# 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 30, 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)
$\boxtimes$	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 8.01 Other Events.

On November 30, 2016, EnteroMedics Inc. (the "Company") hosted a conference call to discuss commercialization and corporate updates and to urge all shareholders of record at the close of business of the Company on November 3, 2016 to vote FOR all of the management proposals at the Company's anticipated special meeting of shareholders to be held on Monday, December 12, 2016. A copy of the transcript is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The full meeting agenda, including all of the management proposals, is detailed in the Company's definitive proxy statement, which was filed with the Securities and Exchange Commission ("SEC") on November 17, 2016. The Company advises all investors and security holders to read the definitive proxy statement and other documents filed with the SEC carefully and in their entirety. Investors and security holders may obtain free copies of the definitive proxy statement and other documents filed with the SEC by the Company through the web site maintained by the SEC at www.sec.gov. Free copies of the definitive proxy statement and other documents filed with the SEC can also be obtained on the Company's website at http://ir.enteromedics.com/sec.cfm.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No. Description

99.1 Conference Call Transcript dated November 30, 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 Youngstrom

Scott Youngstrom

Chief Financial Officer and Chief Compliance Officer

Date: December 5, 2016

## EXHIBIT INDEX

Exhibit No. 99.1

<u>Description</u>
Conference Call Transcript dated November 30, 2016

#### EnteroMedics Commercialization and Corporate Update Conference Call November 30, 2016

**Operator**: Good day, ladies and gentlemen, and welcome to the EnteroMedics Commercial Update Call. (Operator Instructions) As a reminder, this call is being recorded.

I would now like to turn the call over to Scott Youngstrom, Chief Financial Officer. You may begin.

**Scott Youngstrom – EnteroMedics, Inc. – Chief Financial Officer**: Good morning, and thank you all for joining us on today's call. I'm pleased to be joined by Dan Gladney, our President, CEO, and Chairman of the Board, who will provide an update on the company's recent commercialization and corporate achievements. Following our prepared remarks, we will be available for questions during the Q&A session.

As a reminder, this conference call, as well as EnteroMedics' SEC filings and website at enteromedics.com, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those discussed due to known and unknown risks, uncertainties, and other factors. These 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 10-Q filed November 14, 2016.

I will now turn the call over to Dan.

Dan Gladney – EnteroMedics, Inc. – Chief Executive Officer: Thank you, Scott. Hello, everybody, and thank you all for joining us this morning. As I look back at my first calendar year as President and CEO of EnteroMedics, I'm truly proud of the progress we've made, expanding the availability of vBloc Therapy, a best-in-class treatment for promoting lasting weight loss to people living with obesity. Obesity is one of the largest, if not the largest, cause of preventable chronic disease and increasing health care costs in our country. As we begin to look towards 2017, I'm pleased to have the opportunity to give you an update on our recent commercialization efforts and talk to you about our upcoming and highly important special meeting of the shareholders on Monday, December 12, 2016.

Let's start off with an update on our commercialization efforts. Perhaps the most significant milestone EnteroMedics achieved this year was making vBloc Therapy available to the millions of U.S. veterans who have served our country as members of the U.S. Military. This was accomplished through an expanded partnership with Academy Medical, a certified service-disabled veteran-owned small business. Through this expanded partnership, vBloc Therapy was added to Academy Medical's five-year sole-source agreement with the U.S. Department of Veterans Affairs. This means that any veteran who qualifies can receive vBloc Therapy at little to no cost in accordance with their health benefit at the Department of Veterans Affairs or VA

medical facilities. This is very similar to a national coverage decision by a private payer. There are over 20 million veterans with well over 1 million that are vBloc Therapy candidates and seeking obesity treatment at VA facilities across the United States. I will speak more on this topic in a minute.

This expanded partnership with Academy Medical, combined with our other partnerships with institutions to cover their employees and families, such as Winthrop University in New York, now makes vBloc Therapy more readily available to an expanded U.S. adult population. In addition to our ongoing strategy to introduce vBloc Therapy to people seeking surgical options to treat their obesity, we have now successfully shown that vBloc Therapy as an option for those who have already had gastric sleeve surgery that has failed.

