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: February 7, 2013 (Date of earliest event reported)

ENTEROMEDICS INC.

(Exact name of registrant as specified in its charter)

Commission File Number: 1-33818

Delaware	**48-1293684**
(State or other jurisdiction of incorporation)	**(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))

Item 8.01 Other Events.

At 5:00 p.m. Eastern Time on February 7, 2013, EnteroMedics Inc. (the "Company") hosted a conference call to discuss the preliminary results of its ReCharge pivotal trial for obesity, following its issuance of a press release announcing the preliminary results. A replay of the conference call will be available on the Company's website at www.enteromedics.com for approximately 90 days. A copy of the transcript for this conference call is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Conference Call Transcript dated February 7, 2013.

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
Senior Vice President and Chief Financial Officer

Date: February 11, 2013

EXHIBIT INDEX

Exhibit Number	Description
99.1	Conference Call Transcript dated February 7, 2013.

ENTEROMEDICS INC.

Moderator: TBD
February 7, 2013
5:00 p.m. ET

Operator: Good day, ladies and gentlemen and thank you for your patience. You join the EnteroMedics Conference Call. At this time, all participants are in a listen only mode. Later we will conduct the question and answer session and instructions will be given at that time. Should you require any additional assistance during the call, please press star then zero on your touchtone telephone. As a reminder this conference maybe recorded.

I would now like to turn the call over to your host Chief Financial Officer, Greg Lea. Sir, you may begin.

Greg Lea: Thank you for joining us today to discuss the results from our Pivotal ReCharge Trial of VBLOC therapy in obesity. As a reminder, this conference call as well as EnteroMedics SEC filings and web site 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 through 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 15th, 2012.

With me on the call from EnteroMedics are Dr. Mark Knudson, our President and CEO, Dr. Katherine Tweden, our Vice President of Clinical and Regulatory. We are also joined today by Dr. Robert Gibbons, Professor of Biostatistics at the University of Chicago who has completed an overview of the results from the ReCharge study.

We will begin with prepared remarks which are accompanied by a slide presentation available at EnteroMedics.com. This will all be — this will be followed by a review of the results from Dr. Gibbons. When these are concluded, we'll open the call for questions.

I'll now turn the call over to Dr. Knudson. Mark.

Mark Knudson: Thank you very much, Greg, and good afternoon everyone. Earlier this afternoon, we announced the outcome of our ReCharge study of VBLOC therapy in the treatment of obesity. We believe based on this study, that VBLOC therapy is a very exciting new and novel treatment for obesity that fills a significant gap in the treatment spectrum for this epidemic disease.

As previously announced, while the ReCharge study achieved its safety endpoint, it did not achieve its two pre-specified efficacy endpoints in the intent to treat population. However, this was not because the treatment was ineffective. In fact, the study demonstrated a clinically meaningful and statistically significant average excess weight loss of 24.4 percent for VBLOC therapy patients versus sham control.

With 52.5 percent of treatment patients achieving at least 25 — 20 percent excess weight loss and 38.3 percent achieving at least 25 percent excess weight loss. In the per protocol group, which included those patients who received therapy per the trial design, treated patients had an average 26.3 percent excess weight loss with 56.8 percent achieving at least 20 percent excess weight loss, which was above our predefined threshold of 55 percent.

Forty-one point eight percent of treated patients also achieved at least 25 percent excess weight loss in this population, which was slightly less than our predefined threshold of 45 percent. Again, we easily meet our safety endpoint.

Dr. Gibbons, will address the significance of these data in greater detail during his remarks. As a result of these compelling safety and efficacy data, which demonstrate an excellent benefit to risk ratio, we plan to move forward with the premarket approval application with the FDA in the second quarter of 2013.

Before I hand it over to Dr. Tweden to review the results in detail, I would like to reinforce what makes VBLOC therapy delivered via our Maestro system such an important and potentially revolutionary treatment option for obesity and its comorbidities.

VBLOC therapy offers a unique neuroblocking approach to weight loss that directly addresses the physiology of obesity. It consists of an active implantable pacemaker-like device, designed to block the signals between the brain and the stomach that control many aspects of the digestive system including hunger, fullness and energy expenditure.

The data show that impacting these three areas over time provides a unique benefit to patients. One that shows an excellent balance of risk, and reward and one that leads to healthy long-term weight loss.

If approved, VBLOC therapy will fill a significant gap in the treatment spectrum for U.S. patients. It does not share the side-effects or compliance shortfalls of systemic pharmaceutical treatments. It involves no surgical alteration of the digestive system nor does it have a barrier to prevent absorption of nutrients.

