# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K
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# **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report: February 26, 2008 (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))	

## Item 7.01 Regulation FD Disclosure.

The following information 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.

On February 26, 2008, EnteroMedics Inc. issued a press release to announce FDA approval of the planned expansion of its pivotal clinical trial, known as the EMPOWER study, from 220 patients to 300 patients. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

## Item 9.01 Financial Statements and Exhibits.

# (d) Exhibits

The following information 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.

99.1 Press release, dated February 26, 2008, entitled "EnteroMedics™ Announces Planned Expansion of EMPOWER Pivotal Study for Obesity to 300 Patients."

# **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: February 26, 2008

# EXHIBIT INDEX

Exhibit Number

Description

99.1 Press Release dated February 26, 2008.

Contact: EnteroMedics Inc. Greg S. Lea, 651.789.2764 ir@EnteroMedics.com

# ENTEROMEDICS ANNOUNCES PLANNED EXPANSION OF EMPOWER PIVOTAL STUDY FOR OBESITY TO 300 PATIENTS

## **Expected Enrollment Completion Remains First Half of 2008**

**St. Paul, Minnesota**—**February 26, 2008**—EnteroMedics Inc, (NASDAQ:ETRM), the developer of medical devices using neuroblocking technology to treat obesity and other gastrointestinal disorders, today announced that the Food and Drug Administration (FDA) has granted approval for the expansion of its pivotal clinical trial, known as the EMPOWER Study, from 220 patients to 300 patients. Full enrollment in the EMPOWER Study is expected in the first half of 2008, consistent with previous projections, despite expansion of the study.

The EMPOWER Study, which is currently enrolling patients at 10 of its projected 15 clinical sites, is a randomized, double-blind, placebo-controlled study being conducted to evaluate the safety and effectiveness of investigational VBLOC™ vagal blocking therapy using the Maestro™ System in obese patients. VBLOC Therapy is designed to empower weight loss by promoting earlier feelings of fullness and reduced hunger while minimizing the side effects and complications associated with existing surgical options and preserving the individual's normal anatomy.

"In obesity trials, the problem is generally not finding patients for recruitment, but supporting our clinical centers in managing the number of patients with obesity seeking help. Because of this, we are able to expand the EMPOWER Study, making its endpoint results more robust, while keeping to our original enrollment timeline." said Mark B. Knudson, Ph.D., President and CEO of EnteroMedics. "Our recruitment and screening systems, which include a registered nurse call center and informational meetings, are in place and have already handled the screening of thousands of potential candidates."

# **About VBLOC Therapy**

EnteroMedics developed VBLOC<sup>TM</sup> 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 EMPOWER Study

The EMPOWER Study is a randomized, double-blind, placebo-controlled study being conducted to evaluate the safety and effectiveness of the Company's investigational VBLOC Therapy after

12 months of use in obese patients. The study will be conducted at up to 15 sites in the U.S. and Australia and will include up to 300 patients with obesity. The company expects to complete enrollment during the first half of 2008. In order to qualify for the study, patients must be 18 years of age or older, with a body mass index (BMI) between 35 and 45. To learn more about the EMPOWER Study, visit <a href="https://www.EMPOWERstudy.com">www.EMPOWERstudy.com</a> or call 866 97 VBLOC (866-978-2562).

#### **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<sup>TM</sup> vagal blocking therapy, is designed to intermittently block the vagus nerves using high-frequency, low-energy, electrical impulses. The Food and Drug Administration recently granted approval for a pivotal clinical trial of EnteroMedics' investigational Maestro<sup>TM</sup> System, the company's initial product for the treatment of obesity, that delivers VBLOC Therapy.

## 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 inability to complete our EMPOWER pivotal trial and other clinical trials, or significant delays in the completion of our clinical trials; our ability to timely 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; 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; 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 Company's Prospectus dated November 14, 2007. 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 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.

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