

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14A

(RULE 14a-101)

SCHEDULE 14A INFORMATION

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ENTEROMEDICS INC.

(Name of Registrant as Specified In Its Charter)

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Filed by EnteroMedics Inc. Pursuant to Rule 14a-12
Under the Securities Exchange Act of 1934
Subject Company: EnteroMedics Inc.
SEC File No. of EnteroMedics Inc.: 001-33818

This filing consists of the transcript of EnteroMedics Inc.'s May 23, 2017 conference call to discuss its previously announced acquisition of BarioSurg, Inc.

DOW JONES

BarioSurg, Inc., EnteroMedics Inc. M&A Call - Final

3,885 words
23 May 2017

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Presentation

OPERATOR: Good day, ladies and gentlemen, and welcome to the EnteroMedics corporate update call. (Operator Instructions) As a reminder, today's conference is being recorded.

I'd now like to introduce your host for today's conference, Mr. Scott Youngstrom, Chief Financial Officer. Sir, please go ahead.

SCOTT P. YOUNGSTROM, CFO AND CHIEF COMPLIANCE OFFICER, ENTEROMEDICS INC.: Thank you. Good morning, everybody, and thank you for joining us on today's call. I'm pleased to be joined by Dan Gladney, EnteroMedics' President, CEO and Chairman of the Board, who will have some commentary; and also by Dr. Scott Shikora, EnteroMedics' Chief Medical Consultant, who is available for the Q&A section.

During today's call, we will discuss our addition of the Gastric Vest System to our development-stage product pipeline through the acquisition of BarioSurg. After a brief statement, 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, contains 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 the 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-K filed March 8, 2017, and our 10-Q filed May 15, 2017.

I will now turn the call over to Dan Gladney.

DAN W. GLADNEY, CHAIRMAN, CEO AND PRESIDENT, ENTEROMEDICS INC.: Thanks, Scott. And good morning, everybody. Thank you for joining us on today's call.

This morning, EnteroMedics announced that we entered into a definitive agreement and acquired the Gastric Vest System and its developer, BarioSurg. The acquisition diversifies and expands our product portfolio and reinforces our commitment to the bariatric and metabolic continuum of care, which is what we believe to be the best description for a lifelong treatment of obesity and its related comorbidities, such as type 2 diabetes.

In the 2 years since its FDA approval, vBloc metabolic therapy has gained significant traction in the

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commercial marketplace. However, unmet need still exist for morbidity — morbidly obese patients seeking a solution to their health challenges. We are excited to work to bring to market the Gastric Vest System, which is designed to offer patients fast excess weight loss, or EWL, over a short period of time. This has already been demonstrated in a pilot clinical trial of the Vest, where data available to date show a mean excess weight loss of 85% after 1 year.

When you compare the Vest 12-month data to date to the expected excess weight loss associated with the bariatric gold standard procedures, gastric bypass at approximately 75% excess weight loss, or the gastric sleeve gastrectomy at approximately 65% EWL, it should be evident that the Vest will compete. When you also consider that the Gastric Vest System offers a minimally invasive alternative that does not permanently alter anatomy and is reversible, you can see why this strategic acquisition is important to our company. If you can imagine what these 2 complementary medical devices for obesity and related comorbidities, vBloc and the Vest, could offer doctors and patients when paired together, you can begin to understand our future path.

By developing innovative weight-loss therapies, we continue to address the significant unmet medical need for those living with obesity, who do not wish to permanently alter or remove any part of their anatomy, yet need durable, lifelong therapy. The Vest not only has the potential to serve as a stand-alone treatment, but also be combined with our FDA-approved vBloc.

I'd like now to turn the call back over to Scott Youngstrom, who will review the terms of the acquisition, after I discuss the differences and potential synergies between the Vest and vBloc as well as discuss the Vest approval and commercialization path, and what the acquisition means for our company and our shareholders.

Scott?