With VBLOC therapy, patients are able to eat normal healthy meals without food restriction. As they learn to make choices that are tolerated within their lifestyle and support a healthy relationship with food.

We view the current weight loss options as a continuum of treatment from diet and exercise, to pharmaceuticals, to existing surgical procedures. VBLOC provides what maybe an important step between the earlier options of diet, exercise, and drugs and the anatomy altering options of surgery, offering meaningful weight loss and fewer side effects with lifestyle — without lifestyle altering decisions and less risk of nutritional deficiency.

With that, I would like to turn to the data which our Vice President of Clinical and Regulatory Dr. Katherine Tweden will summarize. Katherine.

Katherine Tweden: Thank you, Mark. Before I go into the results, I'd like to briefly discuss the design of the ReCharge study. As we see in slide two the ReCharge study is a prospective double-blind, sham controlled randomized trial in 239 subjects of which 233 were implanted.

The first co-primary efficacy endpoint is to demonstrate at least 10 percent difference in EWL by super-superiority margin of treated over sham control at 12-month post randomization. The second co-primary efficacy endpoint is the responder analysis in the treated arm, were 55 percent of subjects are to achieve at least 20 percent EWL. And 45 percent of subjects are to achieve at least 25 percent EWL, all by BMI method at 12-month post randomization.

Finally, the primary safety objective is for the composite rate of implant revision procedure, device and therapy-related serious adverse events through 12-month post randomization to be less than 15 percent in the treatment group.

The key baseline demographics for the ReCharge Trial were as follow. A mean BMI of 40.9kg per meter squared, mean age of 47 years with 85 percent of the population female and 15 percent of the population male.

A key takeaways from the ReCharge Trial result as seen on slide three are as follows. The overall outcome of the trial in the intent-to-treat population defined as all 239 randomized patients demonstrated an excellent benefit to risk ratio at 12 months.

With regard to efficacy in terms of percent EWL, a clinically meaningful, statistically significant superiority of surgical sham control was demonstrated. With regard to efficacy in terms of the responder analysis, clinically meaningful weight loss in favor of VBLOC therapy treated patients was observed at all EWL thresholds. And importantly the primary safety endpoint was met.

Next I'll transition to a detailed discussion of the efficacy and the safety data. The first co-primary efficacy measure, mean percent EWL at 12 months in the intent-to-treat population is shown on slide four. Of the 239 randomized subjects, 162 subjects were randomized to the treated arm. And 77 subjects were randomized on the control arm. And 233 subjects were implanted.

What we observe at 12 months was a meaningful weight loss of 24.4 percent in the treated group and 15.9 percent in the surgical sham control group or a difference of 8.5 percentage points. This difference was statistically significant with the P-value of 0.002. However, we did not meet the primary efficacy endpoint of 10 percent super-superiority margin over sham control.

On slide five, mean percent EWL over the first 12 months of the ReCharge study in the control and treated group as observed is shown. The treated group is shown in blue and the control group is shown in orange. This data clearly shows superiority of weight loss of VBLOC therapy over sham control throughout the study's first 12 months. Separation between the groups occurs early and is sustained throughout the study. The ongoing trend of these differences is sustained for the two months where we have sufficient data past 12 months with weight loss continuing in the treated group.

The responder analysis in the intent-to-treat population is summarized on slide six. Again, the results show a clear treatment benefit over sham control at all percent EWL threshold. Specifically the first two thresholds which are the study's co-primary endpoint demonstrate that 52.5 percent of treated subjects achieved 20 percent EWL compared to 32.5 percent of the sham subjects for a difference of 20 percent. And this difference is statistically significant with the P-value 0.004.

This effect continues at the 25 percent threshold with 38.3 percent of treated subjects achieving 25 percent EWL, compared to 23.4 percent for sham, which again, is also statistically significant with the P-value of 0.02. These differences carry through to the highest thresholds where the relative odds of attaining greater weight loss increased dramatically in where these differences are significant. A clear consistent and clinically relevant treatment effect is observed.

While the respective co-primary endpoint targets of 55 and 45 percent were not met, the endpoint targets where within the 95 percent confidence intervals for the observed rates. And therefore, the observed rates were not significantly lower than those pre-specified rates. These efficacy data demonstrates VBLOC therapy's positive effect on weight loss.

On slide seven, we see the odds ratio reflected in graphic form. The black dots represented — represent the estimated odds ratio. And the red dash lines represent the 95 percent confidence limits. As you can see, the treatment patients have significantly higher odds of achieving higher EWL over sham control at every threshold 20 percent and above.

