UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

Commission file number: 1-33818

ENTEROMEDICS INC.
(Exact name of registrant as specified in its charter)

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Name of Exchange on which Registered
Common stock, $0.01 par value per share	**The NASDAQ Capital Market**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☑ (Do not check if a smaller reporting company)	Smaller Reporting Company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

At June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock as reported by the NASDAQ Capital Market on that date was $37,854,901.

As of February 29, 2016, 8,111,763 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Definitive Proxy Statement, which will be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2016 Annual Meeting of Stockholders, to be held May 4, 2016 (the Proxy Statement), are incorporated by reference into Part III of this report. Except with respect to information specifically incorporated by reference in this report, the Proxy Statement is not deemed to be filed as a part hereof.

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Registered Trademarks and Trademark Applications: In the United States we have registered trademarks for VBLOC®, ENTEROMEDICS® and MAESTRO®, each registered with the United States Patent and Trademark Office, and trademark applications for VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN. In addition, some or all of the marks VBLOC, ENTEROMEDICS, MAESTRO, MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS, VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, India, Kuwait, Mexico, Saudi Arabia, Switzerland and the United Arab Emirates. This Annual Report on Form 10-K contains other trade names and trademarks and service marks of EnteroMedics and of other companies.

PART I.

ITEM 1. *BUSINESS*

This Annual Report on Form 10-K contains forward-looking statements. These forward-looking statements are based on our current expectations about our business and industry. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "could," "intends," "might," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue," or the negative of such terms and other comparable terminology. These statements involve known and unknown risks and uncertainties that may cause our results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among others, those discussed in this report in Item 1A "Risk Factors." Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Our Company

We are a medical device company with approvals to commercially launch our product, the Maestro Rechargeable System, in the United States, Australia, the European Economic Area and other countries that recognize the European CE Mark. We are focused on the design and development of devices that use neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders. Our proprietary neuroblocking technology, which we refer to as vBloc Therapy, is designed to intermittently block the vagus nerve using high frequency, low energy, electrical impulses.

The Maestro Rechargeable System, our initial product, uses vBloc Therapy to limit the expansion of the stomach, help control hunger sensations between meals, reduce the frequency and intensity of stomach contractions and produce a feeling of early and prolonged fullness. We believe the Maestro Rechargeable System offers obese patients a minimally-invasive treatment that can result in significant, durable and sustained weight loss. We believe that our Maestro Rechargeable System allows bariatric surgeons to offer a new option to obese patients who are concerned about the risks and complications associated with currently available anatomy-altering, restrictive or malabsorptive surgical procedures.

We received U.S. Food and Drug Administration (FDA) approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, for the treatment of adult patients with obesity who have a Body Mass Index (BMI) of at least 40 to 45 kg/m2, or a BMI of at least 35 to 39.9 kg/m2 with a related health condition such as high blood pressure or high cholesterol levels, and who have tried to lose weight in a supervised weight management program and failed within the past five years. We have begun a controlled commercial launch at select bariatric centers of excellence in the United States and had our first commercial sales in 2015. During 2015, we started the process of building a sales force and a controlled expansion of our operations and recently hired three new executives in January 2016 to oversee this expansion. The direct sales force is supported by field technical managers who provide training, technical and other support services to our customers. Throughout 2015 our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven bariatric centers of excellence that met our certification criteria, which led to the training and certification of over 50 centers and 75 surgeons in implanting and administering vBloc Therapy. We plan to build on these efforts in 2016 through geography and self-pay patient focused direct-to-patient marketing, key opinion leader and center specific partnering, and a multi-faceted reimbursement strategy. To date, we have relied on, and anticipate that we will continue to rely on, third-party manufacturers and suppliers for the production of our Maestro Rechargeable System.

Data from our ReCharge trial was used to support the premarket approval (PMA) application for the Maestro Rechargeable System, submitted to the FDA in June 2013. The ReCharge trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial testing the effectiveness and safety of vBloc Therapy utilizing our Maestro Rechargeable System. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or sham control groups. The sham control group received a non-functional device during the trial period. All patients were expected to participate in a standard weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. As announced, the ReCharge trial met its primary safety endpoint with a 3.7% serious adverse event rate. The safety profile at 12 months was further supported by positive cardiovascular signals including a 5.5 mmHg drop in systolic blood pressure, a 2.8 mmHg drop in diastolic blood pressure and a 3.6 bpm drop in average heart rate.

Although the trial did not meet its predefined co-primary efficacy endpoints, it did demonstrate in the intent to treat (ITT) population (n=239) a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% (approximately 10% total body weight loss (TBL)) for vBloc Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. In the per protocol population, the trial demonstrated an EWL of 26.3% for vBloc Therapy-treated patients, with 56.8% of patients achieving at least 20% EWL.

In the ReCharge trial, two-thirds of vBloc Therapy-treated patients achieved at least 5% TBL at 12 months. According to the Centers for Disease Control and Prevention (CDC), 5% TBL can have significant health benefits on obesity related risk factors, or comorbidities, including reduction in blood pressure, improvements in Type 2 diabetes and reductions in triglycerides and cholesterol. Further analysis of our data at 12 months showed a meaningful impact on these comorbidities as noted in the below table showing the improvements seen at 10% TBL, the average weight loss in vBloc Therapy-treated patients.

Risk Factor	10% TBL
Systolic BP (mmHg)	-9
Diastolic BP (mmHg)	-6
Heart Rate (bpm)	-6
Total Cholesterol (mg/dL)	-15
LDL (mg/dL)	-9
Triglycerides (mg/dL)	-41
HDL (mg/dL)	3
Waist Circumference (inches)	-7
HbA1c (%)	-0.5

We subsequently announced that vBloc Therapy-treated patients were maintaining their weight loss at 18 months and 24 months with an EWL of 23.5% and 21.1%, respectively. The trial's positive safety profile also continued throughout this reported time period.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011 for the treatment of obesity. The CE Mark approval for our Maestro Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. In January 2012, the final Maestro Rechargeable System components were listed on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA). The costs and resources required to successfully commercialize the Maestro Rechargeable System internationally are currently beyond our capability. Accordingly, we intend to devote our near-term efforts toward mounting a successful system launch in the United States. We intend to explore select international markets to commercialize the Maestro Rechargeable System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates.

To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in our human clinical trials. We have also not observed any long-term problematic clinical side effects in any patients. In addition, data from our VBLOC-DM2 ENABLE trial outside the United States demonstrate that vBloc Therapy may hold promise in improving obesity-related comorbidities such as diabetes and hypertension. We are conducting, or plan to conduct, further studies in each of these comorbidities to assess vBloc Therapy's potential in addressing multiple indications.

Our Market

The Obesity and Metabolic Disease Epidemic

Obesity is a disease that has been increasing at an alarming rate with significant medical repercussions and associated economic costs. Since 1980, the worldwide obesity rate has more than doubled, with about 13% of the world's adult population now being obese. The World Health Organization (WHO) currently estimates that as many as 600 million people worldwide are estimated to be obese and more than 1.9 billion adults are estimated to be overweight. Being overweight or obese is also the fifth leading risk for global deaths, with approximately 3.4 million adults dying each year as a result.

According to the WHO, there are over 70 progressive obesity-related diseases and disorders associated with obesity, which are also known as comorbidities, including Type 2 diabetes, hypertension, infertility and certain cancers. Worldwide, 44% of the diabetes burden, 23% of the heart disease burden and between 7% and 41% of certain cancer burdens are attributable to overweight and obesity.

We believe that this epidemic will continue to grow worldwide given dietary trends in developed nations that favor highly processed sugars, larger meals and fattier foods, as well as increasingly sedentary lifestyles. Despite the growing obesity rate, increasing public interest in the obesity epidemic and significant medical repercussions and economic costs associated with obesity, there continues to be a significant unmet need for effective treatments.

The United States Market

Obesity has been identified by the U.S. Surgeon General as the fastest growing cause of disease and death in the United States. Currently, the CDC estimates that 35.7% of U.S. adults (or approximately 73,000,000 people) are obese, having a BMI of 30 or higher. BMI is calculated by dividing a person's weight in kilograms by the square of their height in meters. It is estimated that if obesity rates stay consistent, 51% of the U.S. population will be obese by 2030. According to data from the U.S. Department of Health and Human Services, almost 80% of adults with a BMI above 30 have a co-morbidity, and almost 40% have two or more of these comorbidities. According to The Obesity Society and the CDC, obesity is associated with many significant weight-related comorbidities including Type 2 diabetes, high blood-pressure, sleep apnea, certain cancers, high cholesterol, coronary artery disease, osteoarthritis and stroke. According to the American Cancer Society, 572,000 Americans die of cancer each year, about one-third of which are linked to excess body weight, poor nutrition and/or physical inactivity. Over 75% of hypertension cases are directly linked to obesity, and approximately two-thirds of U.S. adults with Type 2 diabetes are overweight or have obesity. Currently, medical costs associated with obesity in the U.S. are estimated to be up to $210 billion per year and nearly 21% of medical costs in the U.S. can be attributed to obesity. Researchers estimate that if obesity trends continue, obesity related medical costs could rise by another $44-$66 billion each year in the U.S. by 2030. The medical costs paid by third-party payors for people who are obese were $2,741 per year, or 42% higher than those of people who are normal weight.

Current Treatment Options and Their Limitations

We believe existing options for the treatment of obesity have seen limited adoption to date due to patient concerns and potential side effects including morbidity. The principal treatment alternatives available today for obesity include:

- ***Behavioral modification.*** Behavioral modification, which includes diet and exercise, is an important component in the treatment of obesity; however, most obese patients find it difficult to achieve and maintain significant weight loss with a regimen of diet and exercise alone.
- ***Pharmaceutical therapy.*** Pharmaceutical therapies often represent a first option in the treatment of obese patients but carry significant safety risks and may present troublesome side effects and compliance issues.

- ***Bariatric surgery*.** In more severe cases of obesity, patients may pursue more aggressive surgical treatment options such as gastric balloon, gastric banding, sleeve gastrectomy and gastric bypass. These procedures promote weight loss by surgically restricting the stomach's capacity and outlet size. While largely effective, these procedures generally result in major lifestyle changes including dietary restrictions and food intolerances and they may present substantial side effects and carry short- and long-term safety and side effect risks that have limited their adoption.

Market Opportunity

Given the limitations of behavioral modification, pharmaceutical therapy and bariatric surgical approaches, we believe there is a substantial need for a patient-friendly, safer, effective and durable solution that:

- preserves normal anatomy;
- is "non-punitive" in that it supports continued ingestion and digestion of foods and micronutrients such as vitamins and minerals found in a typical, healthy diet while allowing the user to modify his or her eating behavior appropriately without inducing punitive physical restrictions that physically force a limitation of food intake;
- enables non-invasive adjustability while reducing the need for frequent clinic visits;
- minimizes undesirable side-effects;
- minimizes the risks of re-operations, malnutrition and mortality; and
- reduces the natural hunger drive of patients.