Dr. Sachin Kukreja, Director of Bariatric Surgery, VA North Texas health care, recently performed his third adjunctive rescue surgery for a failed gastric sleeve using vBloc Therapy. This successful surgery was broadcast live at the largest obesity conference for surgeons in the United States in early November for all conference attendees to view. The previous two adjunctive rescue surgeries using vBloc Therapy took place in May and in June. I'm pleased to report that those first two patients have experienced weight loss results in line with their doctors' expectations. We expect to be able to discuss more details about their progress in the near future.

I would like to emphasize that in all three of these cases, the patients were given multiple options following gastric sleeve failure, and all chose vBloc Therapy as a safe, effective, long-lasting weapon in their continued battle with obesity. We're also working closely with our current patients to help ensure that they continue to reach their health care goals with vBloc Therapy. These efforts not only include patient assistance and support programs such as a vBloc Achieve program, our comprehensive personalized weight-loss support program involving dietitian, counseling, and other support tools, but also the technical support for the actual vBloc device and the personalized therapy that it delivers.

Our most recent software update for our mobile charger, known as MC Accelerated, which offers more user-friendly upgrades, was recently approved by the U.S. Food and Drug Administration for commercial distribution. This is the most significant premarket approval application, or PMA supplement approval we've received since the launch of vBloc back in January of 2015.

As we continue to grow our market position in the competitive obesity device landscape, our engineering talents and continued success with FDA approvals is key to establishing and maintaining a leadership position. In addition to these specific examples of our commercial efforts, the company has also continued to aggressively pursue positive payer coverage decisions and implemented a targeted marketing campaign designed to build awareness for vBloc Therapy and expand the commercial vBloc institutes to focus on specific patient groups, specifically those patients that would most benefit from vBloc Therapy, such as failed sleeves, young adults or the elderly.

Supporting our commercial expansion is a strong portfolio of clinical research data. During our last call, I updated you on the progress of our pivotal double-blind sham-controlled ReCharge

trial conducted on a population of 239 patients with obesity. Since then, we found that at 24 months post-surgery, patients from the ReCharge clinical study were randomized to vBloc demonstrated durable weight loss. Approximately 50% of the patients with pre-diabetes or metabolic syndrome at baseline experienced a resolution to their pre-diabetes or metabolic syndrome compared to baseline. The long-term results confirmed the durable nature of the weight loss achieved with vBloc Therapy and the positive impact it had on patients with obesity-related comorbidities. These commercial milestones and others provide positive proof that our strategy to position vBloc as a minimally invasive alternative to traditional bariatric surgery built on our ability to show efficacy and safety of vBloc Therapy through positive clinical data as well as support from key opinion leaders and disseminating patients' success stories does indeed work.

As far as our outlook for 2017, we are in the middle of our planning efforts and feel bullish on our potential opportunities to build on successes of this past year. Specifically, our plans for 2017 will include the following. Through a targeted direct to veterans marketing campaign, we will expand our presence in VA facilities across the United States and work to ensure all veterans seeking obesity treatment are aware of the vBloc technology and their deserved coverage benefit. With our marketing efforts, we will target the millions of obese veterans to ensure they are informed of their vBloc treatment options and directed to the appropriate treatment facility. Two, we will more than double our number of active vBloc institutes across the United States to expand our number of surgeon advocates, our number of cash pay patients and ultimately drive covered lives within the integrated delivery networks such as Winthrop Hospital in New York and with private payers. We will initiate and publish commercial clinical data to further support the safety, efficacy, and cost effectiveness of vBloc Therapy to treat obesity and related comorbidities, specifically diabetes. We will expand our sales internationally by entering the Canadian market and their already-mature cash pay market that exist for gastric balloons — gastric bands, balloons, and sleeves. Our earliest access to this market may be as soon as the first quarter of 2017 through Health Canada's Special Access Programme or SAP. The SAP allows doctors to gain access to medical devices that have not been approved for sale in Canada. Lastly and most importantly, we anticipate all of our efforts will build upon our current payer coverage strategy and support favorable coverage decisions in 2017 from a private payer and/or Medicare administrative contractor. We are very excited about the momentum this is building in each of our strategies and look forward to providing you with updates as these efforts progress.