In fact the odds ratio for achieving a 50 percent EWL is 13 for treatment over sham, which means that they have 13 times greater chance of achieving at least 50 percent EWL if they're in the treatment group compared to if they are in the sham control group.

Let's now turn our attention to the active participants in the study, shown here in the per protocol analysis on slide eight. These data are especially compelling and relevant. Specifically these population excludes patients who have missing 12 months value, which includes 6 patients who were never implanted, five of which who were in the treatment group, patients who received incorrect treatment per randomization or patients who were not initiated 45 days after implant. This group still includes 88 percent of the total randomized patients.

You can see here that the EWL at 12 months in treated arm was 26.3 percent. And that we observed that 56.8 percent of the treated subjects achieved 20 percent EWL which was above our predefined threshold of 55 percent. And 41.8 percent for treated subjects achieved 25 percent EWL in the responder analysis which was slightly below our predefined threshold of 45 percent.

One other analysis worthy of note is what we call the complier group which is the per protocol population that had at least 12 hours of therapy delivery per day over the 12 months. This group consisted of 121 treated subjects and they achieved on average 27.8 percent EWL.

Let's next transition to our safety results which are summarized on slide nine. In this study we observed no deaths and no unanticipated adverse device effects. With regard to our primary safety outcome, our composite rate of implant revision procedure device and therapy related serious adverse events in the treatment arm was 3.1 percent post randomization at 12 months. This easily beat our pre-specified threshold of a 15 percent limit. And the outcome was statistically significant with the P-value of less than 0.0001.

Lastly 93 percent of subjects were active in the blinded trial at 12 months, which is consistent with our rigorous well-managed study and suggest a well-acceptance — accepted therapy.

The last data set that I will review today is the cardiovascular safety data, with regard to blood pressure and heart rate changes in the treated group which are shown on slide 10. On average, we had a 5.5mm mercury drop in systolic blood pressure. And a 2.8mm mercury drop in diastolic blood pressure. And then finally the heart rate was decreased by 3.6 beats per minute all at 12 months. These data confirm that no adverse cardiovascular signal was observed with VBLOC therapy over the first 12 months of the study, consistent with our previously reported experience.

With that, I will turn the call over to Dr. Robert Gibbons, Professor of Biostatistics at the University of Chicago. Dr. Gibbons frequently serves on high profile FDA advisory panels. And he has analyzed many drug and device trials which is why we've asked him to perform an independent review of the ReCharge data.

Dr. Gibbons is a member of the Institute of Medicine at the National Academy of Scientists, and one of the authors of the Institute of Medicine Report on the Future of Drug Safety. Dr. Gibbons.

Robert Gibbons: Thank you, Dr. Tweden. My review considers all patients randomized to treatment, the primary endpoints of the study and the corresponding efficacy of treatment in terms of those endpoints.

My review look at data from only the intent-to-treat population that is all patients who are randomized, including patients who were randomized but not implanted as well as those patients who did not complete the full study at 12 months. Unlike many such reviews in which the study fails to meet its primary endpoints overall, but an important subgroup is fortuitously discovered in post-hoc analysis of the data, this is not the case of what I'm presenting to you here.

Referring to the data that Dr. Tweden just reviewed with you, while it is clear neither of the two primary endpoints of the study were met from a simple regulatory standpoint, from a statistical perspective, the trial did demonstrate excellent benefit for patients with minimal associated risk.

First, the average percent EWL in treated patients is nearly 25 percent. Relative to traditional therapy, this is a huge and clinically important advantage. Further, we would expect increased compliance and benefit from a sham control over a non-surgical control and indeed we found one. The sham control demonstrated an average of 16 percent which was higher than anticipated in the study design. And it's approximately four times greater than what is been routinely observed for non-surgical control conditions in randomized clinical trials in this area.

Second, the result of the trial in terms of a responders analysis are both statistically significant and passed the commonly used 20-20 criterion, and that is the difference between response rates defined as the 20 percent benefit exhibit at least a 20 percent difference between treated and control groups.

As we've heard 52.5 percent of the treated patients achieved a 20 percent EWL at 12 months following implant whereas, 32.5 percent of the controls achieved this difference. As such, the difference between treated and control groups in the proportion of patients who achieved at least the 20 percent EWL is 20 percent meeting this 20-20 criterion.

Furthermore, this difference is statistically significant and has an associated odds ratio of 2.3. Indicating that treated patients had 2.3 times greater likelihood than control patients of achieving at least the 20 percent EWL.