Our Technology

The vagus nerve regulates many activities in the human body, including those affecting digestion, energy metabolism, blood pressure regulation and activities of the stomach, intestine and pancreas, and provides direct two-way communication between the brain and body. By intermittently blocking, or interrupting, naturally occurring neural impulses on the vagus nerve, our therapy reduces hunger feelings between meals, limits the expansion of the stomach during eating and reduces the frequency and intensity of stomach contractions. In addition, vBloc Therapy reduces the absorption of calories by decreasing the secretion of digestive enzymes. The resulting physiologic effects of vBloc Therapy produce a feeling of early and prolonged fullness following smaller meal portions and, by intermittently blocking the vagus nerve and allowing it to return to full function between therapeutic episodes, our therapy limits the body's natural tendency to circumvent the therapy, all of which results in long-term weight loss.

We have designed our Maestro Rechargeable System to address a significant market opportunity that we believe exists for a patient-friendly, safe, effective, less-invasive and durable therapy that is intended to address the underlying causes of hunger and obesity. Our Maestro Rechargeable System offers each of the following benefits, which we believe will lead to the adoption of vBloc Therapy as the surgical therapy of choice for obesity and its comorbidities:

- preserves normal anatomy;
- allows continued ingestion and digestion of most foods;
- may be implanted on an outpatient basis and adjusted non-invasively;
- offers a favorable safety profile; and
- targets multiple factors that contribute to hunger and obesity.

The Vagus Nerve and the Digestive System

Beginning in the brain, the vagus nerve travels down alongside the esophagus to the stomach and other gastrointestinal organs and is primarily responsible for autonomic regulation involved in heart, lung and gastrointestinal function. The vagus nerve regulates many activities in the human body, affecting digestion, energy metabolism, blood pressure regulation and activities of the stomach, intestine and pancreas, providing direct two-way communication between the brain and body. Vagus nerve function has been shown to play a role in enabling multiple gastrointestinal and metabolic mechanisms, including:

- expansion of the stomach as food enters;
- stomach contractions that break food into smaller particles;
- emptying of the stomach contents into the small intestine;
- secretion of digestive pancreatic enzymes that enable absorption of calories;
- control of natural production of glucose within the body (endogenous or hepatic gluconeogenesis); and
- sensations of hunger, satisfaction and fullness.

vBloc Therapy

Several studies of the vagus nerve and its effect on the digestive system have focused on the effects of surgical vagotomy, the permanent severing of the vagus nerve at the level of the junction between the esophagus and the stomach. Given the role of the vagus nerve in regulating the release of gastric acid, early researchers originally used vagotomy as a treatment for peptic ulcers. They discovered that their patients often experienced weight loss or, at a minimum, failure to gain weight following vagotomy. However, weight loss after vagotomy alone, particularly over the long-term, likely dissipates as the body compensates for, or circumvents, the anatomical disruption by partial restoration of nervous system function.

vBloc Therapy is designed to block the gastrointestinal effects of the vagus nerve by replicating a vagotomy using high-frequency, low-energy electrical impulses to intermittently interrupt naturally occurring neural impulses on the vagus nerve between the brain and the digestive system. Our therapy controls hunger sensations between meals, limits the expansion of the stomach and reduces the frequency and intensity of stomach contractions, leading to earlier fullness. In addition, vBloc Therapy reduces the absorption of calories by decreasing the secretion of digestive enzymes. The resulting physiologic effects of vBloc Therapy produce a feeling of early and prolonged fullness following smaller meal portions. By intermittently blocking the vagus nerve and allowing it to return to full function between therapeutic episodes, our therapy limits the body’s natural tendency to circumvent the therapy, which can result in long-term weight loss.

We have designed our Maestro Rechargeable System to address a significant market opportunity that we believe exists for a patient-friendly, safe, effective, less-invasive and durable therapy that is intended to address the underlying causes of hunger and obesity. Our Maestro Rechargeable System offers each of the following benefits, which we believe could lead to the adoption of vBloc Therapy as the surgical therapy of choice for obesity and its comorbidities:

- ***Preserves Normal Anatomy.*** The Maestro Rechargeable System is designed to deliver therapy that blocks the neural signals that influence a patient’s hunger and sense of fullness without altering digestive system anatomy. Accordingly, patients should experience fewer and less severe side effects compared to treatments that incorporate anatomical alterations.
- ***Allows Continued Ingestion and Digestion of Foods Found in a Typical, Healthy Diet.*** Because our therapy leaves the digestive anatomy unaltered, patients are able to maintain a more consistent nutritional balance compared to existing surgical approaches, thus allowing them to effect positive changes in their eating behavior in a non-forced and potentially more consistent way.

- ***May be Implanted on an Outpatient Basis and Adjusted Non-Invasively.*** The Maestro Rechargeable System is designed to be laparoscopically implanted within a 60-90 minute procedure, allowing patients to leave the hospital or clinic on the same day. The implantable system is designed to be turned off and left in place for patients who reach their target weight. When desired, the follow-up physician can simply and non-invasively turn the therapy back on. Alternatively, the implantable system can be removed in a laparoscopic procedure.
- ***Offers Favorable Safety Profile.*** We have designed our ReCharge and EMPOWER clinical trials to demonstrate the safety of the Maestro Rechargeable System. In our clinical trials to date, including the ReCharge and EMPOWER trials, we have not observed any mortality related to our device or any unanticipated adverse device effects. We have also not observed any long-term problematic clinical side effects in any patients, including in those patients who have been using the Maestro System for more than one year.
- ***Targets Multiple Factors that Contribute to Hunger and Obesity.*** We designed vBloc Therapy to target the digestive, metabolic and information transmission functions of the vagus nerve and to affect the perception of hunger and fullness, which together contribute to obesity and its metabolic consequences.

vBloc Therapy, delivered via our Maestro Rechargeable System, is intended to offer patients an effective, safe, outpatient solution that minimizes complications. It enables patients to lose weight and maintain long-term weight loss while enjoying a normal, healthy diet. We also believe that the Maestro Rechargeable System will appeal to physicians based on the inherent physiological approach of vBloc Therapy and its favorable safety profile.

The Maestro Rechargeable System, Implantation Procedure and Usage

The Maestro Rechargeable System. Our Maestro Rechargeable System delivers vBloc Therapy via two small electrodes that are laparoscopically implanted and placed in contact with the trunks of the vagus nerve just above the junction between the esophagus and the stomach, near the diaphragm. The Maestro Rechargeable System (shown below) is powered by an internal rechargeable battery.

The major components of the Maestro Rechargeable System include:

- ***Neuroregulator.*** The neuroregulator, a pacemaker-like device, is an implanted device that controls the delivery of vBloc Therapy to the vagus nerve. It is surgically implanted just below, and parallel to, the skin, typically on the side of the body over the ribs.

- ***Lead System.*** Proprietary leads are powered by the neuroregulator and deliver electrical pulses to the vagus nerve via the electrodes. The leads and electrodes are similar to those used in traditional cardiac rhythm management products.
- ***Mobile Charger.*** The mobile charger is an electronic device worn by the patient externally while recharging the device. It connects to the transmit coil and provides information on the battery status of the neuroregulator and the mobile charger.
- ***Transmit Coil.*** The transmit coil is positioned for short periods of time over the implanted neuroregulator to deliver radiofrequency battery charging and therapy programming information across the skin into the device.
- ***Clinician Programmer.*** The clinician programmer connects to the mobile charger to enable clinicians to customize therapy settings as necessary and retrieve reports stored in system components. The reports include patient use and system performance information used to manage therapy. The clinician programmer incorporates our proprietary software and is operated with a commercially available laptop computer.

Implantation Procedure. The Maestro Rechargeable System is implanted by a bariatric surgeon using a procedure that is typically performed within 60-90 minutes. During the procedure, the surgeon laparoscopically implants the electrodes in contact with the vagal nerve trunks and then connects the lead wires to the neuroregulator, which is subcutaneously implanted. The implantation procedure and usage of the Maestro Rechargeable System carry some risks, such as the risks generally associated with laparoscopic procedures as well as the possibility of device malfunction. Adverse events related to the therapy, device or procedure may include, but are not limited to: transient pain at the implant site, heartburn, constipation, nausea, depression, diarrhea, infection, organ or nerve damage, surgical explant or revision, device movement, device malfunction and allergic reaction to the implant.

Usage of the Maestro Rechargeable System. The physician activates the Maestro Rechargeable System after implantation. vBloc Therapy is then delivered intermittently each day as scheduled (recommended during the patient's waking hours) through the neuroregulator. The scheduled delivery of the intermittent pulses blocking the vagus nerve is customized for each patient's weight loss and overall treatment objectives.

The physician is able to download reports to monitor patient use and system performance information. This information is particularly useful to physicians to ensure that patients are properly using the system. Although usage of our Maestro Rechargeable System generally proceeds without complications, as part of the therapy or intentional weight loss, patients in our clinical trials have observed side-effects such as transient pain at the implant site, heartburn, bloating, dysphagia, eructation, cramps, diarrhea, nausea, constipation, and excessive feelings of fullness, especially after meals. In addition, patient noncompliance with properly charging the Maestro Rechargeable System may render vBloc Therapy less effective in achieving long-term weight loss.

Our Clinical Experience

We have conducted a series of clinical trials to date, which have shown that vBloc Therapy offers physicians a programmable method to selectively and reversibly block the vagus nerve resulting in clinically and statistically significant EWL.

We have not observed any mortality related to our device or any unanticipated adverse device effects in any of our completed or ongoing studies. Reported events include those associated with laparoscopic surgery or any implantable electronic device. The effects of vBloc Therapy include changes in appetite, and, in some patients, effects that may be expected with decreased intra-abdominal vagus nerve activity, such as temporary abdominal discomfort and short episodes of belching, bloating, cramping or nausea.

Findings from our clinical trials have resulted in publication in numerous peer-reviewed journals including The Journal of the American Medical Association, Journal of Obesity, Obesity Surgery, Surgery for Obesity and Related Diseases, Surgery and Journal of Neural Engineering, and data have been presented at several scientific sessions including the American Society for Metabolic and Bariatric Surgery, International Federation for Surgery of Obesity and Metabolic Disorders, the Obesity Surgery Society of Australia & New Zealand and The Obesity Society.

Below is a more detailed description of our ongoing clinical studies.

ReCharge Trial

In October 2010, we received an unconditional Investigational Device Exemption (IDE) Supplement approval from the FDA to conduct a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial, called the ReCharge trial, testing the effectiveness and safety of vBloc Therapy utilizing our second generation Maestro Rechargeable System. Enrollment and implantation in the ReCharge trial was completed in December 2011 in 239 randomized patients (233 implanted) at 10 centers. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or control groups. The control group received a non-functional device during the trial period. All patients were expected to participate in a standard weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. The ReCharge trial met its primary safety endpoint with a 3.7% serious adverse event rate, significantly lower than the threshold of 15% ($p<0.0001$). The safety profile at 12 months was further supported by positive cardiovascular signals including a 5.5 mmHg drop in systolic blood pressure, a 2.8 mmHg drop in diastolic blood pressure and a 3.6 bpm drop in average heart rate.

