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EnteroMedics Reports Third Quarter 2016 Financial Results

Company Highlights Progress in Clinical Data, Reimbursement Coverage, Patent Portfolio During Third Quarter

ST. PAUL, Minn., Nov. 10, 2016 /PRNewswire/ -- 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 months ended September 30, 2016.



"Over the last few months, EnteroMedics has worked towards achieving several key commercial milestones, including securing vBloc[®] coverage for the veterans of our armed forces served by the U.S. Department of Veterans Affairs thanks to a contract with Academy Medical," said Dan Gladney, EnteroMedics' President, Chief Executive Officer and Chairman of the Board. "Both our maturing clinical data and the first-hand patient success stories from the field continue to support vBloc Therapy as a safe, effective and durable treatment for obesity and its co-morbidities, addressing the costs and profound health risks associated with this disease. We remain committed to our continued efforts to secure broad reimbursement coverage and to ensuring that this innovative, proven therapy is widely available to patients."

Mr. Gladney added: "As we continue to execute on our commercial strategy, we are actively exploring means of addressing our financial strategy. Once we determine the appropriate path forward, we ask our shareholders to provide support for this strategy, to ensure we are able to build sufficient capital runway to fully unlock the potential of this unique therapy."

Recent Highlights

- | **Announced vBloc Therapy Available to U.S. Veterans at U.S. Department of Veterans Affairs (VA) Medical Facilities through Partnership with Academy Medical.** In October 2016, the Company announced that vBloc Therapy was added to Academy Medical's five-year sole source agreement with the U.S. Department of Veterans Affairs that allows any VA surgeon in the U.S. to purchase the vBloc System from Academy Medical under a national contract. This is made possible through the previously-announced EnteroMedics partnership with Academy Medical, LLC, a certified Service-Disabled Veteran-Owned Small Business specializing in the distribution of medical products to VA and Department of Defense (DoD) facilities.
- | **Announced Receipt of Notice of Intention to Grant European Patent Safety Features of vBloc Therapy.** In September 2016, the Company announced that the European Patent Office has issued a Notice of Intention to Grant a European Patent covering safety features of the Company's vBloc Therapy System, strengthening the Company's neuromodulation intellectual property portfolio of more than 70 patents worldwide.
- | **Announced Positive Clinical Success at vBloc Institute.** In September 2016, the Company announced clinical success at the Bariatric Center at Sky Ridge Medical Center in Colorado, a vBloc Institute partner, where several vBloc procedures have been performed to date by Frank H. Chae, MD, FACS, Chief Surgeon and Head of the Center. Patients experienced more than 30 percent improvement in the percent total weight loss (TWL) in the first three months, ultimately trending greater than TWL reported in the Company's pivotal ReCharge Study.
- | **Appointed Scott Youngstrom as Chief Financial Officer and Chief Compliance Officer.** In September 2016, the Company announced the appointment of Scott Youngstrom as Chief Financial Officer and Chief Compliance Officer. Mr. Youngstrom brings to EnteroMedics over 25 years of strategic financial and operational experience in a variety of medical device companies.
- | **Announced the Publication of 24 Month Results from the Company's Pivotal ReCharge Study.** In August 2016, the Company announced the publication of 24 month results from the Company's ReCharge Clinical Study. The article, titled "Two-Year Outcomes of Vagal Nerve Blocking (vBloc) for the Treatment of Obesity in the ReCharge

Trial," was published in *Obesity Surgery* (DOI: 10.1007/s11695-016-2325-7), and is available online [here](#). At 24 months, patients randomized to vBloc demonstrated durable weight loss, with approximately 50% of patients with pre-diabetes or metabolic syndrome at baseline experiencing a resolution of pre-diabetes or metabolic syndrome at 24 months compared to baseline. Further, the authors noted that 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.

