
**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: November 4, 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 2.02 Results of Operations and Financial Condition.

On November 9, 2015, EnteroMedics Inc. (the “Company”) issued a press release announcing its financial results for the three and nine months ended September 30, 2015. 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.

The information furnished herewith pursuant to Item 2.02 of this Current Report and in Exhibit 99.1 hereto 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.

Item 8.01 Other Events.

Release of 24 Month Results.

On November 4, 2015, the Company issued a press release to announce 24-month results for the Company’s ReCharge pivotal trial for obesity. A copy of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

First Closing of Note and Warrant Offering.

On November 9, 2015, the first of the three closings (the “First Closing”) of the Company’s senior convertible note and warrant offering occurred. Pursuant to the securities purchase agreement, dated November 4, 2015, between the Company and the buyers listed thereto (the “Buyers”), at the First Closing, the Company issued and sold 7% senior convertible notes due 2017 with an aggregate principal amount of \$1.5 million to the Buyers, along with the accompanying warrants initially exercisable for 1,762,862 shares at an exercise price of \$0.31 per share. The Company received aggregate gross proceeds of \$1.5 million at the First Closing.

Further information on the terms of the Company’s senior convertible note and warrant offering can be found on the Company’s Current Report on Form 8-K filed with the Securities and Exchange Commission on November 5, 2015.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 9, 2015.
99.2	Press Release dated November 4, 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: November 9, 2015

EXHIBIT INDEX

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EnteroMedics Reports Third Quarter 2015 Financial Results and Commercial Progress Update

ST. PAUL, Minnesota, November 9, 2015 – EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced financial results for the three and nine months ended September 30, 2015 as well as an update on its commercial progress to date.

With the recent announcement of the appointment of Mr. Dan Gladney as Chief Executive Officer, effective November 16, the Company will host a year-end conference call, in lieu of hosting a third quarter conference call, allowing Mr. Gladney to fully transition into his role. The details of the year-end conference call will be provided at a later date.

Commercial Update

EnteroMedics' commercial strategy for vBloc® Neurometabolic Therapy continues to build momentum, with a focus on three critical areas: 1) engaging and certifying centers, 2) increasing the patient base considering vBloc Therapy and 3) achieving reimbursement for vBloc Therapy. The successful partnerships that the Company has established with certified centers allowed the Company to add considerable emphasis within the last quarter to driving patient adoption and moving them into the vital reimbursement process.

As reported previously, vBloc trained and certified physicians and centers have exceeded stated goals for 2015. EnteroMedics' vBloc Access programs is building on that success to guide the reimbursement effort by increasing the potential patient base using geography-focused, direct-to-consumer marketing and patient engagement efforts. vBloc Access also supports patients throughout the "prior authorization" process. Prior authorization could help patients gain access to vBloc Therapy, on a case-by-case basis, as well as demonstrate demand and physician support for vBloc Therapy. The purpose of the targeted prior authorization efforts is to establish demand and support for vBloc Therapy and build a foundation that can lead to future wide spread insurance coverage.

To support these efforts, the Company has partnered with a group of leading reimbursement experts to help patients understand their benefits and navigate the prior authorization process. EnteroMedics has also partnered with a marketing firm that specializes in helping medical device companies achieve their patient recruitment and retention goals in the commercial environment. During the third quarter, these combined early efforts have resulted in over 50 patients entering the full vBloc Access pathway.

The Company also continues to evaluate several innovative options for reimbursement partnerships, including self-insured and risk sharing arrangements with providers and payers, where vBloc's safety performance and outcomes have an advantage when determining coverage levels. Active discussions with Integrated Delivery Networks have been engaged to partner and demonstrate the clinical and economic effectiveness of vBloc for their members. These collaborative evaluations will ultimately lead to coverage determinations within those networks.

While the Company continues to create demand from patients and physicians using the prior authorization process and evaluate unique partnerships for immediate reimbursement, the Company is working to achieve other milestones necessary to establish widespread and formalized reimbursement. One such goal was met with the announcement by CMS that they had made a final determination for vBloc payment policy that becomes effective on January 1, 2016. CMS has designated the vBloc CPT codes as eligible for payment as an "Outpatient" procedure and assigned vBloc to the same outpatient facility payment category as other neuromodulation devices at approximately \$27,000. This determination, which covers the facility expenses and device costs, reflects CMS's recognition of the unique mechanism of action of vBloc as separate and distinct from other bariatric surgeries and is a critical step toward the final goal of obtaining coverage.

Lastly, the Company has also made progress in another critical area to reimbursement — publication of long-term data and building awareness among medical societies. The Company announced in October the publication in the journal *Obesity Surgery* of 24 month weight loss durability in the vBloc DM2 Trial and presented 24 month safety and efficacy data from the pivotal ReCharge RCT last week at the American Society for Metabolic and Bariatric Surgery and The Obesity Society's combined annual Obesity Week 2015 meeting.