Although the trial did not meet its predefined co-primary efficacy endpoints, it did demonstrate in the ITT population (n=239) a clinically meaningful and statistically significant EWL of 24.4% (approximately 10% TBL) for vBloc Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. In the per protocol population, the trial demonstrated an EWL of 26.3% for vBloc Therapy-treated patients, with 56.8% of patients achieving at least 20% EWL. As a result of the positive safety and efficacy profile of vBloc Therapy, we used the data from the ReCharge trial to support a PMA application for the Maestro Rechargeable System, which was submitted to the FDA in June 2013 and was accepted for review and filing in July 2013. An Advisory Panel meeting was held on June 17, 2014 to review our PMA application for approval of the Maestro Rechargeable System. The Advisory Panel voted 8 to 1 “in favor” that the Maestro Rechargeable System is safe when used as designed and voted 4 to 5 “against” on the issue of a reasonable assurance of efficacy. The final vote, on whether the relative benefits outweighed the relative risk, was 6 to 2 “in favor,” with 1 abstention. We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, for the treatment of adult patients with obesity who have a BMI of at least 40 to 45 kg/m2, or a BMI of at least 35 to 39.9 kg/m2 with a related health condition such as high blood pressure or high cholesterol levels, and who have tried to lose weight in a supervised weight management program and failed within the past five years.

Further analysis of the 12 month data show that in the primary analysis (ITT) population (n=239), vBloc Therapy-treated patients achieved a 24.4% average EWL (approximately 10% TBL) compared to 15.9% for sham control patients. This 8.5% difference demonstrated statistical superiority over sham control ($p=0.002$), but not super-superiority at the pre-specified 10% margin ($p=0.705$). In total, 52.5% of vBloc Therapy-treated patients had 20% or more EWL compared to 32.5% in the control group ($p=0.004$), and 38.3% of vBloc Therapy-treated patients had 25% or more EWL compared to 23.4% in the sham control group ($p=0.02$). While the respective co-primary endpoint targets of 55% and 45% were not met, the endpoint targets were within the 95% confidence intervals for the observed rates and therefore the observed rates were not significantly lower than these pre-specified rates. These efficacy data demonstrate vBloc Therapy’s positive effect on weight loss.

In the per protocol group, which included only those patients who received therapy per the trial design (n=211), the vBloc Therapy-treated patients had a 26.3% average EWL (approximately 10% TBL) compared to

17.3% for the sham control group (p=0.003). In total, 56.8% of vBloc Therapy-treated patients achieved at least 20% EWL, which was above the predefined threshold of 55% compared to 35.4% in the sham control group (p=0.004). 41.8% of vBloc Therapy-treated patients also achieved at least 25% EWL in this population, which is slightly less than the predefined threshold of 45%, compared to 26.2% in the sham control group (p=0.03).

Additionally, two-thirds of vBloc Therapy-treated patients achieved at least 5% TBL at 12 months. According to the CDC, 5% TBL can have significant health benefits on obesity related risk factors, or comorbidities, including reduction in blood pressure, improvements in Type 2 diabetes and reductions in triglycerides and cholesterol. Further analysis of our data at 12 months showed a meaningful impact on these comorbidities as noted in the below table showing the improvements seen at 10% TBL, the average weight loss in vBloc Therapy-treated patients.

Risk Factor	10% TBL
Systolic BP (mmHg)	-9
Diastolic BP (mmHg)	-6
Heart Rate (bpm)	-6
Total Cholesterol (mg/dL)	-15
LDL (mg/dL)	-9
Triglycerides (mg/dL)	-41
HDL (mg/dL)	3
Waist Circumference (inches)	-7
HbA1c (%)	-0.5

Approximately 93% of patients reached the 12 month assessment in the trial, consistent with a rigorously executed trial. vBloc Therapy-treated patients maintained their weight loss at 18 months and 24 months with an EWL of 23.5% and 21.1%, respectively. The trial's positive safety profile also continued throughout this reported time period.

VBLOC-DM2 ENABLE Trial

Enrollment of the VBLOC-DM2 ENABLE trial began in 2008. The VBLOC-DM2 ENABLE trial is designed to evaluate the efficacy and safety of vBloc Therapy on obese subjects as well as its effect on glucose regulation in approximately 30 patients who are using the Maestro Rechargeable System. The trial is an international, open-label, prospective, multi-center study. At each designated trial endpoint the efficacy of vBloc Therapy is evaluated by measuring average percentage EWL, HbA1c (blood sugar), FPG (fasting plasma glucose), blood pressure, calorie intake, appetite and other endpoints at one week, one month, three, six, 12 and 18 months and longer. The following results were reported at 12 month intervals.

- Percent EWL (from implant, Company updated interim data):

Visit (post-device activation)	% EWL	N
12 Months	-24.5	26
24 Months	-22.7	22
36 Months	-24.3	18

- HbA1c change in percentage points (Baseline HbA1c = 7.8 ± 0.2%) (Company updated interim data):

Visit (post-device activation)	% HbA1c change	N
12 Months	-1.0	26
24 Months	-0.5	24
36 Months	-0.6	17

- Fasting Plasma Glucose change (Baseline 151.4 + 6.5 mg/dl average) (Company updated interim data):

Visit (post-device activation)	Glucose change (mg/dl)	N
12 Months	-27.6	25
24 Months	-20.3	24
36 Months	-24.0	17

- Change in mean arterial pressure (MAP) in hypertensive patients (baseline 99.5 mmHg) (Company updated interim data):

Visit (post-device activation)	MAP change (mmHg)	N
12 Months	-7.8	14
24 Months	-7.5	12
36 Months	-7.3	10

To date, no deaths related to our device or unanticipated adverse device effects have been reported during the VBLOC-DM2 ENABLE trial and the safety profile is similar to that seen in the other vBloc trials.

Caloric Intake Sub-study: A sub-study, conducted as part of the VBLOC-DM2 ENABLE trial, evaluated 12-month satiety and calorie intake in 10 patients with Type 2 diabetes mellitus enrolled in the trial. Follow-up measures among patients enrolled in the sub-study included EWL, 7-day diet records assessed by a nutritionist, calorie calculations and visual analogue scale (VAS) questions to assess satiety by 7-day or 24-hour recall at the following time periods: baseline, 4 and 12 weeks and 6 and 12 months post device initiation. A validated program, Food Works™, was used to determine calorie and nutrition content. Results include:

- Mean EWL for the sub-study was 33±5% (p<0.001) at 12 months;
- Calorie intake decreased by 45% (p<0.001), 48% (p<0.001), 38% (p<0.001) and 30% (p=0.02), at 4 and 12 weeks, 6 months and 12 months, respectively, from a baseline of 2,062 kcal/day; and
- VAS recall data, using a repeated measures analysis, documented fullness at the beginning of meals (p=0.005), less food consumption (p=0.02) and less hunger at the beginning of meal (p=0.03) corroborating the reduction in caloric intake.

EMPOWER Trial

The EMPOWER trial is a randomized, double-blind, controlled pivotal study that began in 2006 and was designed to evaluate the safety and efficacy of our first-generation Maestro RF System in the treatment of obesity in 294 patients. The purpose of the EMPOWER trial is to measure the safety and efficacy of our Maestro RF System in obese patients after 12 months of vBloc Therapy. After all patients completed 12 months of follow up, the trial was unblinded and all patients, including those in the control group, had the option to receive ongoing vBloc Therapy. Patients will continue to be followed out to 60 months as part of the trial and we will continue to monitor average percentage EWL and safety during this extended period. At 12 months from implant, patients in the treated group who used the system for greater than or equal to 12 hours a day saw an average EWL of nearly 30%. The trial produced the following safety results:

- No deaths, a one-year surgical revision rate of 4.8% and serious adverse event rate related to the device or implant/revision procedure of 3%;
- No therapy-related serious adverse events in the entire study population through 12 months; and
- No changes in intra-cardiac conduction, ventricular repolarization or ventricular arrhythmias were seen in either study group.

At the 36 month endpoint, EMPOWER EWL was approximately 20% in 45 subjects receiving at least 9 hours of therapy per day. In addition, a subgroup analysis of EMPOWER trial patients was conducted to determine if vBloc Therapy would improve blood pressure prior to significant weight loss in obese subjects with hypertension, as defined by elevated blood pressure at baseline by JNC-7 guidelines (n=37, Group A) or history of hypertension (n=58, Group B) at baseline. The analysis was performed in a subset of subjects receiving at least 9 hours of therapy per day to 12 months.

- Change in systolic blood pressure (SBP) and diastolic blood pressure (DBP) from baseline:

	Baseline	Week 2	Week 4	12 Months
Group A (subjects with elevated blood pressure) (p<0.001)				
SBP (mmHg)	145+/-2	-17+/-3	-17+/-3	-18+/-3
DBP (mmHg)	89+/-2	-9+/-2	-8+/-2	-10+/-2
% EWL	N/A	9+/-2	12+/-1	21+/-4
Group B (subjects with history of hypertension) (p<0.001)				
SBP (mmHg)	134+/-2	-10+/-2	-9+/-2	-13+/-2
DBP (mmHg)	84+/-1	-6+/-1	-6+/-1	-7+/-1
% EWL	NA	9+/-1	13+/-1	23+/-3

Our Commercialization Strategy

Our goal is to establish vBloc Therapy, delivered via our Maestro Rechargeable System, as the leading obesity management solution. The key business strategies by which we intend to achieve these objectives include:

Commercialize Our Products Using a Geography Focused Direct-to-Patient Marketing Effort Within the United States. We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System. We have begun a controlled commercial launch at select bariatric centers of excellence in the United States and had our first commercial sales in 2015. During 2015, we started the process of building a sales force and a controlled expansion of our operations and recently hired three new executives in January 2016 to oversee this expansion. The direct sales force is supported by field technical managers who provide training, technical and other support services to our customers. Throughout 2015 our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven bariatric centers of excellence that met our certification criteria, which led to the training and certification of over 50 centers and 75 surgeons in implanting and administering vBloc Therapy. We plan to build on these efforts in 2016 through geography and self-pay patient focused direct-to-patient marketing and key opinion leader and center specific partnering. We plan to grow the sales and marketing organization as necessary to support future growth.

Our direct sales force is initially targeting outcome-focused, aftercare-based centers in key self-pay markets and will promote the Maestro Rechargeable System to physicians and patients who have concerns with current bariatric surgical procedures. We are calling on physicians, weight-management specialists, nurses and others involved in the obesity management process who influence patient adoption.

Account management and patient registration processes used during the clinical trial are being transitioned to a commercial registration structure. Centers responsible for implanting our product will be expanded and trained to perform patient selection, implant the Maestro Rechargeable System and manage appropriate follow-up procedures.

Our sales representatives are supported by field clinical experts who are responsible for training, technical support, and other support services at various implant centers. Our sales representatives implement consumer marketing programs and provide surgical centers and implanting surgeons with educational patient materials. We also market to potential referral source clinicians such as general practitioners, internists, endocrinologists and nurses in order to build awareness.

We market directly to patients but sell our product to select surgical centers throughout the United States that have patients that would like to use the Maestro Rechargeable System to treat obesity and its comorbidities. The surgical centers then sell our product to the patients and implant and administer vBloc Therapy. In 2015, the patients that purchased the Maestro Rechargeable System paid for the therapy themselves and did not receive reimbursement from an insurance provider, and we expect that most of our sales will come from self-pay patients in 2016. We are working to obtain coverage for our product from the U.S. Centers for Medicare and Medicaid Services (CMS), major insurance carriers, local coverage entities and self-insured plans, including Integrated Delivery Networks (IDNs). We received coverage from one significant IDN in the northeast in 2016 and are in active discussions with other IDNs throughout the country.

Our commercial success depends on our ability to develop an effective sales organization and obtain insurance coverage for our product. Developing a direct sales force can be expensive and time consuming, and can delay the success of any product launch. Our direct sales force will likely be competing against the experienced and well-funded sales and marketing operations of our competitors.