Now, switching gears to the company's financial performance. We've taken every effort to cut costs, and in the third quarter, we decreased operating expenses over the previous year's third quarter by 23.7%. That is significant. We've accomplished this by evaluating all the company's discretionary spending and in some cases, made tough decisions on where our funds are spent and which particular projects we allocate resources to; all this while maintaining customer service and making sure that our patients come first.

Assuming that the shareholder proposals all pass on December 12, 2016, we will continue with our plan to wind down the convertible notes payable that are still outstanding. We anticipate these notes will all be converted by the end of this calendar year. We will perform a reverse stock split that will raise our share price above the \$1.00 minimum NASDAQ requirement, and

we will commence our efforts to securing the financing that will properly capitalize the company through 2017.

As just mentioned, in 2017, we plan to continue to focus our commercialization efforts on both VA customers and on new prospective payers in an effort to gain additional reimbursement coverage decisions. Along with the continued tightening of our operating expenses, we will continue to invest in clinical support, new research and development, and manufacturing opportunities. The company is poised to have a successful 2017.

Finally, I want to speak for a moment about three important topics that I know many of you are greatly interested in. First, recognizing we have had several inquiries from investors, I will state that while we are not in any definitive agreements with any strategic partners at this time, we are in contact with potential partners on a regular basis that could be of benefit to our company and to our shareholders. If any of these materialize, we will report the specifics to you at that time.

Secondly, while we have working capital on hand to execute our commercial activities through the first quarter of 2017, our share price trading level continues to hinder long-term financial growth prospects. In order to deliver on our commitment to bring vBloc Therapy to as many patients as possible, we feel that it is imperative that we remain compliant with the \$1 minimum price requirement and 2.5 million positive stockholders' equity requirement to maintain our listing on NASDAQ stock exchange. Pursuant to this requirement, we have requested and have been granted a hearing before a NASDAQ hearings panel to address these issues, which has stayed the delisting process. This hearing is currently scheduled for January 12, 2017. The reverse split will greatly help our case.

The third topic I would like to discuss with you is our upcoming special shareholder meeting and proxy vote. If you were a shareholder of record at the close of business on November 3, 2016, and even if you no longer own the shares, you can still vote. You should have received the letter containing instructions on how to cast a proxy vote at the special meeting. Even if you don't have your proxy card available, you can still vote by calling the Proxy Advisory Group at 1-888-557-7699, or you can also use this number if you would like to change your vote. Again, that number is 1-888-557-7699. You will be asked to vote on four proposals from the management team: an increase in the number of authorized shares; a reverse split of our issued and outstanding shares; approval of our stock incentive plan; and approval of adjournments to the special meeting.

The passing of this shareholder vote is vital to our continued success. In order for our company to successfully market vBloc in an appropriate manner with the necessary resources, we need our shareholders to vote yes on all four proposals. Failure to do so could have a very negative impact on our future operations. Not voting for either of the first two proposals is essentially equivalent to a "No" vote. Therefore, I urge everyone to exercise their voting right and, as a fellow shareholder, to vote "Yes" in favor of all four proposals.

We remain grateful for your continued support as shareholders, and we are committed to working hard to build value for EnteroMedics.

With that, I'd like to open up the call to questions.

**Operator**: (Operator Instructions) Our first question comes from Suraj Kalia of Northland Securities.

**Suraj Kalia – Northland Securities – Analyst**: So, Dan, thank you for providing a corporate update. I guess if I can just drill down a little bit, fully knowing that there are certain things you might not feel comfortable at this time sharing. The VA arrangement, Dan, can you help us understand the funneling of patients' process? It is — admittedly, it is a pretty big deal for vBloc to get in. But help us understand the logistics, the funneling, at what point should we start looking at metrics specifically related to the VA arrangement and Academy?

