
**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 14, 2015
(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 January 14, 2015, EnteroMedics Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration (the “FDA”) has approved VBLOC® Vagal Blocking Therapy, delivered via the Maestro® System, for the treatment of adult patients with obesity. The Company also announced that it will be hosting a conference call to discuss the FDA’s approval of the Maestro® System at 12:00 p.m. Eastern Time on January 14, 2015. The information needed to access the conference call is provided in the press release. 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.

Item 9.01. Financial Information and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated January 14, 2015.

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

Chief Financial Officer and Chief Operating Officer

Date: January 14, 2015

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1 Press Release dated January 14, 2015.



Media Contact:
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**EnteroMedics Announces FDA Approval of
VBLOC® Vagal Blocking Therapy for the Treatment of Obesity**

First New Medical Device Approved for Obesity in Over a Decade

Novel Neuroscience-Based Technology Enables Safe, Durable Weight Loss

Company to Host Conference Call Today at 12:00 PM ET

ST. PAUL, Minnesota, January 14, 2015 – EnteroMedics Inc. (NASDAQ: ETRM) today announced that the U.S. Food and Drug Administration (FDA) has approved VBLOC® vagal blocking therapy, delivered via the Maestro® System, for the treatment of adult patients with obesity who have a Body Mass Index (BMI) of at least 40 to 45 kg/m², or a BMI of at least 35 to 39.9 kg/m² with a related health condition such as high blood pressure or high cholesterol levels, and who have tried to lose weight in a supervised weight management program within the past five years. The Maestro System is the first new medical device to be approved by the FDA for obesity in over ten years. EnteroMedics anticipates that the device will be available, on a limited basis, at select Bariatric Centers of Excellence in the U.S. this year. The Maestro System has received CE Mark and is listed on the Australian Register of Therapeutic Goods.

“VBLOC Therapy offers an entirely new approach to the treatment of obesity,” said Scott Shikora, MD, FACS, EnteroMedics’ Chief Consulting Medical Officer. “By blocking signals along the nerves that connect the brain and stomach, VBLOC reduces feelings of hunger and promotes earlier feelings of fullness, which can help people with obesity reduce the number of calories consumed and promote safe, healthy and durable weight loss.”

The Maestro System is a pacemaker-like device that is implanted, usually in an outpatient procedure, to control both hunger and fullness by intermittently blocking the primary nerve which regulates the digestive system, the vagus nerve. VBLOC Therapy does not surgically alter or restrict the digestive system, does not create barriers to prevent absorption of nutrients and is completely reversible, allowing patients to lose weight without lifestyle compromises.

“Obesity is a global epidemic with far-reaching cost and consequences to both public and personal health,” said Caroline M. Apovian, MD, FACP, FACN, Professor of Medicine at Boston University School of Medicine, and Director, Nutrition and Weight Management at Boston Medical Center. “From diet and exercise to bypass surgery, existing treatment options have failed to stop the advance of this disease. The Maestro System adds a safe and effective new weapon to our armamentarium, offering the patient a treatment option that does not physically restrict or alter the anatomy, and is reversible.”

“The Obesity Action Coalition applauds the FDA and EnteroMedics for making available the first device for the treatment of obesity in more than a decade. There is no ‘one-size-fits-all’ approach to treating the disease of obesity. We believe strongly that expanded treatment options are essential to individuals affected by obesity, so that along with their healthcare provider, they can make an informed decision on which option, or options, may work best to improve their health,” said Joe Nadglowski, Obesity Action Coalition President and CEO.

“FDA approval of VBLOC Therapy is a transformational event for not only EnteroMedics and the many supporters who have helped us achieve this milestone but, more importantly, for the people with the disease of obesity that have been waiting for a new option,” said Mark B. Knudson, Ph.D., EnteroMedics’ President and Chief Executive Officer. “The Maestro System fills a significant gap in the currently available treatment options, offering clinically meaningful weight loss without the fear or many of the side effects associated with existing bariatric options. We thank the many patients, and their families, who have participated in the clinical trials of VBLOC Therapy. We are also grateful to the physicians and healthcare providers who have worked with us on these clinical trials, our dedicated employees, as well as to the FDA for their efforts in making this technology available.”