- 1 **Announced Key Appointments to Board of Directors.** During the third quarter, the Company announced two key appointments to its Board of Directors, including the appointment of President and Chief Executive Officer Dan Gladney as Chairman of the Board of Directors. Gary Blackford was also named to the Board of Directors, bringing over 30 years of executive experience in the healthcare industry, having most recently served as Chief Executive Officer of Universal Hospital Services Inc.

vBloc Therapy is approved for use in helping with weight loss in people aged 18 years and older 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 Type 2 diabetes, high blood pressure, high cholesterol levels or obstructive sleep apnea.

Financial Results

For the three months ended September 30, 2016, the Company reported sales of \$296,760 with gross profit totaling \$150,129. Selling, general and administrative expenses for the quarter were \$3.4 million, and research and development expenses were \$1.3 million. Combined, these two operating expenses decreased 23.7% from the third quarter of 2015. The Company reported a net loss for the quarter of \$6.5 million, or \$0.17 per share.

For the nine months ended September 30, 2016, the Company reported sales of \$644,760 with gross profit totaling \$302,690. Operating expenses for the nine months ended September 30, 2016, totaled \$19.0 million, a 7.0% decrease as compared to the prior year total of \$20.4 million. For the nine months ended September 30, 2016, the Company reported a net loss of \$18.9 million, or \$0.99 per share. On September 30, 2016, the Company's cash, cash equivalents and short-term investments totaled \$6.8 million.

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 vBloc® System, is designed to intermittently block the vagus nerves using high-frequency, low-energy, electrical impulses. EnteroMedics' vBloc® 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® 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 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 limited commercial sales experience with our vBloc® 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® 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® System; physician adoption of our vBloc® 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 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.

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

	<u>September 30,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
ASSETS		
Cash, cash equivalents and short-term investments	\$ 6,842	\$ 7,927
Accounts receivable	192	58
Inventory	2,134	1,686
Prepaid expenses and other current assets	371	831
Property and equipment, net	228	326
Other assets	809	759
Total assets	<u>\$ 10,576</u>	<u>\$ 11,587</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Liabilities:		
Accounts payable	\$ 681	\$ 172
Debt	5,676	1,267
Other liabilities	3,064	6,475
Total liabilities	<u>9,421</u>	<u>7,914</u>
Stockholders' equity	1,155	3,673
Total liabilities and stockholders' equity	<u>\$ 10,576</u>	<u>\$ 11,587</u>

ENTEROMEDICS INC.
Consolidated Statements of Operations (unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Sales	\$ 296,760	\$ 64,000	\$ 644,760	\$ 143,000
Cost of goods sold	<u>146,631</u>	<u>23,346</u>	<u>342,070</u>	<u>54,109</u>
Gross profit	150,129	40,654	302,690	88,891
Operating expenses:				
Selling, general and administrative	3,361,572	4,289,017	15,088,297	13,952,899
Research and development	1,253,390	1,762,013	3,879,378	6,451,406
Total operating expenses	<u>4,614,962</u>	<u>6,051,030</u>	<u>18,967,675</u>	<u>20,404,305</u>
Operating loss	<u>(4,464,833)</u>	<u>(6,010,376)</u>	<u>(18,664,985)</u>	<u>(20,315,414)</u>
Other income (expense):				
Interest income	1,493	157	4,991	1,446
Interest expense	(1,391,134)	(565,522)	(3,393,374)	(840,491)
Change in value of warrant liability	241,741	2,416,443	3,330,254	2,416,443
Change in value of convertible notes payable	(909,030)	—	(200,004)	—
Other, net	(700)	8,628	(3,272)	9,561
Net loss	<u>\$ (6,522,463)</u>	<u>\$ (4,150,670)</u>	<u>\$ (18,926,390)</u>	<u>\$ (18,728,455)</u>
Net loss per share - basic and diluted	<u>\$ (0.17)</u>	<u>\$ (0.60)</u>	<u>\$ (0.99)</u>	<u>\$ (3.35)</u>
Shares used to compute basic and diluted net loss per share	<u>38,781,980</u>	<u>6,931,306</u>	<u>19,162,561</u>	<u>5,587,847</u>

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