# 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 (Date of earliest event reported) : February 12, 2014**

# ENTEROMEDICS INC.
**(Exact name of registrant as specified in its charter)**

**Commission File Number: 1-33818**

| **Delaware** | **48-1293684** |
|---|---|
| **(State or other jurisdiction of incorporation)** | **(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 February 12, 2014, EnteroMedics Inc. (the "Company") issued a press release announcing its financial results for the three months and full year ended December 31, 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.

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**

On February 12, 2014, the Company issued a press release announcing that the U.S. Food and Drug Administration has scheduled a meeting of the Center for Devices and Radiologic Health's Advisory Committee on Thursday May 29, 2014 to review the Maestro® System delivering VBLOC® vagal blocking therapy as a treatment for morbid obesity. A copy of the press release is filed as Exhibit 99.2 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 February 12, 2014, announcing the Company's financial results. |
| 99.2 | Press Release dated February 12, 2014, announcing the U.S. Food and Drug Administration has scheduled a meeting of the Center for Devices and Radiologic Health's Advisory Committee. |

**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: February 12, 2014

## EXHIBIT INDEX

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**Exhibit 99.1**

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

**EnteroMedics Reports Fourth Quarter 2013 Financial Results**

**ST. PAUL, Minnesota, February 12, 2014** – 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 and twelve months ended December 31, 2013.

For the full year ended December 31, 2013, the Company reported a net loss of $25.8 million, or $0.47 per share. For the three months ended December 31, 2013, the Company reported a net loss of $6.6 million, or $0.11 per share, including research and development expenses of $2.9 million and selling, general and administrative expenses of $3.5 million. Operating expenses were primarily associated with the cost of supporting multiple ongoing clinical trials, including the ReCharge Study, the Company's VBLOC® vagal blocking therapy Premarket Approval (PMA) application, and the continued development of VBLOC Therapy delivered through the Company's Maestro® Rechargeable System. On December 31, 2013, the Company's cash, cash equivalents and short-term investments totaled $23.3 million, which includes approximately $11.0 million raised through the Company's "at-the-market" (ATM) equity facility. As of February 11, 2014 the Company has raised a total of approximately $13.5 million under its $20.0 million ATM equity facility.

"As we announced early today, the U.S. FDA has scheduled an Advisory Panel meeting for May 29, 2014 to review our PMA application for approval of the Maestro System," said Greg S. Lea, Senior Vice President, Chief Financial Officer and Chief Operating Officer. "Our primary focus remains on the regulatory process for VBLOC Therapy and preparing for a positive approval decision by FDA shortly after the Advisory Panel meeting."

**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.

**About the ReCharge Pivotal Study**

The ReCharge Pivotal Study is a randomized, double-blind, sham-controlled, multicenter pivotal clinical study 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 study 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 study period. In February 2013, EnteroMedics announced that its ReCharge Study 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 study measures, with both a positive benefit-risk equation and a medically meaningful and clinically significant effect over the control group, the results did not meet the study's predefined super-superiority efficacy endpoints.

**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 Maestro® System**

The Maestro® 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.

**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 studies; 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 studies; 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.

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 study 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 December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| Sales | $ — | $ — | $ — | $ 312 |
| Cost of goods sold | — | — | — | 232 |
| Gross profit | — | — | — | 80 |
| Operating expenses: | | | | |
| Research and development | 2,868 | 3,147 | 11,075 | 10,668 |
| Selling, general and administrative | 3,506 | 3,614 | 13,659 | 11,961 |
| Total operating expenses | 6,374 | 6,761 | 24,734 | 22,629 |
| Operating loss | (6,374) | (6,761) | (24,734) | (22,549) |
| Other income (expense), net | (199) | (266) | (1,047) | (911) |
| Net loss | $ (6,573) | $ (7,027) | $ (25,781) | $ (23,460) |
| Net loss per share—basic and diluted | $ (0.11) | $ (0.17) | $ (0.47) | $ (0.59) |
| Shares used to compute basic and diluted net loss per share | 61,378 | 41,698 | 55,010 | 39,537 |

**ENTEROMEDICS INC.**
(A Development Stage Company)
Condensed Consolidated Balance Sheets (unaudited)
(in thousands)

| | December 31, 2013 | December 31, 2012 |
|---|---|---|
| **ASSETS** | | |
| Cash, cash equivalents and short-term investments | $ 23,297 | $ 22,309 |
| Restricted cash | 0 | 200 |
| Inventory | 1,128 | 1,271 |
| Prepaid expenses and other current assets | 564 | 624 |
| Property and equipment, net | 577 | 610 |
| Other assets | 822 | 1,082 |
| Total assets | $ 26,388 | $ 26,096 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Liabilities: | | |
| Accounts payable | $ 127 | $ 341 |
| Debt | 6,868 | 9,684 |
| Other liabilities | 4,714 | 4,196 |
| Total liabilities | 11,709 | 14,221 |
| Stockholders' equity | 14,679 | 11,875 |
| Total liabilities and stockholders' equity | $ 26,388 | $ 26,096 |

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**Exhibit 99.2**

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

**EnteroMedics Announces Food and Drug Administration Advisory Committee Meeting Date for Review of the Maestro® Rechargeable System for the Treatment of Obesity**

**Center for Devices and Radiologic Health Advisory Committee Scheduled for May 29, 2014**

**ST. PAUL, Minnesota, February 12, 2014** – 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 U.S. Food and Drug Administration's Office of Device Evaluation has scheduled a meeting of the Center for Devices and Radiologic Health's (CDRH) Advisory Committee on Thursday, May 29, 2014 to review the Maestro® System delivering VBLOC® vagal blocking therapy as a treatment for morbid obesity. The CDRH Advisory Committee is an independent panel of clinical and scientific experts that helps evaluate medical devices for safety and efficacy and makes recommendations regarding Benefit-Risk to the FDA.

EnteroMedics' PMA application for VBLOC Therapy, which was accepted for review by the FDA in July of 2013, contains data from the Company's ReCharge Pivotal Study. The ReCharge Pivotal Study is a randomized, double-blind, sham-controlled, multicenter pivotal clinical study in 239 randomized patients (233 implanted) at 10 sites testing the effectiveness and safety of VBLOC Therapy utilizing EnteroMedics' second generation Maestro System.

"We are pleased that the FDA has decided to move the PMA application for our innovative technology forward towards possible approval by scheduling an Advisory panel meeting to discuss the Maestro System. We very much look forward to presenting VBLOC Therapy to the panel members as we work to address the significant and widening gap in treatment alternatives for obesity and its associated diseases," said Mark B. Knudson, Ph.D., EnteroMedics' President and Chief Executive Officer. "We will continue to focus on thoroughly preparing for panel with the goal of delivering on the promise of this new treatment option to the millions of Americans who suffer with obesity."

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