To this point I've described the results of the co-primary endpoint, percent EWL and response defined in terms of achieving a pre-specified 20 percent EWL. All of the analyses are based on the intent-to-treat sample.

I now extend these analysis one step further by examining super-responses 50 percent or greater EWL. This threshold was achieved by 15 percent of the treated patients but only 1 percent of the sham control. This difference was significant at the P less than 0.01 level. And the associated odds ratio here was 13.2, indicating that the treated patients had 13 times greater likelihood of achieving a 50 percent or greater EWL compared to the sham controls.

In summary, we know that the treatment works and that it is statistically differentiable from a sham control condition and that the absolute benefit is clinically significant and of a magnitude that has critically important public health implications. Given the excellent safety profile, these data reveal an excellent benefit to risk equation. Thank you.

Mark Knudson: Thank you very much, Dr. Gibbons. An excellent safety profile, together with a statistic — statistically significant superiority analysis over sham control based on percent excess weight loss, a statistically significant responder analysis based on both 20 percent excess weight loss and 50 percent excess weight loss threshold, and an overall average of 24.4 percent excess weight loss for the treated patients make it clear that the Maestro RC device has a positive benefit to risk ratio in all randomized patients.

In light of the data we have discussed, I want to close with a quote from a paper titled “Benefit Risk Paradigm for Clinical Trial Design of Obesity Devices FDA Proposal,” written by Dr. Herbert Lerner, Deputy Division Director in the Office of Device Evaluation at the FDA and his colleagues addressing the evolution of FDA’s view on benefit risk paradigms for obesity devices. This paper was published on December 18th, 2012 in Surgical Endoscopy.

I quote, “We do not want this process to be overly burdensome, nor do we intend for this tool to be a substitute for our detailed assessment of a device’s overall safety and effectiveness during review of a marketing application.” The article continues, “For example, if a device fails to meet the predetermined primary endpoints of the trial but has a good safety profile, the agency will review the submission in its entirety and make a final determination based on both benefit and risk.” It is based on this evolving view at the FDA as well as the significant weight loss advantages of VBLOC therapy in both absolute, and comparative terms and an excellent benefit risk profile based on the superior safety outcome that we will move ahead confidently into the premarket approval application process with the U.S. FDA as planned in the second quarter of 2013.

This concludes our prepared remarks. I will now open the line for questions. Operator.

Operator: Thank you, Sir. Ladies and gentlemen to ask a question, please press star one on your touchtone telephone. If your question has been answered or you wish to remove yourself from the question queue, please press the pound key. Again, to ask a question, press star one on your touchtone telephone. That’s star one on your touchtone telephone.

Our first question comes from Matt Hewitt of Craig-Hallum. Your line is open.

Matt Hewitt: Thank you for taking our questions. First question, it sounds that you're going to continue on with the PMA process as planned and that is you apply or send in the application here in the second quarter. Will there be — given the outcome of the data, will you need to add additional data or will there a need additional trial information as you'll need to incorporate given that you didn't meet the efficacy endpoints?

Mark Knudson: Hi, Matt, this is Mark. Thanks for the question. Right now it is our belief that this was a very positive outcome in this trial. This is as you know the first device trial with the sham control in this space that achieved the positive outcome. The data are very robust as you could tell from the review of the close compliance of the — or the close congruence of the data between the ITT, the per protocol and the complier populations. We think that we have a very strong data set to go to the FDA with.

So we do not anticipate that we will need to do any more work to be able to show a very high benefit and low risk and have a very — and move very confidently forward with our application to the agency.

Matt Hewitt: OK. Thank you. Along the lines of the 10 percent delta that was needed between the two treatment arms and the control arm, how is that number determined? And maybe could you provide some comparison to for example the two drugs that were recently approved this past year, what was the delta between the treatment and control arms in those — in those patients?

Mark Knudson: Well, let me just say that in terms of how these — or determined, it's always a process in developing a protocol with the FDA. And the FDA wanted to have a super-superiority margin which is something that is a very highly statistical process. And I might ask Dr. Gibbons to comment on that for us. Dr. Gibbons.

Robert Gibbons: Sure. Many of you today are wondering what in the world is super-superiority because you've never heard of it before. That's not unusual. Not too many people have heard about super-superiority.

Technically, we normally state the null hypothesis in terms of no difference between treated and controlled conditions. But in the case of super-superiority, we instead state the null hypothesis in terms of some minimally significant difference. And in this case that was agreed upon to be 10 percent. And we need to show statistically significant benefit above and beyond 10 percent. For those of you familiar with confidence intervals will understand that the — that the lower confidence limit is greater than 10 percent. So the actual gain would be much larger.