Identify Appropriate Coding, Obtain Coverage and Payment for the Maestro Rechargeable System. While payors are not our direct customers, their coverage and reimbursement policies influence patient and physician selection of obesity treatment. We are employing a focused campaign to obtain payor support for vBloc Therapy. We plan to seek specific and appropriate coding, coverage and payment for our Maestro Rechargeable System from CMS and from private insurers. We plan to establish a market price for the Maestro Rechargeable System in the United States that is comparable to other high-end, active implantable devices such as implantable cardioverter defibrillators, neurostimulation devices for chronic pain and depression, and cochlear implant systems.

We believe that establishing appropriate third-party coverage for the therapy should be achievable as important structural elements are already in place. Physician claims for payment use Current Procedural Terminology, Fourth Edition (CPT) billing codes to describe procedures and services performed. Category I billing codes represent procedures that are consistent with contemporary medical practice and are widely performed. Currently, there are established CPT Category I codes for the implantation of cranial nerve pulse generators and related leads, and we expect providers may seek payment for our therapy based on these codes. In 2012, we applied for and received six unique CPT Category III codes with the American Medical Association's CPT Advisory Committee for a Vagus Nerve Blocking Therapy procedure. Category III codes represent temporary codes for new and emerging technologies that allow for data collection and utilization tracking for new procedures or services. We intend to use the approved CPT Category III codes to build evidence to support individual prior authorization requests for coverage and denial appeals to gain coverage and payment for vBloc Therapy treatment through various private insurance plans. We intend to continue to use the CPT Category III codes as we consider the timing and strategic benefit to the Company and surgeons and patients of possible conversion to CPT Category I codes in the future.

We expect that most procedures will be performed in the outpatient setting, but with respect to possible usage of our product in the hospital inpatient setting, hospital inpatient billing is referenced by International Classifications of Diseases, 10^{th} Revision, Clinical Modification (ICD-10-CM) procedure codes. There is an existing ICD-10-CM diagnosis code for morbid obesity and our studies are intended to provide the necessary outcomes data to link appropriate billing codes with the ICD-10-CM diagnosis code for morbid obesity. Under a recent Act of Congress, health plans and providers began using the ICD-10-CM system for billing hospital inpatient procedures on October 1, 2015. Our clinical trial data substantiating vBloc Therapy will also be used to seek coverage of vBloc Therapy for patients with morbid obesity and appropriate reimbursement for surgeons and hospitals under the codes already in place.

CMS issued a national coverage determination for several specific types of bariatric surgery in 2006, which we view as positive potential precedent and guidance factors that CMS might use in deciding to cover our therapy. That policy indicated that Medicare will cover these bariatric surgical procedures when they are performed in an approved Bariatric Center of Excellence by a bariatric surgeon who also meets established requirements. Subjects with a BMI greater than or equal to 35, at least one obesity-related disease or disorder and who were previously unsuccessful with medical treatment for obesity are considered eligible. However, the policy reiterates that treatments for obesity alone are not covered, because such treatments are not considered reasonable and necessary. Although Medicare policies are often emulated or adopted by other third-party payors, other governmental and private insurance coverage currently varies by carrier and geographic location. We have begun to actively work with major insurance carriers, local coverage entities and self-insured plans, as well as CMS, beginning the process to obtain coverage for procedures using our product. Initial coverage for vBloc will likely occur in self-contained healthcare systems that operate as IDNs, as these systems are able to evaluate risk-benefit ratios in a closed environment. For example, we recently announced coverage for its employees from the Winthrop Hospital System in New York, a significant IDN in the northeast. Other similar arrangements are in active discussion.

Other manufacturers of neuromodulation devices for a variety of indications have been successful in securing third-party coverage and reimbursement for use of their devices after early commercialization. We will actively pursue all similar opportunities to secure appropriate payment for our device.

Drive the Adoption and Endorsement of vBloc Therapy Through Obesity Therapy Experts and Patient Ambassadors. Our Clinical Development strategy is to collaborate closely with regulatory bodies, obesity therapy experts and others involved in the obesity management process, patients and their advocates and scientific experts. We have established credible and open relationships with obesity therapy experts and have identified vBloc Therapy patient ambassadors and we believe these individuals will be important in promoting patient awareness and gaining widespread adoption of the Maestro Rechargeable System.

Expand and Protect Our Intellectual Property Position. We believe that our issued patents and our patent applications encompass a broad platform of neuromodulation therapies, including vagal blocking and combination therapy focused on obesity, diabetes, hypertension and other gastrointestinal disorders. We intend to continue to pursue further intellectual property protection through U.S. and foreign patent applications.

Leverage our vBloc Technology for Other Disease States. We intend to continue to conduct research and development for other potential applications for our vBloc Therapy and believe we have a broad technology platform that will support the development of additional clinical applications and therapies for other metabolic and gastrointestinal disorders in addition to obesity.

Concentrate Our Resources on the U.S. Market. We obtained European CE Mark approval for our Maestro Rechargeable System in 2011 for the treatment of obesity. The CE Mark approval for our Maestro Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. In January 2012, the final Maestro Rechargeable System components were listed on the ARTG by the Australian TGA. The costs and resources required to successfully commercialize the Maestro Rechargeable System internationally are currently beyond our capability. Accordingly, we intend to devote our near-term efforts toward mounting a successful system launch in the United States. We intend to explore select international markets to commercialize the Maestro Rechargeable System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates.

Our Research and Development

Current R&D Focus

We have an experienced research and development team, including clinical, regulatory affairs and quality assurance, comprised of scientists, electrical engineers, software engineers and mechanical engineers with significant clinical knowledge and expertise. Our research and development efforts are focused in the following major areas:

- supporting the current Maestro Rechargeable System;

- developing the next-generation Maestro Rechargeable System;
- identifying the effect of vagal blocking on nerve and organ function; and
- investigating the Maestro platform for the treatment of gastrointestinal disorders and comorbidities in addition to obesity.

We have spent a significant portion of our capital resources on research and development. Our research and development expenses were $8.1 million in 2015, $11.0 million in 2014 and $11.1 million in 2013. Our annual research and development expenditures remained consistent in 2013 and 2014 as we worked through the unblinding of the ReCharge trial, PMA submission, Advisory Panel meeting and FDA approval process. Having obtained FDA approval in January 2015, our main focus has been on commercialization efforts, resulting in decreased spending on research and development in 2015.

Other Diseases and Disorders

We believe that our vBloc Therapy may have the potential, if validated through appropriate clinical studies, to treat a number of additional gastrointestinal disorders or comorbidities frequently associated with obesity, including the following:

- ***Type 2 Diabetes.*** Type 2 diabetes is an escalating global health epidemic often related to obesity that affects nearly 200 million people worldwide, 50 million in the United States alone. Those with diabetes are susceptible to cardiovascular morbidity and mortality, and up to two out of three people with diabetes have high blood pressure. We believe that vBloc Therapy has significant potential in treating metabolic syndrome (diabetes with high blood pressure). We have launched an international feasibility trial, VBLOC-DM2 ENABLE, to further explore the efficacy of vBloc Therapy in this patient population and have reported preliminary findings in the “Our Clinical Experience” section above.
- ***Hypertension.*** Blood pressure normally rises and falls throughout the day. When it consistently stays too high for too long, it is called hypertension. Globally, nearly one billion people have high blood pressure (hypertension); of these, two-thirds are in developing countries. About one in three American adults has high blood pressure or hypertension. Hypertension is one of the most important causes of premature death worldwide and the problem is growing; in 2025, an estimated 1.56 billion adults will be living with hypertension. Hypertension kills nearly 8 million people every year worldwide. We believe that vBloc Therapy may improve mean systolic and diastolic blood pressure in hypertensive patients. We completed a subgroup analysis of EMPOWER trial patients and have included an evaluation of the blood pressure effects of vBloc Therapy in our international feasibility trial, VBLOC-DM2 ENABLE, to further explore the efficacy of vBloc Therapy in this patient population and have reported preliminary findings in the “Our Clinical Experience” section above.
- ***Pancreatitis.*** Primary and recurrent cases of acute pancreatitis are estimated to number from 150,000 to 200,000 annually, resulting in approximately 80,000 hospital admissions each year in the United States. In animal studies, we have shown that vBloc Therapy suppresses pancreatic exocrine secretion, suggesting its potential efficacy in treating pancreatitis.
- ***Other Gastrointestinal Disorders.*** We believe that vBloc Therapy may have potential in a number of other gastrointestinal disorders, including irritable bowel syndrome and inflammatory bowel disease.

None of the above conditions were included in our PMA application that was approved by the FDA on January 14, 2015, nor are they approved for sale internationally. Additional approvals will be required to market the Maestro Rechargeable System for these indications in the United States or internationally.

Mayo Clinic Relationship

Our research and development team has worked with clinicians from Mayo Clinic, Rochester, Minnesota pursuant to exclusive know-how, license and consulting agreements from 2005 through 2014. Mayo Clinic clinicians with multiple specialties such as bariatric surgery, gastroenterology and laparoscopic surgery consulted with our research and development team on an exclusive basis. Specifically, Mayo Clinic clinicians, along with other of our consultants, have offered their expertise to advise us with regard to our clinical trials and surgical techniques for our implantation procedure and participate on our medical advisory board and therapeutic algorithm panel. The agreements with Mayo Clinic also included a similar collaboration for the development of products to address a wide variety of disorders susceptible to treatment by electrically blocking neural impulses on the vagus nerve. We retain the exclusive rights to obesity-related device inventions developed through this collaboration. We have also licensed-in three issued obesity-related patents from Mayo Clinic, which are unrelated to our vBloc technology.

Medical Advisors

In addition to our collaboration with Mayo Clinic, we also have medical advisors who provide strategic guidance to our development programs, consult with us on clinical investigational plans and individual study protocols, and advise on clinical investigational site selection. Members of our medical advisory group also:

- serve on our Data Safety Monitoring Board and Clinical Events Committee;
- provide consultation on professional meeting presentations and journal manuscript submissions; and
- develop and participate in clinical site training programs, including study surgical technique training and study subject follow-up training.

Our Competition

The market for obesity treatments is competitive, subject to technological change and significantly affected by new product development. Our primary competition in the obesity treatment market is currently from surgical obesity procedures and from various devices used to implement neurostimulation and gastric stimulation systems. We believe we are the first company pursuing neuroblocking therapy for the treatment of obesity. There are currently no other FDA-approved neuromodulation or neuroblocking therapies for the treatment of obesity, but in the future we expect other new stimulation systems and neurotechnology devices to come on the market.

We expect our Maestro Rechargeable System will compete with surgical obesity procedures, including gastric bypass, gastric balloon, gastric banding, sleeve gastrectomy, vertical-banded gastroplasty and biliopancreatic diversion. These current surgical procedures are performed in less than 1% of all eligible obese patients today. Current manufacturers of approved gastric balloon and banding products include Apollo Endosurgery Inc. (Lap-Band and ORBERA Intragastric Balloon System), ReShape Medical, Inc. (ReShape Integrated Dual Balloon System) and Johnson & Johnson (Realize Adjustable Gastric Band). We are also aware that GI Dynamics, Inc. has received approvals in various international countries to sell its EndoBarrier Gastrointestinal Liner. We also compete against the manufacturers of pharmaceuticals that are directed at treating obesity. We are aware of a number of drugs that are approved for long-term treatment of obesity in the United States: Orlistat, marketed by Roche as Xenical and GlaxoSmithKline as Alli, Belviq marketed by Arena Pharmaceuticals, Inc., Qsymia, marketed by VIVUS, Inc. and Contrave, marketed by Orexigen Therapeutics, Inc.