SCOTT P. YOUNGSTROM: Thank you, Dan. Our acquisition of the Gastric Vest System includes a robust patent portfolio consisting of 4 granted U.S. patents, with one pending U.S. application; 7 granted foreign patents, with 5 pending applications for Europe, Australia, China, India and Israel. Our due diligence effort was thorough and provided a high level of confidence in the value of the acquired assets. With the acquisition, we are also welcoming a new member to our executive team, Dr. Raj Nihalani, the founder and former CEO of BarioSurg, who will be joining EnteroMedics as our Chief Technology Officer.

Under the terms of the acquisition, the consideration paid by EnteroMedics for BarioSurg, Inc. consists of 1.38 million unregistered shares of EnteroMedics' common stock — I'm missing a line here. And also 1 million shares of unregistered preferred stock that are convertible into 5 million unregistered shares of common stock upon the receipt of the required approval of EnteroMedics stockholders under NASDAQ rules. And we also contributed \$2 million in cash. The shares of common stock issued in the acquisition represent 19.99% of EnteroMedics' outstanding common stock immediately prior to the acquisition. EnteroMedics expects to hold a special meeting of its stockholders to seek the required approval of the conversion of the conditional convertible preferred stock in the summer of 2017.

I will now turn the call back over to Dan.

DAN W. GLADNEY: Thanks, Scott. The Vest is an investigational weight-loss device that we believe will treat the obese or morbidly obese individuals with a BMI of at least 35. It is minimally invasive, laparoscopic, implantable device that restricts the intake of food and provide a feeling of fullness without cutting or permanently removing portions of the stomach or bypassing any portion of the gastrointestinal tract. In addition, unlike currently available gastric restricting devices, the Vest does not require ongoing adjustments.

Dr. Scott Shikora, Director at the Center of Metabolic and Bariatric Surgery at Brigham and Women's Hospital, the former president of the American Society of Metabolic and Bariatric Surgery and our Chief Medical Consultant was a member of our due diligence team and deeply involved in the decision process to acquire the Gastric Vest System. He is on the call and will answer clinical questions.

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I would like to restate what Dr. Scott Shikora has said about the Vest. In his words, "If the Vest continues to yield similar results to those observed to date, it will be a game changer in the field of bariatrics."

14 patients have enrolled and have completed their 12-month follow-up visit. Results from these 14 patients showed that the Vest demonstrated a mean excess weight loss, or EWL, of 85% compared to approximately 75% and 65% for gastric bypass and sleeve gastrectomy, respectively. The patients also experienced an average HbA1c decrease of 2.1% and an average waist circumference reduction of 38 centimeters or 15 inches. Again, these significant reductions were at 12 months.

We are extremely encouraged by the results we've seen so far and look forward to learning more about the potential that exists for the Vest, not only as a stand-alone treatment, but also combined with vBloc Therapy. When we compare the 2 devices, the Vest has been shown to offer higher excess weight loss over a shorter period of time. However, as vBloc has already done, the Vest will have to prove itself to be a durable solution for keeping weight off. And while we intend to study its efficacy over time, we expect the Vest to be a shorter-term solution for rapid weight loss.

vBloc Therapy is designed to be a long-term BMI management and comorbidity reduction solution, lasting up to 10 years, slowly but durably helping patients lose and control weight, while often reversing comorbidity factors. These trade-offs are key to understanding why a patient and their provider may choose either device or both.

Through additional clinical trials and following the anticipated FDA approval of the Vest, the company will be able to offer 3 distinct approaches as weight loss solutions for obesity and its related comorbidities: one; the vBloc system; two, the Gastric Vest; and three, the combination of both, vBloc and the Vest.

The entire team at EnteroMedics has been actively strategizing a plan for how we will proceed with clinical trials and a pathway to obtaining FDA approval. In addition to having health economics data for payer coverage, we are acutely aware of the costs and timing of such an endeavor and plan to leverage our past learnings and current resources to make the path to approval not only successful, but as financially efficient as possible. We will update everyone in due course with additional details regarding our strategy here.

