)	(1,170)
Net loss	<u>\$ (8,056)</u>	<u>\$ (3,955)</u>	<u>\$ (25,997)</u>	<u>\$ (17,347)</u>
Net loss per share — basic and diluted	<u>\$ (0.22)</u>	<u>\$ (0.34)</u>	<u>\$ (0.86)</u>	<u>\$ (2.06)</u>
Shares used to compute basic and diluted net loss per share	<u>36,751</u>	<u>11,472</u>	<u>30,205</u>	<u>8,420</u>

**ENTEROMEDICS INC.**  
(A Development Stage Company)

Condensed Consolidated Balance Sheets (unaudited)  
(in thousands)

	December 31, 2011	December 31, 2010
<b>ASSETS</b>		
Cash, cash equivalents and short-term investments	\$ 29,493	\$ 30,841
Restricted cash	200	6,527
Inventory	1,069	—
Prepaid expenses and other current assets	805	437
Property and equipment, net	630	742
Other assets	289	142
Total assets	<u>\$ 32,486</u>	<u>\$ 38,687</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Liabilities:		
Accounts payable	\$ 434	\$ 125
Debt	5,188	5,905
Other liabilities	6,822	2,950
Total liabilities	12,445	8,980
Stockholders' equity	20,041	29,707
Total liabilities and stockholders' equity	<u>\$ 32,486</u>	<u>\$ 38,687</u>

###