In addition to competition from surgical obesity procedures, we compete with several private early-stage companies developing neurostimulation devices for application to the gastric region and related nerves for the treatment of obesity. These companies may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. They also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

In addition, there are many larger potential competitors experimenting in the field of neurostimulation to treat various diseases and disorders. For example, Medtronic, Inc., which develops deep brain stimulators and spinal cord stimulators, acquired TransNeuronix, which sought to treat obesity by stimulating the smooth muscle of the stomach wall and nearby tissue. St. Jude Medical, Inc., through its acquisition of Advanced Neuromodulation Systems, is developing spinal cord stimulators. LivaNova PLC is developing vagus nerve stimulators to modulate epileptic seizures and other neurological disorders. Boston Scientific Corporation, through its Advanced Bionics division, is developing neurostimulation devices such as spinal cord stimulators and cochlear implants. Ethicon-Endo Surgery acquired LivaNova PLC's patents and patent applications pertaining to vagus nerve stimulation for the treatment of obesity and two related comorbidities, diabetes and hypertension, in overweight patients.

We believe that the principal competitive factors in our market include:

- acceptance by healthcare professionals, patients and payors;
- published rates of safety and efficacy;
- reliability and high quality performance;
- effectiveness at controlling comorbidities such as diabetes and hypertension;
- invasiveness and the inherent reversibility of the procedure or device;
- cost and average selling price of products and relative rates of reimbursement;
- effective marketing, education, sales and distribution;
- regulatory and reimbursement expertise;
- technological leadership and superiority; and
- speed of product innovation and time to market.

Many of our competitors are either publicly-traded or are divisions of publicly-traded companies, and they enjoy several competitive advantages over us, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- greater experience in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals, obtaining reimbursement and marketing approved products; and
- greater financial and human resources.

As a result, we cannot assure you that we will be able to compete effectively against these companies or their products.

Our Intellectual Property

Our success will depend in part on our ability to obtain and defend patent protection for our products and processes, to preserve our trade secrets and to operate without infringing or violating the proprietary rights of third parties. We own numerous U.S. and foreign patents, and have numerous patent applications pending, most of which pertain to treating gastrointestinal disorders and we believe provide us with broad intellectual property protection covering electrically-induced vagal blocking and methods for treating obesity. Assuming timely payment of maintenance fees as they become due, many of these patents will expire in 2023. We have also received or applied for patents in Europe, Australia, China, India and Japan. These applications primarily pertain to our vagal blocking technology and its application to obesity as well as other gastrointestinal disorders. In addition to our patents and applications, we have a license agreement with the Mayo Foundation for Medical Education and Research for three issued U.S. patents, which are unrelated to our vBloc Therapy.

We also register the trademarks and trade names through which we conduct our business. To date, in the United States we have registered trademarks for VBLOC®, ENTEROMEDICS® and MAESTRO®, each registered with the United States Patent and Trademark Office, and trademark applications for VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN. In addition, some or all of the marks VBLOC, ENTEROMEDICS, MAESTRO, MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS, VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, India, Kuwait, Mexico, Saudi Arabia, Switzerland and the United Arab Emirates.

In addition to our patents, we rely on confidentiality and proprietary information agreements to protect our trade secrets and proprietary knowledge. These confidentiality and proprietary information agreements generally provide that all confidential information developed or made known to individuals by us during the course of their relationship with us is to be kept confidential and not disclosed to third parties, except in specific circumstances. The agreements also provide for ownership of inventions conceived during the course of such agreements. If our proprietary information is shared or our confidentiality agreements are breached, we may not have adequate remedies, or our trade secrets may otherwise become known to or independently developed by competitors.

Our Manufacturers and Suppliers

We have designed and developed all of the elements of our Maestro Rechargeable System, except for the clinician programmer hardware, which uses a commercially available laptop computer. To date, all of the materials and components of the system are procured from qualified suppliers and contract manufacturers in accordance with our proprietary specifications. We use third parties to manufacture our Maestro Rechargeable System to minimize our capital investment, help control costs and take advantage of the expertise these third parties have in the large-scale production of medical devices. We do not currently plan to manufacture our Maestro Rechargeable System ourselves. All of our key manufacturers and suppliers have experience working with commercial implantable device systems, are ISO certified and are regularly audited by us. Our key manufacturers and suppliers have a demonstrated record of compliance with international regulatory requirements.

We received FDA approval on January 14, 2015, and commenced commercialization of the Maestro Rechargeable System in the United States shortly thereafter. We expect to increase our production volume slowly as we bring the Maestro Rechargeable System to the United States through a controlled commercial launch. Given that we rely primarily on third-party manufacturers and suppliers for the production of our products, our ability to increase production will depend upon the experience, certification levels and large scale production capabilities of our suppliers and manufacturers. Qualified suppliers and contract manufacturers have been and will continue to be selected to supply products on a commercial scale according to our proprietary specifications. We also intend to increase our inventory levels to support commercial forecasts as we expand our implanting centers. Our FDA approval process required us to name and obtain approval for the suppliers of key components of our Maestro Rechargeable System.

Many of our parts are custom designed and as a result, we may not be able to quickly qualify and establish additional or replacement suppliers for the components of our Maestro Rechargeable System. Any new approvals of vendors required by the FDA or other regulatory agencies in other international markets for our Maestro Rechargeable System as a result of the need to qualify or obtain alternate vendors for any of our components would delay our ability to sell and market the Maestro Rechargeable System and could have a material adverse effect on our business.

We believe that our current manufacturing and supply arrangements will be adequate to continue our controlled commercial launch and our ongoing and planned clinical trials. In order to produce the Maestro Rechargeable System in the quantities we anticipate to meet future market demand, we will need our manufacturers and suppliers to increase, or scale up, manufacturing production and supply arrangements by a significant factor over the current level of production. There are technical challenges to scaling up manufacturing capacity and developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and suppliers and hiring and retaining additional management and technical personnel who have the necessary experience. If our manufacturers or suppliers are unable to do so, we may not be able to meet the requirements for the launch of the product in the United States or internationally or to meet future demand, if at all. We may also represent only a small portion of our suppliers' or manufacturers' business and if they become capacity constrained they may choose to allocate their available resources to other customers that represent a larger portion of their business. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of the Maestro Rechargeable System following commercialization. If we are unable to obtain a sufficient supply of our product, our revenue, business and financial prospects would be adversely affected.

Government Regulations

United States

Our Maestro Rechargeable System is regulated by the FDA as a medical device under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the regulations promulgated under the FFDCA. Pursuant to the FFDCA, the FDA regulates the research, design, testing, manufacture, safety, labeling, storage, record keeping, advertising, sales and distribution, post-market adverse event reporting, production and advertising and promotion of medical devices in the United States. Noncompliance with applicable requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket approval for devices and criminal prosecution.

Medical devices in the United States are classified into one of three classes, Class I, II or III, on the basis of the amount of risk and the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I, low risk, devices are subject to general controls (e.g., labeling and adherence to good manufacturing practices). Class II, intermediate risk, devices are subject to general controls and to special controls (e.g., performance standards, and premarket notification). Generally, Class III devices are those which must receive premarket approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices), and require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class II devices. In both the United States and certain international markets, there have been a number of legislative and regulatory initiatives and changes, such as the Modernization Act, which could and have altered the healthcare system in ways that could impact our ability to sell our medical devices profitably.

The FFDCA provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FFDCA, where the manufacturer submits to the FDA a premarket notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the 510(k) procedure, the manufacturer must file a premarket approval (PMA) application with the FDA. This procedure requires more extensive pre-filing clinical and preclinical testing than the 510(k) procedure and involves a significantly longer FDA review process.

Premarket Approval

Our Maestro Rechargeable System is an implanted device that required PMA from the FDA to market in the United States. The FDA approved the Maestro Rechargeable System on January 14, 2015 with post-approval conditions intended to ensure the safety and effectiveness of the device. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of the PMA, new PMAs or supplemental PMAs will be required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a PMA except that the supplement is limited to information needed to support any changes from the device covered by the original PMA. In addition, holders of an approved PMA are required to submit annual reports to the FDA that include relevant information on the continued use of the device.

Clinical Trials

A clinical trial is almost always required to support a PMA. Clinical trials for a "significant risk" device such as ours require submission to the FDA of an application for an IDE for clinical studies to be conducted within the United States. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device in the United States may begin once the IDE application is approved by the FDA and by the Institutional Review Boards (IRBs) overseeing the clinical trial at the various investigational sites.

Clinical trials require extensive recordkeeping and detailed reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for each participating clinical trial site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice requirements. We, the trial Data Safety Monitoring Board, the FDA or the IRB for each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Pervasive and Continuing U.S. Regulation

Numerous regulatory requirements apply. These include:

- Quality System Regulation, which requires manufacturers to follow design, testing, control, documentation, complaint handling and other quality assurance procedures during the design and manufacturing processes;
- regulations which govern product labels and labeling, prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- notices of correction or removal and recall regulations;
- periodic reporting of progress related to clinical trials, post approval studies required as conditions of PMA approval and relevant changes to information contained within the PMA approval; and
- reporting of transfers of value and payments to physicians and teaching hospitals.

Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have resulted in enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act, competitors and others can initiate litigation relating to advertising claims.

Compliance with regulatory requirements is enforced through periodic facility inspections by the FDA, which may be unannounced. Because we rely on contract manufacturing sites and service providers, these additional sites are also subject to these FDA inspections. Failure to comply with applicable regulatory requirements can result in enforcement action, which may include any of the following sanctions:

- warning letters or untitled letters;
- fines, injunction and civil penalties;
- recall or seizure of our products;
- customer notification, or orders for repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials;
- refusing our request for premarket approval of new products;
- withdrawing premarket approvals that are already granted; and
- criminal prosecution.

International

Australia

The Company's Maestro Rechargeable System, which is listed on the ARTG by the TGA, is regulated as a medical device under the Therapeutic Goods Act (TG Act), which regulates the research, design, testing, manufacture, safety, labeling, storage, record keeping, advertising, sales and distribution, post-market adverse event reporting, production and advertising and promotion of medical devices in Australia. The TG Act requires medical devices to be included on the ARTG before they can be supplied in Australia. The TGA's requirements in relation to the inclusion process depend on the classification of devices based on risk level and other factors. All implantable components of the Maestro Rechargeable System, and most of the external components, required a full conformity assessment prior to inclusion on the ARTG to satisfy the TGA that the device and its manufacturer comply with the "Essential Principles" under the TG Act relating to the safety and performance characteristics of medical devices. Accordingly, among other things, the TGA reviewed data demonstrating the safety and performance of the device including data obtained through clinical trials. TGA regulations continue to apply to a device after inclusion on the ARTG. For example, the sponsor will be required to submit annual reports to the TGA, and when applicable, report certain adverse events to the TGA, and if a recall is required, it will need to comply with TGA requirements. Even after the device is included, the TGA may conduct audits from time to time in relation to the product to ensure ongoing compliance. In addition, advertising material to consumers relating to the device is regulated by the TG Act and the Therapeutic Goods Advertising Code. Advertising material in general is also subject to trade practices legislation, the regulatory agency for which is the Australian Competition and Consumer Commission.