Dan Gladney: Sure, sure. So it'll work somewhat similar to a national coverage decision. So the way this will work is, first, we have to get out into the VA hospitals and let those surgeons know that we're on contract. They're not typically going over all new contracts to see new products available. So we've got to notify them through e-mails and through calling and knocking on doors, let them know it's available. We have to educate the ones that are interested in it, and then we have to certify them. So they have to go off to a vBloc training program where they'll be trained for a day on using vBloc. And then they will line up their first patients, and of course, we would be there physically supporting them in the operating room. We'll have a technician available for them and a specialist available for them with any questions they might have during the procedure.

The other thing we have to do, Suraj, is we have to find those VA — those veterans that have an obesity problem and let them know that this is available in VA hospitals. So what we plan to do is somewhat similar to what we did with our looking-for-cash pay patients. First of all identify the doctors in those hospitals that are interested in doing the procedure. And then what we'll do is we'll do local advertising on the radio, on the Internet and on the TV. We have — we also identified and have a mailing list that's available to us for all these surgeons.

So that's how we'll start the process. So it'll probably — realistically, it's probably going to take — I can tell you the award was given about a month and a half ago and it still doesn't show up on the VA — on the veteran hospitals' computer screens yet. So the government's a little bit slow in just getting these all lined up and on their software. But we would expect that by the first of the year that this will be on the computer screens and the surgeon can order it for his patient.

The process will take a little time to get it going. We will have to develop that the funnel patients, notify those patients, get those patients educated on the system. My guess is realistically, it'll be in the neighborhood of four months before we start seeing patients actually getting the procedure done at VA hospitals, four to five months.

**Suraj Kalia**: Got it. And, Dan, in terms of the DTC campaign or cash pay, out-of-pocket in the U.S., help us understand the status of this effort and whether it's a number of implants, number of hits, number of prospects. At one point, there were like 1,000 patients in the funnel. I believe this was prior to the DTC campaign. Any metrics you can share at this stage?

**Dan Gladney**: Sure. I can tell you that as we previously reported, we're seeing over twice the conversion of viable cash pay patients leads that we generate to vBloc versus the 1% of viable patients that are covered for other bariatric procedures nationally. So, yes, that's very, very encouraging. So in other words, of all the patients that call in, we've had about, I'd say, 6,000, 7,000 patients that have called to show an interest here. And what happens in direct-to-patient marketing campaigns is most of these don't necessarily fall into a category of our BMI. Some are — weigh less than that BMI or they might be way over it, plus others might have — be checking for a family member.

So by the time we get through all those folks, what I can tell you is that the patients that do qualify for our surgery, we're converting about 2% of them to cash pay, which is pretty significant. What that tells us is that that's twice the percentages that we're seeing nationally for patients that get bariatric surgery because only 1% of patients are qualified for bariatric surgery in the United States. Only 1% that qualify for surgery actually get the surgery and its paid for. So we're getting 2% of ours that qualify, that are calling in from the direct-to-patient campaign are actually getting the procedure and paying for it themselves.

Now those aren't big numbers that I've mentioned before, and I would bring you back to last December, one of the analysts, I think it was from Canaccord Genuity, wrote a report on EnteroMedics and forecasted that he thought that considering the costs and considering how difficult it is to find these patients at cash pay environment that there would be about 50 units that would be implanted and sold by EnteroMedics in 2016. I could tell you that through October, we've had 59. And remember, the first three months of the year, we're just filling the funnel of 2016. So we didn't have — we virtually had very little in the first three months of the year.

So we'll do significantly better than what was projected by the analyst. And, again, we do this because we have to because private payers have said to us that there's three things they are looking for before they give coverage. One is they want to see an uptick in patient interest and patients reaching out and patients willing to actually pay for this themselves. Two is they want to hear from surgeons, the surgeons saying that we really need this. And three is they want to see commercial published data on the vBloc successes. What I can tell you that as of today, we have contacted payers 440 times so far this year to verify patient benefits. We've had approximately 60 surgeon-related contacts with payers in actual meetings or in letters written or in calls. And we've had — of all that, we've had the private payers pay for two patients, okay, in the preauthorization approval. So it's a slugfest trying to get it done. But we are making progress.