"We continue to execute on a controlled launch of the Maestro® Rechargeable System, with our efforts and resources directed toward expanding our commercial presence by focusing on reimbursement via the prior authorization process," said Brad Hancock, Chief Commercial Officer. "We look forward to delving deeper into our commercial strategy as it continues to evolve."

Financial Results

For the three months ended September 30, 2015, the Company reported sales of \$64,000 with gross profits totaling \$41,000. The Company reported a net loss of \$4.2 million, or \$0.04 per share, including selling, general and administrative expenses of \$4.3 million and research and development expenses of \$1.8 million. For the nine months ended September 30, 2015, the Company reported sales of \$143,000 with gross profits totaling \$89,000. For the nine months ended September 30, 2015, the Company reported a net loss of \$18.7 million, or \$0.22 per share. Operating expenses were primarily

associated with commercialization of the Company's vBloc® Neurometabolic Therapy, including marketing and reimbursement activities, the cost of supporting multiple ongoing clinical trials, and the continued development of vBloc Therapy delivered through the Company's Maestro® Rechargeable System. On September 30, 2015, the Company's cash, cash equivalents and short-term investments totaled \$12.3 million. This total does not include the securities purchase agreements the company announced on November 5 that it had entered into with four institutional investors to issue \$25.0 million of Senior Amortizing Convertible Notes. The Notes will be payable in monthly installments, will accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the initial closing. \$1.5 million of the Notes will be funded at the initial closing, and the balance will be funded in two tranches of \$11.0 million and \$12.5 million which are subject to the shareholders of the Company approving a reverse stock split of the Company's common stock and the approval of the issuance of the securities purchased by the investors.

"The resources that our recent financing will add to the Company are critical to the ongoing success of our commercial efforts that are just beginning to build momentum," said Greg S. Lea, Chief Financial Officer and Chief Operating Officer. "We remain focused on careful expense management as we move into 2017 and beyond. We are pleased to announce the appointment of Dan Gladney as our new Chief Executive Officer last week, and look forward to benefiting from his insights and expertise as we execute against our goals," Mr. Lea added.

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® Neurometabolic 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. EnteroMedics' Maestro Rechargeable System has received U.S. Food and Drug Administration approval, CE Mark and is listed on the Australian Register of Therapeutic Goods.

Information about the Maestro® Rechargeable System and vBloc® Neurometabolic Therapy

You should not have an implanted Maestro Rechargeable 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 Maestro Rechargeable 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 the Maestro Rechargeable System. For additional prescribing information, please visit www.enteromedics.com.

If you are interested in learning more about vBloc Therapy, please visit www.vbloc.com 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 lack of commercial sales experience with our Maestro® Rechargeable 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 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® 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 13, 2015. 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.

(See attached tables)

ENTEROMEDICS INC.
Condensed Consolidated Statements of Operations (unaudited)
(in thousands, except per share data)

	<u>Three Months Ended</u> <u>September 30,</u>		<u>Nine Months Ended</u> <u>September 30,</u>	
	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Sales	\$ 64	\$ —	\$ 143	\$ —
Cost of goods sold	<u>23</u>	<u>—</u>	<u>54</u>	<u>—</u>
Gross profit	<u>41</u>	<u>—</u>	<u>89</u>	<u>—</u>
Operating expenses:				
Selling, general and administrative	4,289	3,288	13,953	11,489
Research and development	<u>1,762</u>	<u>2,306</u>	<u>6,451</u>	<u>8,017</u>
Total operating expenses	<u>6,051</u>	<u>5,594</u>	<u>20,404</u>	<u>19,506</u>
Operating loss	(6,010)	(5,594)	(20,315)	(19,506)
Other income (expense), net	<u>1,859</u>	<u>(120)</u>	<u>1,587</u>	<u>(442)</u>
Net loss	<u>\$ (4,151)</u>	<u>\$ (5,714)</u>	<u>\$ (18,728)</u>	<u>\$ (19,948)</u>
Net loss per share - basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.08)</u>	<u>\$ (0.22)</u>	<u>\$ (0.30)</u>
Shares used to compute basic and diluted net loss per share	<u>103,970</u>	<u>68,885</u>	<u>83,818</u>	<u>67,415</u>

ENTEROMEDICS INC.
Condensed Consolidated Balance Sheets (unaudited)
(in thousands)

	September 30, 2015	December 31, 2014
ASSETS		
Cash, cash equivalents and short-term investments	\$ 12,261	\$ 11,619
Inventory	1,376	981
Prepaid expenses and other current assets	258	424
Property and equipment, net	367	482
Other assets	748	880
Total assets	<u>\$ 15,010</u>	<u>\$ 14,386</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Accounts payable	\$ 196	\$ 399
Debt	—	2,976
Other liabilities	7,072	4,347
Total liabilities	<u>7,268</u>	<u>7,722</u>
Stockholders' equity	7,742	6,664
Total liabilities and stockholders' equity	<u>\$ 15,010</u>	<u>\$ 14,386</u>

