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: March 28, 2011 (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)

cceptione number, menuting

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)

Dere-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 1.01. Entry into a Material Definitive Agreement.

On March 28, 2011, EnteroMedics Inc. (the "Company") entered into a Distribution Agreement by and between the Company and Device Technologies Australia Pty Limited ("Device Technologies"), effective as of March 8, 2011 (the "Distribution Agreement"), whereby the Company appointed Device Technologies as its exclusive distributor of the Maestro RC System (the "Product") in Australia and New Zealand (the "Territory") during the term of the agreement.

The initial term of the Distribution Agreement began on the effective date and ends on the fourth anniversary of the date on which the Company receives Australian Therapeutic Goods Administration ("TGA") approval. The Distribution Agreement will continue for successive 12 month terms unless a new agreement is negotiated between the parties, either party provides three months written notice prior to the expiration of the current term or the Distribution Agreement is otherwise terminated as described below.

Pursuant to the Distribution Agreement, the Company also granted Device Technologies a non-exclusive, non-transferable license to use certain of the Company's trademarks in connection with its distribution, sale, promotion and/or advertising of the Product in the Territory. In addition, Device Technologies agreed to use its best efforts to promote and increase the sale of the Product in the Territory and agreed to work with the Company and its collaboration partner, the Australian Institute of Weight Control, to develop the market for the Product in the Territory. Device Technologies also agreed that, without mutual agreement of the parties, it will not manufacture, import, sell, supply, develop, provide, promote or market competitive products, which for purposes of this agreement means any implanted product approved for implant for six months or longer by the TGA, U.S. Food and Drug Administration or CE Mark authorities which has a clinical indication for use in patients with obesity who have a body mass index between 30 and 45.

Pursuant to the Distribution Agreement, Device Technologies will purchase certain quantities of the Product from the Company beginning with an initial order to be placed six weeks after the Company submits its application for TGA approval. The prices for the Product are fixed for the first six months and the initial order and thereafter may be increased or decreased by the Company upon 180 days written notice. The Distribution Agreement requires the parties to establish mutually agreed upon sales performance objectives for each year of the agreement beginning 30 days after the Company may immediately terminate the Distribution Agreement or amend the agreement to change Device Technologies' status to that of a non-exclusive distributor.

The Distribution Agreement may be terminated by either party upon 60 days written notice of any substantial breach of the terms of the agreement and a failure or inability to remedy the breach. The Distribution Agreement also may be terminated immediately upon written notice for certain events, including failure to pay moneys due under the agreement within 45 days of a written notice to pay and failure to meet the sales performance objectives. If the Distribution Agreement is terminated for any reason other than breach, force majeure or Device Technologies' insolvency, the Company is obligated to reimburse Device Technologies for its costs associated with regulatory and reimbursement approvals. In addition, if such termination occurs during the initial term of the Distribution Agreement, the Company is also obligated to make certain payments to Device Technologies as compensation for the loss of the distributorship.

Other than through the Distribution Agreement, Device Technologies does not have any material relationships with the Company or its affiliates.

Item 8.01 Other Events.

On March 28, 2011, the Company issued a press release announcing that it received CE Mark Certification for its Maestro RC System and entered into the Distribution Agreement. 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 Statements and Exhibits.

- (d) Exhibits.
 - 99.1 Press Release dated March 28, 2011.

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: March 28, 2011

EXHIBIT INDEX

Exhibit Number Description

99.1 Press Release dated March 28, 2011.



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

EnteroMedics Receives CE Mark Certification for the Maestro RC System, Allowing Australian Regulatory Application to Move Forward

Company Signs Australian Distribution Agreement with Device Technologies Australia,

Announces Progress Update for Pivotal ReCharge Trial

ST. PAUL, Minnesota, March 28, 2011 – EnteroMedics Inc., (NASDAQ: ETRM), the sole developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, announced today that is has received CE Mark approval of its second generation Maestro® RC System for the treatment of obesity using VBLOC® vagal blocking therapy. The Maestro RC System, a pacemaker-like device, offers a patient-oriented obesity therapy that affects the physiology of hunger and fullness without forcing punitive, mechanical limits to lifestyle and diet, or requiring surgical alteration of the anatomy. As announced in August 2010, the Company plans to commercialize the Maestro RC System in Australia through an application for approval and listing with the Australian Therapeutic Goods Administration (TGA), a process for which CE Mark approval is a prerequisite. CE Mark is a conformance mark granted by the European Commission and recognized by many nations, including Australia. With CE Mark approval achieved, the Company plans to move forward with its application for TGA approval and once approval is granted, the Company expects first commercial sales of the Maestro System in the second half of 2011.

The Company also announced that it has entered into an exclusive, multi-year distribution agreement with Device Technologies Australia Pty Limited, a major supplier of leading edge medical equipment and consumables to hospitals and healthcare professionals in Australia and New Zealand, for commercialization and distribution of the Maestro RC System. Device Technologies Australia Chief Executive Officer Peter Ord said, "EnteroMedics technology is viewed as cutting edge and this partnership is an exciting move into the obesity market for Device Technologies."

EnteroMedics also announced that the Company's pivotal ReCharge Trial remains on track, with patient enrollment and implants beginning in the first half of 2011 and enrollment completion anticipated by the end of 2011. The ReCharge Trial is a pivotal clinical trial evaluating the safety and efficacy of VBLOC therapy delivered via the Maestro RC System in the treatment of obesity.

"CE Mark certification and the Australian distribution agreement represent two important milestones for the Maestro System as we look to bring this innovative technology to markets around the globe where obesity has become epidemic," said President and CEO Mark B. Knudson, Ph.D. "Our agreement with Device Technologies Australia, a leader in medical technology distribution, allows us to immediately begin working toward our goal of commercial launch of the Maestro System in Australia, once TGA approval is granted. While we work toward this goal, we remain on-track to complete enrollment of the ReCharge Trial, the cornerstone of our U.S. commercialization strategy, by the end of 2011."

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 Device Technologies Australia Pty Limited

Device Technologies Australia Pty Limited, founded in 1992, is the largest private importer of quality, high technology medical devices into the Australian and New Zealand healthcare markets. The Company is privately owned and managed and employs over 400 healthcare specialist staff that support Clinical Education, Technical Service, Sales Management and Regulatory Affairs management. Its founders, Mr. Peter Ord, Chief Executive Officer and Mr. Kevin Ryan, Managing Director have focused on providing patient access to the best medical devices and systems available worldwide.

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 the ReCharge Pivotal Trial

EnteroMedics' ReCharge Trial is a randomized, double-blind, parallel-group, multicenter pivotal clinical trial of its Maestro RC System in 234 morbidly obese patients enrolled at up to 12 U.S. centers. All patients in the study will receive an implanted device and would be randomized in a 2:1 allocation to treatment or control groups. The control group will receive a functional, but non-active device that will deliver no charge to the vagus nerve during the study period. All patients are expected to participate in a weight management program.

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 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 RC System, which is powered by an integrated rechargeable battery. For more information, visit <u>www.enteromedics.com</u>.

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 regulatory approval for our Maestro® System for the treatment of obesity; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 7, 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 - U.S. Investigational device. Limited within the United States by U.S. Federal law to investigational use.

The implantation procedure and usage of the Maestro® System carry some risks, such as the risk generally associated with laparoscopic procedures and those related to treatment as described in the EMPOWER clinical trial informed consent.