The idea of super-superiority is not to make it overly burdensome to meet an endpoint but rather to try and combine clinical significance and statistical significance in a single analysis. There is not too much about super-superiority but there's been a lot of debate that that's not the best way to do it. This study has shown statistical significance and it has shown clinical significance.

The real reason for doing super-superiority is those cases where in the present context if the patients had — who are randomized to control had actually gained weight. And the patients who got the active treatment has little or no benefit, then this would be a case where super-superiority would have been helpful. That clearly is not the case. We have a sham control that did well. And we have an active treatment that did significantly better than the sham controls.

Mark Knudson: Thank you, Dr. Gibbons.

Matt Hewitt: Oh, absolutely, thank you. I guess a couple of related items — or it pertains your business anyway. What type of impact if any would this have on your OUS opportunity or is this a non-event? You can still point to a very, very strong data and you would anticipate that you will still be able to ramp outside of the U.S.?

Mark Knudson: Matt, you hit it exactly right. I mean, this is the first time that a trial such as this has been done in a randomized control fashion. And we were able to demonstrate statistical superiority over a sham control, not a placebo, a sham control. And a significant responder analysis which shows clinically meaningful benefit at a very low risk profile. So we have high benefit, low risk. And we believe that this will strongly support our OUS activities.

Matt Hewitt: Great. One more for me and then I'll jump back in the queue. I realize probably not an immediate issue. But from a cash perspective, does this change your needs over the next 9 to 12 months? Or are you — do you have sufficient cash in the balance sheet, whereas, you can go through the PMA process and work towards a commercialization anyways?

Greg Lea: Matt, this is Greg. We announced 27.4 million of cash when we exited the third quarter. And we still feel that we are sufficiently capitalized for now. You know as a company though, we're transitioning from a clinical focus to early stages of regulatory approval and commercialization. So you can be confident that we're going to be — we're going to continue to emphasize wise cash management going forward.

Matt Hewitt: Great. Thanks Greg. I'll jump back into the queue.

Operator: Thank you. Once again, ladies and gentlemen to ask a question, please press star one on your touchtone telephone. Our next question comes from Chris Lewis of ROTH Capital Partners. Your line is open.

Chris Lewis: Good afternoon guys. Can you hear me?

Mark Knudson: Yes, we can Chris.

Chris Lewis: Great. Thanks for taking the question. First of all, can you just talk a little bit in more detail about the intent-to-treat group versus the per protocol group? What differentiated that data? And going forward there in the PMA application process, which cohort the FDA willing to evaluate there?

Katherine Tweden: So Chris, hi. This is Katherine Tweden. The intent-to-treat group was all randomized subjects. And the per protocol group were subjects who did not have a 12-month visit or were not randomized to the …

Mark Knudson: It did have, excuse me.

Katherine Tweden: Oh, I'm sorry, did have a 12-month visit. And were not randomized to the (inaudible) group or were not — the device wasn't activated within 45 days.

Mark Knudson: It also — Chris, excuse me to interrupt. But it also did not include the six patients who were not implanted. Five of whom, were actually in the treated arm. And within in the intent-to-treat group have been treated as a zero EWL.

Sorry, KT but go ahead.

Katherine Tweden: No, no. And in addition we had a total of 16 subjects that dropped out the treated group for per protocol. And a total of 12 subjects had dropped out of the control group for the per protocol. So we still had 88 percent of subjects in the trial.

Now, both the intent-to-treat and the per protocol were part of our statistical analysis plan. They were pre-specified. So we would go forward with both sets of data to the FDA.

Chris Lewis: And they'll be willing to look at both groups?

Katherine Tweden: Yes.

Chris Lewis: OK, thanks. And then can we just move towards the control group here for a bit. EWL is 16 percent, another sham control, you know, it's hard to compare. But why do you think that was maybe as high as it was? And how (will you) position that to the FDA, and what do you expect the FDA's response to that level will be?

Mark Knudson: I think that what we demonstrated here was that if a patient is willing to undergo a surgical procedure in which the device is implanted under their skin and they receive five surgical incisions on their abdomen in general anesthesia that they become very committed to doing everything they can to lose weight regardless of whether they're getting the therapy as well. So I think that FDA will find these data to be very important because it shows what the most motivated subjects that you could possibly have could receive without having therapy.