Information about the Maestro System and VBLOC Therapy

Approval of the Maestro Rechargeable System was based on the ReCharge Study, a randomized, double-blind, sham-controlled trial to evaluate the safety and effectiveness of the Maestro Rechargeable System in treating obesity. In an intention to treat (ITT) analysis of the study results, VBLOC-treated patients achieved 24.4% excess weight loss (EWL) at 12 months. At 18 months, VBLOC-treated patients maintained a 23.5% EWL. In a responder analysis of the ITT population at 12 months, over 50% of VBLOC-treated patients achieved 20% or greater EWL.

The SAE (severe adverse event) rate, defined as the proportion of subjects in the VBLOC treated group who experienced an implant/revision procedure, device or therapy-related SAE through 12 months post-implant, was 3.7% (n=6; 95% CI: 1.4% to 7.9%) in the ITT population. The most common (>10%) non-serious adverse events related to device, implant/revision procedure or therapy were pain at the neuroregulator site, and transient sensations of therapy such as heartburn/dyspepsia.

VBLOC Therapy is contraindicated for use in patients with cirrhosis of the liver, portal hypertension, esophageal varices or an uncorrectable, clinically significant hiatal hernia; patients for whom magnetic resonance imaging (MRI) or diathermy use is planned; patients at high risk for surgical complications; and patients who have a permanently implanted, electrical-powered medical device or gastrointestinal device or prosthesis (e.g. pacemakers, implanted defibrillators, neurostimulators).

If you are interested in learning more about VBLOC Therapy, please visit www.enteromedics.com/vbloc or call 1-800-MY-VBLOC.

For additional prescribing information, please visit www.enteromedics.com.

Obesity Facts and Figures

According to the CDC, more than one-third of U.S. adults live with obesity¹. The estimated annual cost of obesity in the U.S. was \$147 billion in 2008, accounting for more than twice previous estimates, approximately 21 percent, of U.S. healthcare costs.^{2,3} Higher BMI is a major risk factor for over 70 comorbidities associated with obesity, such as cardiovascular disease which was the leading cause of death in 2012, diabetes, hypertension, musculoskeletal disorders and some cancers.⁴

Conference Call for Investors

EnteroMedics will host a webcast and conference call for investors to discuss the recent FDA action today at 12:00 PM Eastern Time (9:00 AM Pacific Time). To participate, please dial (877) 280-7473 (US) or (707) 287-9370 (International). Use conference ID 67146231. To access a live audio webcast of the conference call, please visit “Events” under “Investors” section on the company’s website at: www.enteromedics.com.

A replay of the call will be made available from 3:00 PM ET on January 15, 2015 until April 14, 2015 at 11:59 PM ET. To hear a replay of the call, dial (855) 859-2056 (US) or (404) 537-3406 (International). A replay of the call will also be available under “Events” in the “Investors” section on the company’s website at: www.enteromedics.com.

- 1 Prevalence of Childhood and Adult Obesity in the United States, 2011-2012 **Cynthia L. Ogden, PhD¹; Margaret D. Carroll, MSPH¹; Brian K. Kit, MD, MPH^{1,2}; Katherine M. Flegal, PhD¹** *JAMA*. 2014;311(8):806-814. doi:10.1001/jama.2014.732.
- 2 Cawley, John, and Chad Meyerhoefer. “The Medical Care Costs of Obesity: An Instrumental Variables Approach.” *Journal of Health Economics* 31.1 (2012): 219-30.
- 3 Eric A. Finkelstein, Justin G. Trogon, Joel W. Cohen and William Dietz Annual Medical Spending Attributable To Obesity: Payer-And Service-Specific Estimates *Health Affairs*, 28, no.5 (2009):w822-w831 (published online July 27, 2009; 10.1377/hlthaff.28.5.w822)
- 4 Cawley, John, and Chad Meyerhoefer. “The Medical Care Costs of Obesity: An Instrumental Variables Approach.” *Journal of Health Economics* 31.1 (2012): 219-30.

