## 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: December 15, 2016 (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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 8.01 Other Events.

#### Clinical Practice Weight Loss Data

On December 15, 2016, EnteroMedics Inc. (the "Company") issued a press release to disclose certain clinical practice weight loss data in patients using the Company's vBloc Therapy in combination with vBloc Achieve. A copy of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

#### Outstanding Share Update

On December 20, 2016, the Company announced that, as of December 16, 2016, there were 167,241,668 shares of the Company's common stock issued and outstanding, an increase of 27,371,201 shares since December 12, 2016, the last date for which the Company had publically announced its issued and outstanding share count. The increase in the Company's share count is a result of the conversion or acceleration of outstanding principal and interest amounts of the Company's outstanding 7.0% senior amortizing convertible notes (the "Notes") by the holders of the Notes.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by EnteroMedics Inc. dated December 15, 2016.

#### 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/ Scott P. Youngstrom

Scott P. Youngstrom Chief Financial Officer and Chief Compliance Officer

Date: December 20, 2016

#### EXHIBIT INDEX

#### Exhibit No. Description

99.1 Press Release issued by EnteroMedics Inc. dated December 15, 2016.



Media Contact: Eliza Schleifstein Argot Partners (917) 763-8106 <u>eliza@argotpartners.com</u> Investor Contact: Scott Youngstrom Chief Financial Officer EnteroMedics Inc. (651) 634-3011 syoungstrom@vbloc.com

#### Commercial Patient Data Confirms Success of EnteroMedics' vBloc<sup>®</sup> Therapy in Combination with vBloc<sup>®</sup> Achieve Program in Patients Struggling to Lose Weight

vBloc Institute Data Corroborates Pivotal Clinical Trial Results at Six and Nine Months

**ST. PAUL, Minnesota, December 15, 2016** – EnteroMedics Inc. (NASDAQ:ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced an assessment of real-world, clinical practice weight loss data in patients using the Company's vBloc<sup>®</sup> Therapy in combination with vBloc<sup>®</sup> Achieve, which confirms previously reported positive results from the ReCharge Pivotal Trial. These data show similar mean percent total weight loss (TWL) through six (9%) and nine months (10%) as compared to results from the rigorous ReCharge Pivotal Trial (9% at 6 months; 10% at 9 months). The data were collected at vBloc Institutes across the United States. vBloc Institutes are facilities that have integrated vBloc Therapy and vBloc Achieve into their practices.

"The patients who received their vBloc Therapy implant at vBloc Institutes and participated in the Company's vBloc Achieve support program achieved total weight loss comparable with the patients in the ReCharge Pivotal Trial, which utilized a very demanding patient follow-up protocol and was used to secure FDA approval," said Dan Gladney, EnteroMedics President, Chief Executive Officer and Chairman of the Board. "The corroboration of our clinical trial results in an everyday environment provides additional support for vBloc as a revolutionary treatment option for morbidly obese patients who do not wish to undergo anatomy-altering weight-loss procedures. These data are yet another important proof point in the advancement of our commercialization strategy and efforts to secure broad reimbursement coverage to make vBloc Therapy widely available to all patients. The commercial results appear to be equal to the solid results from our clinical trial and we will be submitting these data for presentation at a future medical meeting and for journal article publication as appropriate."

As previously reported, the ReCharge Pivotal Trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial of vBloc Neurometabolic Therapy in 239 patients with obesity. At 24 months, 76% percent of the randomized vBloc participants (n=123) remained in the trial. The mean excess weight loss (EWL) among vBloc participants who presented for their 24-month visit was 21%, with a mean percent total weight loss (TWL) of 8%. Of the 24 Sham control patients who had not yet crossed over to vBloc at 24 months, the EWL and TWL was 4% and 1%, respectively. The ReCharge Trial confirmed the durable nature of weight loss achieved with vBloc Therapy and the positive impact it had on patients' obesity-related comorbidities. Patients' quality of life improvements, as measured by the Impact of Weight on Quality of Life-Lite (IWQOL-Lite) questionnaire, were shown to be durable with a sustained increase of 20 units from their preoperative level, and the Three-Factor Eating Questionnaire (TFEQ) showed that patients continued to have a 50% reduction in hunger. The safety profile of vBloc Therapy remained favorable at 24 months compared to complications observed with conventional bariatric procedures such as sleeve gastrectomy and gastric bypass.

vBloc Therapy works to control sensations of hunger using a pacemaker-like device that is implanted under the skin during a safe, minimally-invasive procedure that does not alter or remove any patient anatomy. This device can be adjusted to optimize patients' therapy needs. Patients feel the sensation of fullness, empowering them to eat less, control their appetite, make healthier choices and lose weight without the major lifestyle implications of traditional weight loss surgeries.

vBloc Therapy is approved for use in helping with weight loss in people aged 18 years and older who are obese, with a BMI of 40 to 45 kg/m<sup>2</sup>, or a BMI of 35 to 39.9 kg/m<sup>2</sup> with a related health condition such as Type 2 diabetes, high blood pressure, high cholesterol levels or obstructive sleep apnea who have had a poor response to trying to lose weight under supervision in the last 5 years.

vBloc Achieve is a comprehensive, personalized weight loss support program to help vBloc patients reach and maintain health goals. While vBloc Therapy addresses hunger signals and cravings, vBloc Achieve provides the coaching and emotional support necessary to help patients make positive lifestyle changes, including healthy, balanced eating and regular exercise that are essential to long-term weight loss success. vBloc can be adjusted postoperatively for a patient's lifestyle or eating patterns in order to optimize therapy when patients need it the most.

#### 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<sup>®</sup> Neurometabolic Therapy, delivered by a pacemaker-like device called the vBloc<sup>®</sup> System, is designed to intermittently block the vagus nerves using high-frequency, low-energy, electrical impulses. EnteroMedics' vBloc<sup>®</sup> System has received U.S. Food and Drug Administration approval and CE Mark.

#### Information about the vBloc® System and vBloc® Neurometabolic Therapy

You should not have an implanted vBloc<sup>®</sup> System if you have cirrhosis of the liver, high blood pressure in the veins of the liver, enlarged veins in your esophagus or a significant hiatal hernia of the stomach; if you need magnetic resonance imaging (MRI); if you have a permanently implanted, electrical medical device; or if you need a diathermy procedure using heat. The most common related adverse events that were experienced during clinical study of the vBloc System included pain, heartburn, nausea, difficulty swallowing, belching, wound redness or irritation, and constipation.

Talk with your doctor about the full risks and benefits of vBloc Therapy and vBloc System. For additional prescribing information, please visit www.enteromedics.com.

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

#### 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 limited commercial sales experience with our vBloc<sup>®</sup> System for the treatment of obesity in the United States or in any foreign market other than Australia and the European Community; our ability to regain and then maintain compliance with the Nasdaq continued listing requirements; our ability to commercialize our vBloc<sup>®</sup> System; our dependence on third parties to initiate and perform our clinical trials; the need to obtain regulatory approval for any modifications to our vBloc<sup>®</sup> System; physician adoption of our vBloc<sup>®</sup> System and vBloc<sup>®</sup> Neurometabolic 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 28, 2016. 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.