Other Countries

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. The primary regulatory environment in Europe is that of the European Economic Community (EEC), which consists of 28 European Union (EU) member states encompassing nearly all the major countries in Europe. Additional countries that are not part of the EU, but are part of the European Economic Area (EEA), and other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the EEC with respect to medical devices. The EEC has adopted Directive 90/385/EEC as amended by 2007/47/EC for active implantable medical devices and numerous standards that govern and harmonize the national laws and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices that are marketed in member states. Medical devices that comply with the requirements of the national law of the member state in which their Notified Body is located will be entitled to bear CE marking, indicating that the device conforms to applicable regulatory requirements, and, accordingly, can be commercially marketed within the EEA and other countries that recognize this mark for regulatory purposes.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011 for the treatment of obesity. The CE Mark approval for our Maestro Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro Rechargeable System (which is considered an Active Implantable Medical Device (AIMD) in Australia and the EEA, and falls into Class III within the United States), the method involved a combination of self-assessment and issuance of declaration of conformity by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body of the design of the device and of our quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a product complies with applicable regulatory requirements. The assessment included, among other things, a clinical evaluation of the conformity of the device with applicable regulatory requirements. We use DEKRA Certification B.V. (formerly known as KEMA Quality) in the Netherlands as the Notified Body for our CE marking approval process.

Continued compliance with CE marking requirements is enforced through periodic facility inspections by the Notified Body, which may be unannounced. Because we rely on contract manufacturing sites and service providers, these additional sites may also be subject to these Notified Body inspections.

Patient Privacy Laws

United States and various international laws have been evolving to protect the confidentiality of certain patient health information, including patient medical records. These laws restrict the use and disclosure of certain patient health information. Enforcement actions, including financial penalties, related to patient privacy issues are globally increasing. The management of patient data may have an impact on certain clinical research activities and product design considerations.

Employees

As of December 31, 2015, we had a total of 37 employees. All of these employees are located in the United States.

From time to time we also employ independent contractors, consultants and temporary employees to support our operations. None of our employees are subject to collective bargaining agreements. We have never experienced a work stoppage and believe that our relations with our employees are good.

Executive Officers

The following table sets forth information regarding our executive officers, including their ages, as of February 29, 2016:

Name	Age	Position
Dan W. Gladney	63	President and Chief Executive Officer
Greg S. Lea	63	Chief Financial Officer and Chief Compliance Officer
Scott A. Shikora, M.D.	57	Executive Vice President of Medical Affairs and Chief Medical Officer
Naqeeb (Nick) A. Ansari	54	Senior Vice President of Sales
Peter M. Delange	47	Senior Vice President of Operations and Business Development
Paul F. Hickey	51	Senior Vice President of Marketing and Reimbursement

Dan W. Gladney has served as our President and Chief Executive Officer since November 16, 2015. Mr. Gladney joined the Company on November 2, 2015 as President-Elect and a member of the Board of Directors. Prior to joining us, Mr. Gladney served as Chairman and Chief Executive Officer of Lanx, Inc., a medical device company focused on developing and commercializing innovative devices for spinal surgery. Prior to his time at Lanx, Inc., Mr. Gladney was a Healthcare Operating Partner at Norwest Equity Partners (NEP) from 2008 until 2010, where he was responsible for strategic planning, business growth and corporate governance for NEP portfolio companies and executing new investment opportunities for the firm. Prior to joining NEP, Mr. Gladney served as President and Chief Executive Officer of several medical device companies including Heart Leaflet Technologies and ACIST Medical Systems, both of which were acquired by The Bracco Group. He also served as Chairman, Chief Executive Officer and President of Complex Technologies, a publicly traded orthopedic and health and wellness electro therapy company, from 2002 until 2006. Mr. Gladney currently serves on the Board of Directors of ARIA CV, Inc. and has been a member of a number of other private and public company boards. After the sale of Lanx, he acted as a private investor and small business consultant. Mr. Gladney holds a Bachelor’s Degree in Business Administration from Eastern Michigan University.

Greg S. Lea has served as our Chief Financial Officer since May 21, 2007 and was appointed Chief Compliance Officer on January 6, 2016. Mr. Lea held also held the position of Chief Operating Officer from February 15, 2013 to January 6, 2016 and held the title of “Senior Vice President” from May 21, 2007 until December 11, 2014, at which point the title was dropped in order to clarify his position in our executive leadership team. Prior to joining us, Mr. Lea served as Chief Financial Officer of Pemstar Inc. from July 2002 through January 2007 when it was acquired by Benchmark Electronics, Inc. Mr. Lea also served as a director of Pemstar from April 2001 through January 2007 and held the position of Corporate Controller from April 2002 through July 2002. From 1993 to April 2002, Mr. Lea served as a corporate Vice President for Jostens Corporation, a commemorative and affiliation products manufacturer, serving most recently as corporate Vice President-Business Ventures. Prior to that, Mr. Lea held several financial management and administrative positions at IBM Corporation from 1974 to 1993 and was President and a director of Ability Building Center, Inc. from 1981 to 1993. Mr. Lea holds a B.S. in Accounting/Business Management from Minnesota State University, Mankato.

Scott A. Shikora, M.D. has served as our Executive Vice President of Medical Affairs and Chief Medical Officer since June 1, 2015. Dr. Shikora has over 20 years of experience in the field of obesity. Currently, he is an Associate Professor of Surgery at Harvard Medical School and the Director of the Center for Metabolic and Bariatric Surgery at Brigham and Women’s Hospital in Boston. Prior to that, Dr. Shikora worked at Tufts Medical Center in Boston for over 16 years, where he was the Director of the Weight and Wellness Center, and Chief of the divisions of Bariatric and General Surgery. He is a member of several medical societies and was active in leadership in the American Society for Parenteral and Enteral Nutrition where he is a past president and former board member. He is past president of the American Society for Metabolic and Bariatric Surgery and a former Executive Council member. Dr. Shikora is the Editor-in-Chief of Obesity Surgery, an Associate Editor of the surgical journal Surgery for Obesity and Related Diseases and has authored numerous book chapters and journal publications and made hundreds of presentations internationally on bariatric surgery, new technologies and nutrition support topics. He received his M.D. from the Columbia University College of Physicians & Surgeons and completed his surgical residency and Nutrition Support fellowship at New England Deaconess Hospital in Boston.

Naqeeb (Nick) A. Ansari has served as our Senior Vice President of Sales since January 6, 2016. Mr. Ansari has over 20 years of experience in the medical device industry, having held various senior sales positions at Stryker Corporation, DePuy, Medtronic, Inc., Lanx, Inc. and Globus Medical Inc. Prior to joining us he spent two years as the owner of an independent distributor solely selling Biomet products. Prior to this, he served as Senior Vice President of Sales at Lanx, Inc. from 2010 to 2013.

Peter M. Delange has served as our Senior Vice President of Operations and Business Development since January 18, 2016. Mr. Delange has spent the last 11 years as the owner and President of Devicex, LLC a medical device engineering development company that was sold in 2015. At Devicex, he contracted with large medical device companies and worked closely with individual surgeons to develop new technologies. Since 2011, Mr. Delange has also served as a Co-Founder and Board Member of FocusStart LLC, an early stage technology development company utilizing a capital efficient business model to advance medical technology. Prior to Devicex, he held software engineer and product development positions at numerous companies including ACIST Medical Systems, Nellcor Puritan Bennett, Emerson EMC and Quester Technology.

Paul F. Hickey has served as our Senior Vice President of Marketing and Reimbursement since January 18, 2016. Mr. Hickey has over 15 years of experience as a medical device executive, most recently having served as Chief Executive Officer of Pantheon Spinal, a small spine implant start-up company based in Austin, Texas, since 2014. Prior to Pantheon, he spent three years as Senior Vice President, Global Commercialization at Lanx, Inc., which was acquired by Biomet Spine in 2013, where he oversaw marketing, clinical reimbursement and R&D. Mr. Hickey also spent 17 years at Zimmer-Spine where he held numerous marketing and developments positions, most recently as Vice President, Global R&D and Emerging Technology from 2004-2008.

Our Corporate Information

We were incorporated in Minnesota in December 2002 as two separate legal entities, Alpha Medical, Inc. and Beta Medical, Inc., both of which were owned 100% by a common stockholder. In October 2003, the two entities were combined and we changed our name to EnteroMedics Inc. In 2004 we reincorporated in Delaware. We file reports and other information with the Securities and Exchange Commission (SEC) including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy or information statements. Those reports and statements as well as all amendments to those documents filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (1) are available at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, DC 20549, (2) may be obtained by sending an electronic message to the SEC at *publicinfo@sec.gov* or by sending a fax to the SEC at 1-202-777-1027, (3) are available at the SEC’s internet site (http://www.sec.gov), which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC and (4) are available free of charge through our website as soon as reasonably practicable after electronic filing with, or furnishing to, the SEC. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

Our principal executive offices are located at 2800 Patton Road, St. Paul, Minnesota 55113, and our telephone number is (651) 634-3003. Our website address is *www.enteromedics.com*. The information on, or that may be accessed through, our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

ITEM 1A. *RISK FACTORS*

Risks Related to Our Business and Industry

We are a medical device company with a limited history of operations, no history of sales in the United States and a limited history of sales in countries outside of the United States, and we cannot assure you that we will ever generate substantial revenue or be profitable.

We are a medical device company with a limited operating history upon which you can evaluate our business. We received FDA approval to sell our product in the United States on January 14, 2015 and we have had commercial sales within the United States in 2015 and 2016. We have also completed the regulatory process required to sell our product in Australia, the European Economic Area and other countries that recognize the European CE Mark, and have not generated revenue from commercial sales outside of the United States since 2012 and then only on a limited basis in Australia and the Middle East. We have been engaged in research and development and clinical trials since our inception in 2002 and have invested substantially all of our time and resources in developing our vBloc Therapy, which we have begun to commercialize in the form of our Maestro Rechargeable System. The success of our business will depend on our ability to establish a sales force, make sales and control costs, as well as our ability to obtain additional regulatory approvals needed to market new versions of our Maestro Rechargeable System and any other products we may develop in the future, all of which we may be unable to do. If we are unable to successfully market our Maestro Rechargeable System for its indicated use, we may never become profitable and may have to cease operations as a result. Our lack of a significant operating history also limits your ability to make a comparative evaluation of us, our products and our prospects.

We have incurred losses since inception and we anticipate that we will continue to incur losses for the foreseeable future.

We have incurred losses in each year since our formation in 2002. Our net loss applicable to common stockholders for the fiscal years ended December 31, 2015, 2014 and 2013 was $25.5 million, $26.1 million and $25.8 million, respectively. We have funded our operations to date principally from the sale of securities and the issuance of indebtedness. Development of a new medical device, including conducting clinical trials and seeking regulatory approvals, is a long, expensive and uncertain process. Although we recently received the regulatory approval required to sell our Maestro Rechargeable System in the United States and have the approvals required for sales in Australia, the European Economic Area and other countries that recognize the European CE Mark, we have only generated limited revenue from commercial sales in the United States and have not generated revenue from commercial sales outside of the United States since 2012 and then only on a limited basis in Australia and the Middle East. We expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our general and administrative expenses to increase as we continue to add the infrastructure necessary to support our initial commercial sales, operate as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur significant operating losses for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders’ equity and working capital. Because of the numerous risks and uncertainties associated with developing new medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or liquidate some or all of our assets.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on the commercialization of our product and on research and development, including conducting current and future clinical trials for our Maestro Rechargeable System and subsequent versions of our product. Cash used in operations was $22.6 million, $19.4 million and $18.4 million for the fiscal years ended December 31, 2015, 2014 and 2013, respectively. We expect that our cash used in operations will continue to be significant in the upcoming years, and that we will need to raise additional capital to commercialize our Maestro Rechargeable System in the United States, Australia, the European Economic Area, other countries that recognize the European CE Mark and other international markets, to explore other indications for our product, to continue our research and development programs, and to fund our ongoing operations.

