
**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: September 24, 2013
(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))
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Item 8.01. Other Events.

On September 24, 2013, EnteroMedics Inc. (the “Company”) issued a press release announcing that the Company had received a formal response letter from the U.S. Food and Drug Administration responding to the filing of the Company’s PMA (Premarket Approval) application for approval of the 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated September 24, 2013.

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: September 24, 2013

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1 Press Release dated September 24, 2013.



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

EnteroMedics on Track for Approval Decision in First Half of 2014 Following Formal Response to Premarket Approval Application from FDA

ST. PAUL, MN — 9/24/2013 — 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 Company has received a formal response, a standard component of the PMA process, from the Food and Drug Administration (FDA) with regard to its Premarket Approval Application (PMA) for approval of the Maestro Rechargeable System as a treatment for obesity. The response contains follow-up questions related to the application pertaining primarily to device testing and clinical data, including training programs for users and a post approval study. The Company anticipates responding to the FDA's questions within the coming weeks.

“We are very encouraged by the responsiveness of the FDA and are confident in our ability to address their questions in a timely manner,” said Mark B. Knudson, Ph.D., EnteroMedics’ President and Chief Executive Officer. “We will continue to work closely with the FDA throughout this process. We believe that the Company continues on track for a panel in late Q4 2013/Q1 2014 with approval decision in the first half of 2014.”

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.

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 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 trial informed consent.