Today is a milestone day here at EnteroMedics as we transform from a single-product company to one with multiple options that focus on minimally invasive, safe and durable weight loss, and the continuum of care for those battling morbid obesity.

We are more excited about our future than ever. We believe that this acquisition adds considerable value to our company. We expect that the Vest will fill the gap for those who are looking for a minimally invasive alternative to faster weight loss over a shorter period of time, which may have a lower price point as compared to bariatric surgery, both gastric bypass and gastric sleeve procedure.

It is our goal for EnteroMedics to be the company of choice for doctors and patients making decisions on how to fight obesity and related comorbidities. vBloc has resulted in great successes for numerous patients over the past decade, and we are committed to the commercialization of vBloc. Our goals discussed today are consistent with those shared with you over the last 1.5 years since I became the CEO. We remain very focused on obtaining broad coverage and reimbursement for vBloc by securing and growing key strategic partnerships, finding cash-pay patients, providing peer-reviewed published commercial data, expanding our presence at and within the Veterans Administration health system and more.

For our doctors and surgeon partners, we hope you are excited with the potential to have an additional option as you battle the world's largest chronic disease and health crisis. For our shareholders and analysts, we are committed to building value in our company, and we will look forward to continuing to capitalize on opportunities here at EnteroMedics. For our prospective patients, we are here to support your journey and provide you and your health care professional with the assistance to obtain the device,

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procedure and reimbursement you deserve.

We remain steadfast in the fight against obesity and its related comorbidities. We look forward to bringing you additional updates as the year progresses. From all of us here at EnteroMedics, we remain grateful to everyone for your continued support.

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

Questions and Answers

OPERATOR: (Operator Instructions) Our first question comes from the line of Suraj Kalia with Northland Securities.

SURAJ KALIA, MD AND SENIOR RESEARCH ANALYST, NORTHLAND CAPITAL MARKETS, RESEARCH DIVISION: So Dan, a bunch of questions. And I believe Raj is also on the line. Am I right?

DAN W. GLADNEY: Not sure he is. I can't commit. Not sure he is. Dr. Shikora is on the line.

SURAJ KALIA: Oh, okay. Okay. So one of the key things, Dan, that maybe we can take it offline also, is I'm very curious on the material of construction for this Vest. And if on these 14 patients, was there any, like the gastric band, right, like the LAP-BAND, these loosen over time. I'm very curious of how it behaved, let's say, at 12 months. And at the same time, if you could walk us through the adverse event profile on these 14 patients based on what you all know today.

DAN W. GLADNEY: Okay. Well, I'll turn that question over to Scott. Before I do, I'll tell you that the Vest is made of silicone, okay. So Dr. Scott Shikora, would you like to address the question?

SCOTT A. SHIKORA, CONSULTING MEDICAL DIRECTOR, ENTEROMEDICS INC.: Yes. There was no loosening of the Vest in any of the patients. The Vest was placed around the stomach and felt to be secured throughout the 12 months. There were 2 patients that had complications. One had just intractable heartburn, and the other one had a small abscess that was easily treated. The other patients had no complications.

SURAJ KALIA: Fair enough. In terms of — and Dr. Shikora, I presume there is no problem, but — with the sleeve over or the pouch over the stomach and anything related to the peristaltic motions of the stomach. I'm sure that has not come up, or that is not a cause for concern. Is that a fair statement?

SCOTT A. SHIKORA: I think that's a fair statement. We interviewed 8 of the patients, and none of them described any symptoms to make you concerned about any movement of the Vest.

SURAJ KALIA: Fair enough. And one last question, Dan, and I'll hop back in the queue. Obviously, you all did a strategic analysis internally and made a determination that going after the Gastric Vest at this time was the right decision. And I — to your earlier comments, you also mentioned about exploring vBloc plus the Gastric Vest. So can you walk us through your strategic analysis at this time the amount required in clinical trials, time and resources? You'll have to seek reimbursement and/or get vBloc commercialized. Just kind of lay out a picture for us, this is how we thought through the space. This is why at this time, the strategic analysis indicated it was the right time to move. Any color there would be great.

