# 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): June 17, 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 8.01. Other Events.**

On June 17, 2014, EnteroMedics Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration Advisory Gastroenterology and Urology Devices Panel had announced its recommendation on the Company's Maestro® ReChargeable Systems' VBLOC® vagal blocking therapy as a treatment for obesity. 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 Information and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated June 17, 2014. |

**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: June 17, 2014

## EXHIBIT INDEX

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release dated June 17, 2014. |

**Exhibit 99.1**

Media Contact:
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McGinn and Company
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Investor Contact:
Greg S. Lea
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**EnteroMedics Announces FDA Advisory Committee Recommendation on VBLOC® Vagal Blocking Therapy for the Treatment of Obesity**

***Panel Votes 6 to 2, with 1 Abstention, that Benefits Outweigh Risks***

**ST. PAUL, Minnesota,** June 17, 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 (FDA) Advisory Gastroenterology and Urology Devices Panel (GUDP) voted 8 to 1 "in favor" that the device is safe when used as designed, and voted 4 to 5 "against" on the issue of a reasonable assurance of efficacy. The final vote, on whether the relative benefits outweighed the relative risk, was 6 to 2 "in favor," with 1 abstention.

The FDA is not bound by the GUDP's recommendation, but will take it into consideration when reviewing the Maestro System Premarket Approval (PMA). As previously announced, the Company expects a decision on approval of the PMA later this year. If approved, the Maestro Rechargeable System will be the first new medical device approved for obesity by the FDA in over ten years.

"Obesity is the most under-treated disease in this country, despite its increasingly well-understood role in co-morbid conditions ranging from hypertension and diabetes to cancer," said Greg Lea, Senior Vice President, Chief Operating Officer and Chief Financial Officer of EnteroMedics, "Where existing options are clearly failing to address the growing epidemic of obesity, we believe VBLOC Therapy may offer a unique approach to treating obesity, a choice that fills this void by offering a safe, reversible option that does not alter the anatomy, allowing patients to take a positive path towards improving their overall health. We thank the Committee members for their insights and look forward to a continued, productive dialogue with the FDA."

In the most recent clinical trial, the ReCharge Study, VBLOC Therapy treated patients demonstrated a clinically meaningful and statistically significant excess weight loss (EWL) at 12 months of 24.4%, sustained out to 18 months. The majority (52.5%) lost 20% or more of their excess weight and nearly one-third of VBLOC Therapy treated patients lost 30% or more. The 24.4% average EWL far exceeds the 10% to 15% thresholds at which patients experience substantial positive health effects. Statistically significant improvements were observed in the VBLOC Therapy treatment group in total cholesterol, LDL, triglycerides, systolic and diastolic blood pressure, heart rate and waist circumference.

**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. 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, which helps control both hunger and fullness. 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.

**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 trials; 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 March 27, 2014. 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.