Our future funding requirements will depend on many factors, including:

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our Maestro Rechargeable System and any products that we may develop;
- the rate of market acceptance of our Maestro Rechargeable System and vBloc Therapy and any other product candidates;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the effect of competing products and market developments;
- the cost of explanting clinical devices;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- any revenue generated by sales of our Maestro Rechargeable System or our future products;
- the scope, rate of progress, results and cost of any clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to these types of transactions.

Until the time, if ever, when we can generate a sufficient amount of product revenue, we expect to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration, licensing arrangements and grants, as well as through interest income earned on cash balances.

Currently, we are prohibited from issuing equity securities until November 9, 2016 under the terms of the securities purchase agreement we entered into on November 4, 2015. When we are able to raise additional capital, it may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we complete may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), as well as rules subsequently implemented by the SEC and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations result in increased legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure. In particular, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. We have incurred and continue to expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. Moreover, if we do not comply with the requirements of Section 404, or if we identify deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

We face significant uncertainty in the industry due to government healthcare reform.

The Patient Protection and Affordable Care Act, as amended, (the Affordable Care Act) as well as other healthcare reform may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The Affordable Care Act contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers that began in 2013. Although a moratorium was placed on the medical device excise tax in 2016 and 2017, if it is reinstated, it may adversely affect our sales and the cost of goods sold. In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future.

We are subject, directly or indirectly, to United States federal and state healthcare fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

Our operations are directly, or indirectly through customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and healthcare companies to have to defend a False Claim Act action. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act.

We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above or other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations.

We operate in a highly competitive industry that is subject to rapid change. If our competitors are able to develop and market products that are safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The health care industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The obesity treatment market in which we operate has grown significantly in recent years and is expected to continue to expand as technology continues to evolve and awareness of the need to treat the obesity epidemic grows. Although we are not aware of any competitors in the neuroblocking market, we face potential competition from pharmaceutical and surgical obesity treatments. Many of our competitors in the obesity treatment field have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly if they pursue competing solutions through collaborative arrangements with large and established companies, such as Allergan, Apollo Endosurgery, Boston Scientific, LivaNova PLC, Johnson & Johnson, Medtronic or St. Jude Medical. Our competitors may develop and patent processes or products earlier than us, obtain regulatory approvals for competing products more rapidly than we are able to and develop more effective, safer and less expensive products or technologies that would render our products non-competitive or obsolete.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We currently rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and will rely on such systems to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements.

Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. We are not aware of any breaches of our information technology infrastructure. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer.

Risks Associated with Development and Commercialization of the Maestro Rechargeable System

Our efforts to commercialize our Maestro Rechargeable System may not succeed or may encounter delays which could significantly harm our ability to generate revenue.

Our ability to generate revenue will depend upon the successful commercialization of our Maestro Rechargeable System. Our efforts to commercialize this product may not succeed for a number of reasons, including:

- our Maestro Rechargeable System may not be accepted in the marketplace by physicians, patients and third-party payors;
- the price of our Maestro Rechargeable System, associated costs of the surgical procedure and treatment and the availability of sufficient third-party reimbursement for the system implantation and follow-up procedures;
- appropriate reimbursement and/or coding options may not exist to enable billing for the system implantation and follow-up procedures;
- we may not be able to sell our Maestro Rechargeable System at a price that allows us to meet the revenue targets necessary to generate enough revenue for profitability;
- the frequency and severity of any side effects of our vBloc Therapy;
- physicians and potential patients may not be aware of the perceived effectiveness and sustainability of the results of vBloc Therapy provided by our Maestro Rechargeable System;
- we, or the investigators of our product, may not be able to have information on the outcome of the trials published in medical journals;
- the availability and perceived advantages and disadvantages of alternative treatments;
- any rapid technological change may make our product obsolete;
- we may not be able to have our Maestro Rechargeable System manufactured in commercial quantities or at an acceptable cost;
- we may not have adequate financial or other resources to complete the development and commercialization of our Maestro Rechargeable System or to develop sales and marketing capabilities for our Maestro Rechargeable System; and
- we may be sued for infringement of intellectual property rights and could be enjoined from manufacturing or selling our products.

Besides requiring physician adoption, market acceptance of our Maestro Rechargeable System will depend on successfully communicating the benefits of our vBloc Therapy to three additional constituencies involved in deciding whether to treat a particular patient using such therapy: (1) the potential patients themselves; (2) institutions such as hospitals, where the procedure would be performed and opinion leaders in these institutions; and (3) third-party payors, such as private healthcare insurers and governmental payors, such as Medicare and Medicaid in the United States, and Medical Services Advisory Committee (MSAC) in Australia, which would ultimately bear most of the costs of the various providers and equipment involved in our vBloc Therapy. Marketing to each of these constituencies requires a different marketing approach, and we must convince each of these groups of the efficacy and utility of our vBloc Therapy to be successful.

If our vBloc Therapy, or any other neuroblocking therapy for other gastrointestinal diseases and disorders that we may develop, does not achieve an adequate level of acceptance by the relevant constituencies, we may not generate significant product revenue and may not become profitable.

After we received FDA approval on January 14, 2015, we began the commercialization process for our Maestro Rechargeable System in the United States, and had our first commercial sales within the United States in 2015. Previously, in 2012, we commenced commercial sales of our Maestro Rechargeable System in Australia and the Middle East, but have not generated revenue from commercial sales outside of the United States since 2012 as we focused our resources on the U.S. regulatory approval process and commercialization of our product in the United States and we do not know when, or if, we will have the resources to commercialize our Maestro Rechargeable System internationally. If we are not successful in the commercialization of our Maestro Rechargeable System for the treatment of obesity we may not generate enough revenue to offset our expenses and may be forced to cease operations as a result.

We have not received, and may never receive, approval from the regulatory bodies of any foreign country other than the Australian TGA or the European Economic Area to market our Maestro Rechargeable System for the treatment of obesity.

We do not have the necessary regulatory approvals to market our Maestro Rechargeable System in any foreign market other than Australia for which the final components of the Maestro Rechargeable System were listed on the ARTG in January 2012, the European Economic Area for which we received CE Mark approval for our Maestro Rechargeable System in March 2011 for the treatment of obesity and other countries which accept these regulatory approvals. The CE Mark approval for our Maestro Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. We commenced commercialization of our product in Australia and the Middle East in 2012, but have not generated revenue from commercial sales outside of the United States since 2012 as we focused our resources on the U.S. regulatory approval process and commercialization of our product in the United States and we do not know when, or if, we will have the resources to commercialize our Maestro Rechargeable System internationally.

In order to market our Maestro Rechargeable System outside of the United States, we will need to establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries may differ from that required to obtain FDA approval. The regulatory approval process in other countries may also include all of the risks detailed below.

Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. While the Maestro Rechargeable System has been listed on the ARTG and has received European CE Marking, we cannot assure you when, or if, we will be able to restart sales in Australia or the Middle East, commence sales in the European Economic Area or other countries that recognize the CE Mark or obtain approval to market our Maestro Rechargeable System in other countries outside the United States.

Because vBloc Therapy represents a novel way to effect weight loss in the treatment of obesity, and because there is a large population of obese patients who might be eligible for treatment, it is possible that other regulatory bodies will review an application for approval of our Maestro Rechargeable System with greater scrutiny, which could cause that process to be lengthier and more involved than that for products without such characteristics. Such regulatory bodies can delay, limit or deny approval of our Maestro Rechargeable System for many reasons, including our inability to demonstrate safety or effectiveness to their satisfaction, insufficient or inadequate data from our clinical trials, the facilities of our third-party manufacturers or suppliers may not meet applicable requirements; and changes in the regulatory bodies' approval policies, expectations with regard to the type or amount of scientific data required or adoption of new regulations may require additional data or additional clinical studies.

We have limited data and experience regarding the safety and efficacy of the Maestro Rechargeable System. Any long-term data that is generated may not be positive or consistent with our limited short-term data, which would affect market acceptance of these products.

Because our technology is relatively new in the treatment of obesity, we have performed clinical trials only with limited patient populations. The long-term effects of using the Maestro Rechargeable System in a large number of patients have not been studied and the results of short-term clinical use of the Maestro Rechargeable System do not necessarily predict long-term clinical benefits or reveal long-term adverse effects.

Clinical trials conducted with the Maestro Rechargeable System have involved procedures performed by physicians who are very technically proficient. Consequently, both short and long-term results reported in these studies may be significantly more favorable than typical results achieved by physicians, which could negatively impact market acceptance of the Maestro Rechargeable System and materially harm our business.

We may be unable to complete our current clinical trials or any additional clinical trials, or we may experience significant delays in completing those clinical trials, which could impact market acceptance of our Maestro Rechargeable System and impair our financial position.

We continue to evaluate the Maestro System in human clinical trials, including the EMPOWER trial and ReCharge trial. Conducting a clinical trial, which involves screening, assessing, testing, treating and monitoring patients at several sites across the country and possibly internationally, and coordinating with patients and clinical institutions, is a complex and uncertain process.

The completion of our ongoing and future clinical trials, could be delayed, suspended or terminated for several reasons, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our preclinical results or clinical trial or requests for supplemental information with respect to our preclinical results or clinical trial results;
- our failure or inability to conduct the clinical trials in accordance with regulatory requirements;
- sites currently participating in the trial may drop out of the trial, which may require us to engage new sites or petition the FDA for an expansion of the number of sites that are permitted to be involved in the trial;
- patients may not remain in or complete, clinical trials at the rates we expect;
- patients may experience serious adverse events or side effects during the trial, which, whether or not related to our product, could cause the FDA or other regulatory authorities to place the clinical trial on hold;
- clinical investigators may not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices; and
- we may be unable to obtain a sufficient supply of our Maestro Rechargeable System necessary for the timely conduct of the clinical trials.

Although we believe that we have adequate personnel and procedures in place to manage the clinical trial process, the complexity of managing this process while also commercializing our Maestro Rechargeable System and fulfilling our disclosure and other obligations to our stockholders, lenders, regulators and other constituents could result in our inadvertently taking actions outside the clinical trial process, which could adversely impact the trial. As is always the case, if the FDA ultimately determined that such actions materially violated the protocol for the trial, the FDA could suspend, terminate or reject the results of the clinical trial and require us to repeat the process.

If our clinical trials are delayed, it will take us longer to ultimately commercialize a product and generate revenue or the delay could result in our being unable to do so. Moreover, our development costs will increase if we have material delays in our clinical trials or if we need to perform more or larger clinical trials than planned.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials, and on other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

We rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, ensure compliance by patients with clinical protocols or comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining or maintaining regulatory approvals for our product. Our agreements with clinical investigators and clinical trial sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, adversely affecting our ability to successfully commercialize our product.