The big one we still have to do is we've got to publish commercial data. And I can tell you that at the end of this month, in the next couple of days, we'll have about 25 patients at nine months that have been implanted for nine months in the commercial market. We have another two or three that have been implanted for a year. So we'll submit — we would hope to submit to have one of our surgeon advocates write the article on these results and submit it for publication in the first quarter of 2017. So that'll be a very important part of continuing to move forward with these private payers. Hopefully, that helps answer the question.

**Suraj Kalia**: Got it. And, Dan, in terms of the cash pay market in the U.S., what are the lessons learned so far that tells you, you know what, we need to go to Canada. This might be a low-hanging fruit.

Dan Gladney: Yes. Well, what we've learned is that in Canada, the Canadian government insurance programs don't pay for bariatric surgery there. So the Canadians, if they want it, they have to pay for it themselves. So this is a market that's already established that the patients are used to doing that. And they — there aren't a lot of procedures there, but there's a fair amount of procedures in Canada. We think that going head-to-head in a cash pay environment that we'll do very well against, let's say, gastric sleeve or gastric bypass. So we're looking forward to getting into Canada. We're hoping to be in Canada by the end of this year, but it's just taking a while with everything that's required there from an administrative point of view. So we would hope that in early quarter one, we'll be there.

**Suraj Kalia**: Fair enough. And finally, Dan, last question and I'll hop back in queue. Just take a step back, Dan, from a company's specific perspective, let's just leave the micro level and go on a macro level. Interestingly, you and I have had discussions also about gastric balloons; they are being positioned more as an elective procedure, out of pay, sort of cosmetic procedure. What goes through what you see going on, on a macro level, the different buckets on these different technologies seem to be headed? And the reason I ask is just to sort of frame right now, frame where you see vBloc emerging, which is the bucket and what are the potential threats on either side?

**Dan Gladney**: Sure. Well, first of all, I think it's a very, very good thing that we have more entrants in the device space entering obesity. That could be nothing but good for us in the long run. So I think that's a positive thing. Secondly, we certainly heard that the balloons are doing well out there. And the realities are you can get that procedure done in a doctor's clinic, you don't have to go to the operating room. I think total cost is somewhere between \$5,000 and \$7,000. So that makes it a lot more affordable in a cash pay environment. The difference is, of course, is that's a short-term solution, right? So we know balloons have to come out within six months, and we've seen from the clinical publications out there that a high percentage of those patients regain their weight within a year. So — but they work. I mean, the balloons work. And certainly for a short-term basis, that's a positive thing. So we think that overall that, that's very good for the obesity space.

Our technology is quite different. Our technology requires being in either a surgery center or an operating room and going through a laparoscopic, minimally invasive procedure to have the device placed. And once our device is placed, it's a life-long, long-term solution to obesity. So as I — as we reported earlier this year, we reported our two-year clinical evidence from our PMA study. And at two years, what we showed is that the patients kept the weight off. In the sham side of the study, patients who were implanted with the device that wasn't turned on, they had lost a fair amount of weight their first year. But the second year, they regained it, they came back. So what we showed with the vBloc Therapy is that from the time that you're implanted that it lasts for a long period of time. You keep the weight off. You lose the weight and you keep the weight off. So that's a very positive thing in this arena.

**Operator**: There are no further questions. I'd like to turn the call back over to Dan Gladney for any closing remarks.

**Dan Gladney**: Okay. Thank you, everybody, for joining our call today. And please feel free to reach out to us today or in the future with any additional questions you might have. Thank you for your time.

**Operator**: Ladies and gentlemen, thank you for participating in today's conference. This does conclude the program and you may all disconnect. Everyone, have a great day.