In light of that, we were able to show a statistically significant and I would say highly statistically significant P equals 0.002 difference between those two groups. And even more importantly, when you look at that graph on the odds ratio and that will be posted to (EnteroMedics) all those slides, you can see that once you get above a 15 percent EWL, there is a substantial improvement in the — in the odds of achieving very high weight loss in — with the therapy.

So I think the FDA is going to feel as if we have run the best trial we could possibly have run, that it was very well executed and that we're going to — that is why we are confident moving ahead with the FDA because there can be no criticism of this trial that we had a control group that knew they were control group. This was a sham control group. This was not a placebo.

Chris Lewis: OK, thanks. And then just in terms of timing, you said, PMA application in Q2, can you give us a reason (for the) timetable when you can possibly expect a response — initial response from the FDA, maybe possible regarding the timing of a possible panel?

Mark Knudson: Absolutely. So we would anticipate that we will submit this — our PMA during the second quarter. As you know, we have already submitted three modules of our PMA to FDA already. So we only have the final module to complete. We are actively working on that as we speak.

We expect to submit that. And then FDA will accept it for — will, you know, after the FDA accepts it for filing, we will then have the 100-day meeting with them. At which point they schedule the panel meeting. So we would anticipate that we would have a panel probably no earlier than fourth quarter of this year.

Chris Lewis: OK, great, thanks. And then if I could just (peak) one more in, you know, now that you've seen the data, this is a bit longer term view. But just — what are your thoughts about the eventual commercial opportunity from what you've seen with the data compared to the alternatives such as drugs and the other surgeries? Thank you.

Mark Knudson: I think — and actually thank you for that question. Because I think that with the very low risk the superb safety profile we've shown, the responder analysis which shows that a very high proportion of patients are able to achieve excellent weight loss in a very safe and controllable manner with the device that has very high compliance. As we said, 93 percent of the patients stuck with this trial from beginning to end, there are no drugs that do that and we all know what happens with diet and exercise.

So there I said, 99 percent of people that fits in this huge unmet therapy gap. This gives me more confidence than I could have had before we ran a randomized control trial which showed unequivocal superiority over a sham control. And shows that this therapy does work and does work well. And clinically meaningfully that this is going to really give us a good opportunity to move forward commercially.

Chris Lewis: OK. Thanks for the time.

Operator: Thank you. Once again, to ask a question, please press star one on your touchtone telephone. Our next question comes from Bill Plavonic of Canaccord. Your line is open.

Bill Plavonic: Great. Thanks, good evening. So a lot of questions have been asked. Just the one I have is as you go to panel, outside of the endpoints, what questions do you anticipate the FDA focusing on? And if Dr. Gibbons is still on the phone, he'd probably, you know, be good if he could respond to that.

Mark Knudson: Great. Thank you. Dr. Gibbons?

Robert Gibbons: (Inaudible) I think that there will be discussion of course about the unmet primary endpoints. There'll be a careful review particularly of the excellent compliance and adherence to this, 93 percent of the patients making it through this trial, that's pretty much unheard of. And, you know, in my view in having worked on these kinds of proposals before, there's not — this device is

significantly more efficacious than the best possible sham control. And the absolute magnitude of the percent EWL is judged to be clinically significant and strongly so by leading clinicians in this area. And the safety data are just out of the park. They're extremely good. The upper confidence limit was one half of the limit that was set for it.

So I really think the focus will be on the question super-superiority. I think that the FDA has moved beyond that. There are very few examples of super-superiority being used. In fact this is the first one I've ever seen.

So it's my hope that FDA will look at these results and view them favorably. And it would be hard in my experience to imagine that a scientific Advisory Board or Panel would look negatively at these data.

Bill Plavonic: And if Mark, at this point, do you have any durability data two or three years that you'll be able to submit as a supplement to this data?

Mark Knudson: As you know, we're coming to the end of the five years of Empower so that those data will be included. And as you know, we still have a large number of patients that are still in that trial. And we have the — by the time we go to panel, we'll have the three-year data on the VBLOC DM2 enable trial in diabetics.

So yes, we will have those data and we'll probably have 15 to 18-month data — excuse me, on the patients in this trial. You know we have over 600 patients that have been implanted with this device. And there are a number of them that are still using this device. So we know that long-term we have safety and we have patient acceptance. So I think that we'll be able to answer those questions at FDA in a very compelling and meaningful way.