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® 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 sales experience with 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.

Important Safety Information

Talk with your doctor about the full risks and benefits of VBLOC® Vagal Blocking Therapy and the Maestro® Rechargeable System.

What is the Maestro System Used For:

The Maestro System is for use in helping with weight loss in people aged 18 years through age 65 who are obese, with a Body Mass Index (BMI) of 40 to 45 kg/m², or a BMI of 35 to 39.9 kg/m² with a related health condition such as high blood pressure or high cholesterol levels. Individuals should have first tried to lose weight by diet and exercise in a supervised program within the last 5 years before receiving the Maestro System.

Contraindications:

You should not have an implanted Maestro Rechargeable System if you have cirrhosis (a disease of the liver), portal hypertension (high blood pressure in the veins of the liver), esophageal varices (enlarged veins at the lower end of the tube between the mouth and the stomach) or an uncorrectable, clinically significant hiatal hernia (a condition where part of the stomach pushes up or through the diaphragm where the tube between the mouth and the stomach passes through to connect to the stomach); patients for whom magnetic resonance imaging (a type of medical imaging that uses strong magnets and pulses of radio waves) is planned; patients at high risk for surgical complications; patients who have a permanently implanted, electrical-powered medical device; or patients for whom diathermy (a type of medical procedure that heats and destroys tissue) is planned.

Warnings/Precautions/Adverse Events:

Seek guidance from your doctor before you undergo a medical or surgical procedure, as interaction of the Maestro System with certain medical therapies, procedures or other implanted or body worn medical devices may harm you, cause damage to the implanted device or may turn therapy off. These may include, but are not limited to, lithotripsy (use of high energy shock waves to break up stones), radiation, mono polar electrosurgical instruments (a type of surgical instrument), positron emission tomography scans (a type of medical imaging), radiofrequency ablation (a method of destroying tissue used during surgery), heart pacemakers or defibrillators, neurostimulators, and insulin pumps. Turning, twisting, or manipulating the implanted components may damage the nerves or implanted device. System components must be kept charged to prevent damage, which may require additional surgery to replace the implanted device. The neuroregulator should be fully charged prior to turning it off. The Maestro System is MR Unsafe, including for patients in which the Maestro System was explanted and not all components were removed. Portable outlets or extension cords should not be connected to the AC recharger. Do not immerse external system components in fluid. Keep strong magnets at least 6 inches away from the implanted device. The Maestro Rechargeable System may activate metal detectors or other security systems. Strong magnetic fields systems that emit radio frequency signals may interfere with the function of the Maestro System. The neuroregulator and mobile charger should be turned off near metal detectors, other security systems, strong magnetic fields and radio frequency emitting systems. The mobile charger should be turned off while aboard aircraft. Infection at the implant site may occur and could require use of antibiotic medications, surgery, or explant. Do not modify any components of the system. Safety and effectiveness of the Maestro Rechargeable System has not been established for use within a hyperbaric chamber (chamber designed to supply oxygen at a higher than normal air pressure), with external defibrillation, during pregnancy, or for use in patients under 18

years of age. The capacity of the rechargeable neuroregulator battery will diminish over time, requiring longer or more frequent charging. Do not operate the system in flammable environments, or if components appear damaged. Do not cover the mobile charger when in use to prevent overheating and damage. You may not be able to operate the Maestro System if you have impaired vision. Make sure all of your health care providers are aware that you have an implanted Maestro System.

The most common related adverse events that were experienced during clinical study of the Maestro Rechargeable System included pain, heartburn, nausea, difficulty swallowing, belching, wound redness or irritation, and constipation.