DAN W. GLADNEY: Sure, sure. Okay, thank you. Thank you, Raj — Suraj, thank you. Yes, a couple of things. First of all, I would point out that the first attraction to us of the Vest was that we've never seen a device offered in the bariatric space that had this kind of — this amount of weight loss that literally competes very effectively with the gold standards of bariatric surgery, so anatomy changing procedures with a minimally invasive product like this. So that itself really drove a high level of interest. And the fact that you would lose that amount of weight, 85% — up to 85% in such a short period of time. And even at 6 months, it was truly significant. At 6 months, quite a bit more than what you see with things like balloons. So yes, with balloons and with vBloc, you lose about the same amount of weight. The difference is vBloc

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is for a much longer period of time, where balloons are a short period of time, over 6-month period, then they have to come out. So the idea of having a device that you're not going to lose 10% of your — or 27% or 25% of EWL, but you're going to lose 85%, and it's minimally invasive was extremely attractive, number one. Number two, we recognize that the device, the Vest product only has, at this point, clinical evidence up to 12 months, okay? We'll do longer-term studies. But we — and don't know if after 12 months, it's going to keep the weight off or if these patients are going to regain. But what we do know is one very positive thing about vBloc is vBloc keeps the weight off. We have long-term studies that show that. So we recognize that there may be some patients that a doctor might want a longer-term solution for, but he might feel the need to have to get this patient for health reasons, significant more lost weight over the 6 months to a year period of time. So this allows him to do both, right? He could get the — up to 85% of the weight off that patient in the first year and then keep it off with vBloc for a long period of time, for multiple years, we believe. So that's certainly an area that we want to investigate. The other thing is, as we looked at this from a clinical study point of view, and I can tell that for the rest of this year, we're not going to be spending much more money than we are right now on just vBloc. Because the rest of this year's going to be spent on doing the final engineering and testing on the Vest with our existing engineering team and investigating and meeting with the regulatory bodies, both in the United States and Europe, to develop a path for approval. So what will the protocols be, et cetera. We wouldn't see this really kicking into gear in terms of a clinical study until 2018. Now as far as clinical study goes, we're evaluating and just starting to meet with these bodies, these regulatory bodies to determine what the actual cost is going to be. But based on an initial meeting with the FDA, I could tell you that we believe that the clinical study will be significantly less than what the clinical study was for vBloc. So we think we're going to have a very manageable path to get through the FDA financially and for the CE Mark.

OPERATOR: Our next question comes from Jeffrey Cohen with Ladenburg.

JEFFREY SCOTT COHEN, MD OF EQUITY RESEARCH, LADENBURG THALMANN & CO. INC., RESEARCH DIVISION: Can you hear me okay?

DAN W. GLADNEY: Sure can, Jeff.

JEFFREY SCOTT COHEN: Just to recap one item. Scott, as far as patent [capability] you said there were 4 granted, 1 pending in the U.S. And was that 7 granted, 4 pending outside U.S.? Is that right?

SCOTT P. YOUNGSTROM: Yes, sir. Yes, 4 granted in the U.S., 1 pending, 7 granted foreign patents, with 5 pending.

JEFFREY SCOTT COHEN: 7 granted foreign, with 5 pending, okay. I got it. So — and Dan, as far as — hypothesize with me a little bit. As far as the patients enrolled, the 14 [as far as] to 12-month follow-up, you said the BMIs were 35 plus. Is that correct?

DAN W. GLADNEY: Correct.

JEFFREY SCOTT COHEN: And is that — you're thinking about that 35 to 40 BMI as far as in clinical work, or yet to be decided?

DAN W. GLADNEY: Yes, we think it's going to be — it could be as low as 30 to 45 or it could be 35 to 45. It depends on when we sit down and talk to regulatory bodies.