Bill Plavonic: OK. And then as you look at the adverse events or complication ratio, we always see every month in the bariatric times, they talk about, you know, 6 percent I believe it is for the lap band and then that goes up pretty quickly and exponentially for other types of procedures. How does that compare to the numbers that you put out there? Are those the same complications that you have versus what they have in the bold data, the 3.1 percent versus the 6 in the higher numbers? Or are there different inclusion-exclusion for what's talked about in the bold data?

Mark Knudson: You know I really don't want to get into comparisons here. The bold data really talked about serious complications. We had no serious complications. What we're talking about here are the FDA defined serious adverse events, which are things like pain at a neuroregulator site or, you know, a device that had to be moved or changed in its position, those sorts of things. Nothing that required a patient to have their abdomen opened or repair a leak or, you know, a slipping of a band or a leak from a sleeve gastrectomy, it could be anything like that.

So qualitatively these are quite different than those. But even there as you can see we are — we are still in the very strong position with regard to safety compared to the surgical therapies that are out there.

Bill Plavonic: OK. And then lastly, just as you looked at weight loss at time points, can you give us some idea kind of the progression of that throughout the year?

Katherine Tweden: Yes, Bill. This is Katherine. We did present that graph over the first 12 months. We have continuous weight loss, you know, out to approximately nine months in the first blinded portion of the trial. And we'll be continuing to look at that weight loss post 12 months.

Bill Plavonic: OK. If I remember that chart correctly, then most of the weight loss comes within the first six months and you get a little more at nine and then stable between 9 and 12 roughly?

Katherine Tweden: Yes. That's a fair assessment.

Bill Plavonic: OK. That's all I had. Thank you.

Operator: Thank you. Our next question comes from Bruce Jackson of Northland Capital. Your line is open.

Bruce Jackson: Thanks for taking my question. If we could go back to the super-superiority measure, now Dr. Gibbons said that it was really only relevant under a certain set of circumstances. And if we're not in those circumstances is there a chance that the FDA doesn't need to look at the super-superiority measure? And then why did they include that measure in the trial protocol in the first place?

Mark Knudson: Bruce, that is — that's a good question. And I will say that the reason they included it is that they, you know, have been evolving in their evaluation of how to look at obesity devices. But I think and I don't want to put words in his mouth but I think what Dr. Gibbons was saying is that they try to come up with — I guess I — I guess I would characterize it as a composite endpoint. In case we had a sham control arm that even gained weight or didn't loss significant weight.

But I only refer back to what, you know, the deputy director of our Division and our original reviewer who's one of the other authors on that paper said, that they are now at the point where they want to review the data in its entirety even if the primary endpoints are not met.

So that's why we are confident moving ahead showing them a very high benefit and low risk device that really treats patients meaningfully with high adherence and compliance.

Bruce Jackson: OK, great. And then to what extent do you think is there — is (the range) to negotiate with what gets presented to the panel between the time that you submit the PMA application in the actual panel (date)?

Mark Knudson: You know we have complete control over what we present. And FDA has control over what they present. It's, you know, it is our belief that we have an excellent plan. We have engaged I think some of the best experts on the regulatory path. In fact over the last 10 days, we've been involved in the review of all these data with several of these experts who are all in concurrence with the direction we're proceeding. And I believe that we'll be able to put together a compelling story which demonstrates very high benefit and very low risk to a panel of scientist and practitioners who are dealing with really the public health epidemic of our time.

So I — as I said, I'm confident as we move into this that we will be able to present a very good story.

Bruce Jackson: All right. Thank you very much.

Operator: Thank you. Our next question comes from Stuart Roberts of Bell Potter. Your line is open.

Stuart Roberts: Thank you. And good evening from Sydney, Australia. Now, my call relates to the intention-to-treat versus per protocol. Now, obviously the endpoints were generated by intention-to-treat. How do you compare intention-to-treat versus per protocol in terms of the difference? And then how do you end up with 211 patients versus 239? And were there any other factors that influence the per protocol outcome?

Katherine Tweden: Yes. This is Katherine Tweden. So the — as you indicated the intent-to-treat populations 239 subjects and the per protocol population is 211 subjects. And we got there by — in the treated group, it's all patients who did not have a 12-month visit, five of those patients were never implanted with the device. We had patients that withdrew and that missed the 12-month visit. And likewise in the control, we had one patient who did — was not implanted. And then the other 10 patients did not — withdrew or missed the visit. So that's how we come up with the numbers.

Stuart Roberts: OK. All right, that's all for me. Thank you.

Katherine Tweden: Thank you.

Operator: Thank you. We have a follow up question from Matt Hewitt of Craig-Hallum. Your line is open.