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vBloc® Therapy Data Demonstrate Two Year Maintenance of Clinically Significant Weight Loss and Sustained Improvements in Obesity Related Risk Factors

EnteroMedics Announces Chief Medical Officer, Scott A. Shikora, M.D., F.A.C.S., Awarded 2015 Outstanding Achievement Award from ASMBS

Results and Award Presented at Obesity Week, November 2-6, 2015

ST. PAUL, Minnesota, November 4, 2015 – EnteroMedics Inc. (NASDAQ: ETRM), the developer of medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders, today announced the presentation of two year follow up results from the ReCharge Study of vBloc Neurometabolic Therapy in obesity. The results were presented in two abstracts at Obesity Week 2015, a joint Annual Meeting of the American Society of Metabolic and Bariatric Surgery and The Obesity Society taking place in Los Angeles November 2-6, 2015.

“Among the major challenges with obesity treatment are maintaining weight loss over time and avoiding the health risks associated with weight gain and cycling,” said Scott Shikora M.D. F.A.C.S, EnteroMedics Executive Vice President and Chief Medical Officer. “At the two-year follow-up, data from the ReCharge Trial demonstrate that intermittent vagal blocking provides maintenance of clinically significant weight loss and a continued favorable safety profile. These data also demonstrate meaningful and sustained reduction in measures of cardiovascular risk factors, improvements in indicators of pre-diabetes and metabolic syndrome, as well as improvements in weight-related quality of life and eating behaviors, pointing to vBloc as a safe and effective long-term weight loss solution.”

The Company also announced that Dr. Shikora was awarded the 2015 Outstanding Achievement Award from the American Society of Metabolic and Bariatric Surgery (ASMBS). The ASMBS Foundation’s Outstanding Achievement Award honors an ASMBS member who supports the goals and vision of the ASMBS Foundation, has displayed a lasting impression and selfless commitment to the ASMBS organization and has made significant contributions to the field of metabolic and bariatric surgery.

Weight Loss at 24 Months

The ReCharge pivotal trial is a prospective double-blind, sham-controlled clinical trial of vBloc Neurometabolic Therapy for the treatment of obesity. The trial includes 239 randomized (2:1) patients with a BMI of 40-45kg/m² or 35-40 kg/m² with at least one obesity-related condition(s). The double-blind period of the ReCharge Trial has been completed and the trial has transitioned to a 5-year, open-label study of the safety and effectiveness of vagal blocking.

Percent excess weight loss (EWL), percent total body weight loss (TBL) and safety in subjects randomized to the active arm of the trial who attended the two-year visit (n=103) were presented. Seventy-six percent of subjects remained in the active arm of the trial. Sham subjects were in the process of crossing over to an active device at the 2-year visit.

At 2 years, the average weight loss was 21% ± 25% EWL or 8% ± 10% TBL. Fifty-eight percent of subjects had at least 5% TBL and 45% had at least 7.5%TBL. Only one serious complication has occurred in the 2 years.

Obesity Related Condition Results in vBloc Group at 24 Months

In addition to EWL, metabolic parameter improvements were sustained to 24 months:

Risk Factor	Time Point	All Subjects	Subjects with Abnormal Baseline Values
Systolic BP (mmHg)	Screening	128 ± 13	142 ± 10
	24 month change	-6***	-11***
Diastolic BP (mmHg)	Screening	81 ± 9	89 ± 8
	24 month change	-3**	-10***
Waist Circumference (cm)	Screening	121 ± 12	123 ± 11
	24 month change	-8***	-10***
LDL Cholesterol (mg/dL)	Screening	122 ± 32	151 ± 21
	24 month change	-5**	-16***
Triglycerides (mg/dl)	Screening	139 ± 61	209 ± 42
	24 month change	-14*	-46***
HbA1c (%)	Screening	5.7 ± 0.6	5.9 ± 0.2
	24 month change	-0.3***	-0.3***

* P <0.05. ** P<0.01. *** P<0.001

Lastly, for those patients with either pre-diabetes or metabolic syndrome at baseline, the 2 year data showed 50% remission rate for pre-diabetes and 47% remission rate for metabolic syndrome.

About the ReCharge Study

The ReCharge Pivotal Trial of vBloc Neurometabolic Therapy for the treatment of obesity is a prospective double-blind, sham-controlled clinical trial involving 239 randomized (2:1) patients with a Body Mass Index (BMI) of 40-45kg/m² or 35-40 kg/m² with at least one obesity-related condition(s). The trial tested the effectiveness and safety of vBloc Therapy utilizing EnteroMedics' Maestro® Rechargeable (RC) System. All patients participated in a weight management counseling program.

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