JEFFREY SCOTT COHEN: Okay. And when you talk about some of the follow-up with the 85% EWL and the reduction of the HbA1c 2.1%, what were similar studies for gastric bypass as well as sleeves for that, for 12 months approximately? Is that known?

SCOTT P. YOUNGSTROM: 75% to 65%.

DAN W. GLADNEY: Yes. Scott Shikora, you want to answer that real quick?

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SCOTT A. SHIKORA: Yes. You're asking what the mean weight loss at 12 months with the sleeve?

JEFFREY SCOTT COHEN: Well, no. You talked about that, the 75% and the 65%. I was asking about the HbA1c level reduction.

SCOTT A. SHIKORA: I can't quote you specifically. It varied from paper to paper. I would have to look it up.

JEFFREY SCOTT COHEN: Okay, got it. And I guess, lastly, Scott, as long as you're thinking about this, can you walk us through what you're thinking on the clinical side? Would this be a comparator trial? And what will be the regulatory pathway for this? And what other kind of parameters as secondary endpoints would be measured as well?

DAN W. GLADNEY: So right now, we're expecting a clinical trial of 200. It could go as high as 250 patients with a 12-month endpoint and a 36-month follow-up. In the U.S., there will be 15 to 20 sites that are established. And the goal at this point is, we believe very achievable endpoint will be 30% EWL and safety endpoints. No comparison products. The device is expected to be classified IIB for the CE Mark requiring a maximum of 100 patients with a 12-month endpoint.

JEFFREY SCOTT COHEN: Okay. And what were you saying for the U.S., Dan, 12-month endpoint with follow-up to where, 36?

DAN W. GLADNEY: Yes, it'd be a 12-month endpoint with a 36-month follow-up.

JEFFREY SCOTT COHEN: Okay. And up to 250, with 15 to 20 sites?

DAN W. GLADNEY: 200 to 250, right.

JEFFREY SCOTT COHEN: Okay. And you've already had at least one discussion with the FDA, it sounds like, over the past couple of months?

DAN W. GLADNEY: Yes. Actually, BarioSurg has. You're correct.

OPERATOR: And I'm showing no further questions in queue at this time. I'd like to turn the call back to Mr. Gladney for any closing remarks.

DAN W. GLADNEY: Well, thank you, everybody, and thank you for your time this morning and for joining our call. Please feel free to reach out to us today or in the future with any additional questions. Thanks, again.

OPERATOR: Ladies and gentlemen, thank you for your participation in today's conference. This concludes the program. You may now disconnect. Everyone, have a great day.

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Document FNDW000020170524ed5n002mk

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Important Additional Information and Where to Find It

EnteroMedics Inc. (the “Company”) intends to file a proxy statement and other relevant materials with the Securities and Exchange Commission (the “SEC”) to obtain approval from the Company’s stockholders of the conversion of the conditional convertible preferred stock of the Company issued to BarioSurg, Inc.’s stockholders in connection with the acquisition into shares of common stock of the Company (the “Stockholder Approval”). INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PROXY STATEMENT AND OTHER RELEVANT MATERIALS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY AS THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE STOCKHOLDER APPROVAL. The proxy statement, any amendments or supplements to the proxy statement and other relevant documents filed by the Company with the SEC will be available free of charge through the web site maintained by the SEC at www.sec.gov or by calling the SEC at telephone number 1-800-SEC-0330. Free copies of these documents may also be obtained from the Company’s website at www.enteroedics.com or by writing to: EnteroMedics Inc., 2800 Patton Road, St. Paul, Minnesota 55113, Attention: Investor Relations.

The Company and its directors and executive officers are deemed to be participants in the solicitation of proxies from the stockholders of the Company in connection with the Stockholder Approval. Information regarding the Company’s directors and executive officers is included in the Company’s definitive proxy statement for its 2017 annual meeting of stockholders to be held on June 1, 2017, which was filed with the SEC on April 27, 2017.

Other information regarding the participants in such proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be included in the proxy statement to be filed in connection with the Stockholder Approval.

Forward-Looking Safe Harbor Statement:

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