Matt Hewitt: There a couple of follow up questions for me. First of all, I want to circle back on — and if you don't have the information I've got to hear it but I want to get your opinion I guess. The delta between the treatment arm and the control arm for your trial was 8.5 percent. For Qsymia who had two separate trials, it was 9.3 and 8.6, for Belviq is only 3.6. With that information does that give you better confidence or more confidence that you can ultimately see your device approved?

Mark Knudson: Thanks for the question, Matt. Yes. And remember that we have a 93 percent compliance. So this is in the intent-to-treat population that includes all the patients, all the way through. And when you look at also the responder analysis where we have the — where we have all the way through very high clinically meaningful weight loss in a large percentage of the patients, I believe that we are well-positioned in that therapy gap between diet, exercise and drugs and the invasive surgeries.

Matt Hewitt: OK. I guess — and then a couple follow up — additional follow ups. What does this data mean for you from a partnership stand point? I know that's something that you've been working on in the past. Does this strengthen your ability to drive some partnerships over the relatively near-term?

Mark Knudson: You know Matt? All I can say is that these are the — are the first positive data in a randomized controlled, sham controlled obesity trial that have ever been generated in this space. So I think that we now have data that show that this therapy works, it works well and that it's very acceptable to the patients with a very, very low risk profile.

So I would — I would think that this is going to be very helpful, not just as I said earlier outside the U.S. but in the discussions that we've been having about, you know, a therapeutic partnerships in various areas.

Matt Hewitt: All right, great. And then lastly for me, I think you mentioned that you are going to have data upon PMA submission for the patients who have 15 and 18 months, will you continue to monitor all of the patients as they proceed? And how long will that monitoring occur?

Katherine Tweden: Yes, Matt, absolutely. The trial is a five-year long trial. So there's four additional years to go. And patients will continue to come in and we'll continue to collect their data.

Matt Hewitt: OK, great. Thank you.

Mark Knudson: And Matt, I just want to clarify that, you know, that I'm not committing to how many months of data we'll have by the time we go to panel because I don't know the exact date we'll be going to panel. But, you know, this — and we will only go to panel with data that have been, you know, monitored and locked. So I, you know, I think that's a range rather than a commitment to a certain number of months of data.

Matt Hewitt: I understand. And thank you for the clarity.

Mark Knudson: OK.

Operator: Thank you. Our next question comes from Leslie Bottorff of ONSET Ventures. Your line is open.

Leslie Bottorff: I just wondered, the FDA has come out and — with their guidelines that say they're going to do more of a risk reward program since you actually started this trial and that super-superiority number was defined. Has the FDA ever come out with any guidelines as you, you know, what results versus what complication rates? Or are they planning to come out with some kind of matrix? I understood they were going to do some kind of matrix approach that you don't have to meet as higher threshold if you were, you know, less complications. But is there anything been defined on that yet?

Mark Knudson: Yes. There have been two things that have come out on that. There was an Ad Com that they had. The slides on which are available publicly. And there's the paper that I referred to which also has a matrix proposal in it. All of those definitions of risk and weight loss benefit also strongly contribute to our confidence that we fit very well into what FDA is looking to try to achieve.

Leslie Bottorff: And what are the — I mean, what are the numbers that you fit into? Or what …

Mark Knudson: You know Leslie, there's a lot of data in those slides. So I would just refer anybody who's interested to look at those and compare those to the results that we talked about today.

Leslie Bottorff: OK.

Mark Knudson: But I — there's really — it would take awhile to go through that on the phone. And I don't think that I could do a justice.

Leslie Bottorff: OK. Thank you.

Mark Knudson: Sure.

Operator: Once again, ladies and gentlemen, to ask a question, please press star one on your touchtone telephone. Again, to ask a question, press star one at this time on your touchtone telephone.

(And there) appear to be no further questions. I'd like to turn the call back over to management for any closing remarks.

Mark Knudson: All right. Well, thank you very much everyone for joining us on this call. We are excited to move forward with the results from this very positive study. Even though, we didn't meet the primary efficacy endpoints, we believe that we have successfully shown that we have clinically meaningful and statistically superior performance in terms of efficacy in the — in both measures that FDA were looking for. And that we have a very, very solid safety profile.

And so, we are moving forward confidently toward the PMA process as we discussed — as we have discussed it over the last several months with you. We appreciate your support. And we look forward to moving into the FDA process for approval of VBLOC therapy and the Maestro system.

Thank you very much for your attention to our call.

Operator: Thank you, Sir. And thank you ladies and gentlemen. That does concludes your program. You may disconnect your lines at this time. Have a great day.

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