Modifications to the Maestro Rechargeable System may require additional approval from regulatory authorities, which may not be obtained or may delay our commercialization efforts.

The FDA, TGA and European Notified Body require medical device companies to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance; however, some of these regulatory authorities can review a company's decision. Any modifications to an approved device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use could require additional clinical studies and separate regulatory applications. Product changes or revisions will require all the regulatory steps and associated risks discussed above possibly including testing, regulatory filings and clinical study. We may not be able to obtain approval of supplemental regulatory approvals for product modifications, new indications for our product or new products. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our commercialization efforts and future growth.

Our neuroblocking therapy for the treatment of obesity is a unique form of treatment. Physicians may not widely adopt our Maestro Rechargeable System and vBloc Therapy unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that vBloc Therapy provides a safe and effective alternative to other existing treatments for obesity.

We believe we are the first and only company currently pursuing neuroblocking therapy for the treatment of obesity. Physicians tend to be slow to change their medical treatment practices because of the time and skill required to learn a new procedure, the perceived liability risks arising from the use of new products and procedures, and the uncertainty of third-party coverage and reimbursement. Physicians may not widely adopt our Maestro Rechargeable System and vBloc Therapy unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our vBloc Therapy provides a safe and effective alternative to other existing treatments for obesity, including pharmaceutical solutions and bariatric surgical procedures.

We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that our vBloc Therapy is an attractive alternative to other obesity treatment procedures. We rely on experienced and highly trained surgeons to perform the procedures in our clinical trials and both short-and long-term results reported in our clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively impact rates of adoption of our Maestro Rechargeable System and vBloc Therapy. We believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our Maestro Rechargeable System and vBloc Therapy will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

If we fail to obtain adequate coding, coverage or payment levels for our product by governmental healthcare programs and other third-party payors, there may be no commercially viable markets for our Maestro Rechargeable System or other products we may develop or our target markets may be much smaller than expected.

Healthcare providers generally rely on third-party payors, including governmental payors, such as Medicare and Medicaid in the United States, and MSAC in Australia, as well as private healthcare insurers, to adequately cover and reimburse the cost of medical devices. Importantly, third-party payors are increasingly challenging the price of medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. We expect that third-party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our Maestro Rechargeable System and the related surgery and facility costs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our Maestro Rechargeable System will be impaired and our future revenue, if any, would be adversely affected. As such, even though we have obtained FDA approval for our Maestro Rechargeable System and began to market it in 2015, the availability and level of third-party coverage and reimbursement could substantially affect our ability to successfully commercialize our Maestro Rechargeable System and other products we may develop.

The efficacy, safety, ease of use and cost-effectiveness of our Maestro Rechargeable System and of any competing products will, in part, determine the availability and level of coverage and payment. In particular, we expect that securing coding, coverage and payment for our Maestro Rechargeable System will be more difficult if healthcare providers and obese individuals do not consider the percentage of EWL from a pre-implementation baseline that our clinical trials have demonstrated to be clinically meaningful, whether or not regulatory agencies consider the improvement of patients treated in clinical trials to have been clinically meaningful.

In some international markets, pricing of medical devices is subject to government control. In the United States and international markets, we expect that both government and third-party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If payment for our Maestro Rechargeable System and the related surgery and facility costs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our Maestro Rechargeable System will be impaired and our future revenue, if any, would be adversely affected.

We cannot predict the likelihood or pace of any significant regulatory or legislative action in any of these areas, nor can we predict whether or in what form healthcare legislation being formulated by various governments will be passed. We also cannot predict with precision what effect such governmental measures would have if they were ultimately enacted into law. However, in general, we believe that such legislative activity will likely continue. If adopted, such measures can be expected to have an impact on our business.

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated product problems, our Maestro Rechargeable System could be subject to restrictions or withdrawal from the market.

Completion of our clinical trials and commercialization of our Maestro Rechargeable System will require access to manufacturing facilities that meet applicable regulatory standards to manufacture a sufficient supply of our product. We rely solely on third parties to manufacture and assemble our Maestro Rechargeable System, and do not currently plan to manufacture or assemble our Maestro Rechargeable System ourselves in the future.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by our European Notified Body and the FDA and other regulatory bodies. In particular we and our manufacturers and suppliers are required to comply with ISO requirements, Good Manufacturing Practices, which for medical devices is called the Quality System Regulation (QSR), and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval. The FDA enforces the QSR through inspections, which may be unannounced, and the CE system enforces its certification through inspections and audits as well. Our quality system has received certification of compliance to the requirements of ISO 13485:2003 and will have to continue to successfully complete such inspections to maintain regulatory approvals for sales outside of the United States. Failure by us or one of our manufacturers or suppliers to comply with statutes and regulations administered by the FDA, CE authorities and other regulatory bodies, or failure to adequately respond to any observations, could result in enforcement actions against us or our manufacturers or suppliers, including, restrictions on our product or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

If any of these actions were to occur it would harm our reputation and cause our product sales to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements. If the FDA or any other regulatory body finds their compliance status to be unsatisfactory, our commercialization efforts could be delayed, which would harm our business and our results of operations.

Additionally, if the FDA determines that our promotional materials, training or other activities constitute promotion of an unapproved use, we could be subject to significant liability, the FDA could request that we cease, correct or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

We are subject to medical device reporting regulations that require us to report to the FDA, TGA, Competent Authorities or other governmental authorities in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. The FDA, TGA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacturing. A government mandated, or voluntary, recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall would divert managerial and financial resources and could harm our reputation with customers. There can be no assurance that there will not be product recalls in the future or that such recalls would not have a material adverse effect on our business. Once the product is approved and implanted in a large number of patients, infrequently occurring adverse events may appear that were not observed in the clinical trials. This could cause health authorities in countries where the product is available to take regulatory action, including marketing suspension and recall.

We may not be successful in our efforts to utilize our vBloc Therapy to treat comorbidities associated with obesity and other gastrointestinal diseases and disorders.

As part of our long-term business strategy, we plan to research the application of our vBloc Therapy to treat comorbidities associated with obesity and other gastrointestinal diseases and disorders. Research to identify new target applications requires substantial technical, financial and human resources, whether or not any new applications for our vBloc Therapy are ultimately identified. We may be unable to identify or pursue other applications of our technology. Even if we identify potential new applications for our vBloc Therapy, investigating the safety and efficacy of our therapy requires extensive clinical testing, which is expensive and time-consuming. If we terminate a clinical trial in which we have invested significant resources, our prospects will suffer, as we will have expended resources on a program that will not provide a return on our investment and missed the opportunity to allocate those resources to potentially more productive uses. We will also need to obtain regulatory approval for these new applications, as well as achieve market acceptance and an acceptable level of reimbursement.

We depend on a limited number of manufacturers and suppliers of various critical components for our Maestro Rechargeable System. The loss of any of these manufacturer or supplier relationships could prevent or delay commercialization of our Maestro Rechargeable System.

We rely entirely on third parties to manufacture our Maestro Rechargeable System and to supply us with all of the critical components of our Maestro Rechargeable System, including our leads, implantable batteries, neuroregulators, transmit coils and controllers. If any of our existing suppliers were unable or unwilling to meet our demand for product components, or if the components or finished products that they supply do not meet quality and other specifications, completion of our clinical trials or commercialization of our product could be delayed. Alternatively, if we have to switch to a replacement manufacturer or replacement supplier for any of our product components, we may face additional regulatory delays, and the manufacture and delivery of our Maestro Rechargeable System could be interrupted for an extended period of time, which could delay completion of our clinical trials or commercialization of our Maestro Rechargeable System.

If our device manufacturers or our suppliers are unable to provide an adequate supply of our product, our growth could be limited and our business could be harmed.

In order to produce our Maestro Rechargeable System in the quantities that we anticipate will be required to meet anticipated market demand, we will need our manufacturers to increase, or scale-up, the production process by a significant factor over our current level of production. There are technical challenges to scaling-up manufacturing capacity and developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. If our manufacturers are unable to do so, we may not be able to meet future demand, if any. We may also represent only a small portion of our supplier’s or manufacturer’s business and if they become capacity constrained they may choose to allocate their available resources to other customers that represent a larger portion of their business. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of the Maestro Rechargeable System. If we are unable to obtain a sufficient supply of our product, our revenue, business and financial prospects would be adversely affected.

If we are unable to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to market and sell our Maestro Rechargeable System, our business may be harmed.

We have limited experience as a company in sales, marketing and distribution of our product and began the process of developing a sales and marketing organization in 2015. We intend to market our products in the United States through a direct sales force supported by field technical managers who provide training, technical and other support services to our customers. We have begun to develop the necessary sales and marketing infrastructure in order to commercialize our product, but developing a sales force is expensive and time consuming. Additionally, we may be unable to develop an effective sales and marketing organization on a timely basis, if at all, which would delay or prevent us from generating enough revenue to become profitable. If we develop our own sales and marketing capabilities, our sales force will be competing with the experienced and well-funded marketing and sales organizations of our more established competitors. If we are unable to establish our own sales and marketing capabilities, we will need to contract with third parties to market and sell our product. In this event, our profit margins would likely be lower than if we performed these functions ourselves. In addition, we would necessarily be relying on the skills and efforts of others for the successful marketing of our product. If we are unable to establish and maintain effective sales and marketing capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

When we have sufficient resources to commercialize our Maestro Rechargeable System internationally, we intend to use direct, dealer and distributor sales models as the targeted geography best dictates. We have entered into an agreement with Device Technologies, a third-party distributor in Australia, to sell our product in Australia and we have entered into an agreement with Bader Sultan & Brothers, a third-party distributor in Kuwait, to sell our product in the Middle East. To generate sales and launch the commercialization of our product in other geographic regions we may need to identify and enter into other third-party distributor agreements. There is no assurance that we can do so on economically acceptable terms or that if we do so, that a third-party distributor will be successful in selling our product.

The commercialization of our product in countries outside the United States will expose our business to certain risks associated with international operations.

When we have sufficient resources to do so, we intend to commercialize our product in the European Economic Area, Australia and the Middle East and other international markets in which we obtain necessary regulatory approvals. Conducting international operations will subject us to unique risks, including:

- unfamiliar legal requirements with which we would need to comply;
- fluctuations in currency exchange rates;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;
- increased financial accounting and reporting burdens and complexities; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of these risks could negatively affect our business and results of operations generally. Additionally, operating in international markets requires significant management attention. We cannot be certain that investments required to establish operations in other countries will produce desired levels of revenues or profitability.

We may be unable to attract and retain management and other personnel we need to succeed.

Our success depends on the services of our senior management and other key employees. The loss of the services of one or more of our officers or key employees could delay or prevent the successful completion of our clinical trials and the commercialization of our Maestro Rechargeable System. Now that we have received regulatory approval for our product in the United States, we have begun a controlled expansion of our operations and have hired three new executives in January 2016 to oversee this expansion. Our continued growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

We may be unable to manage our growth effectively.

Our business strategy entails significant future growth. For example, we will have to expand existing operations in order to conduct additional clinical trials, increase our contract manufacturing capabilities, hire and train new personnel to handle the marketing and sales of our product, assist patients and healthcare providers in obtaining reimbursement for the use of our product and create and develop new applications for our technology. This growth may place significant strain on our management and financial and operational resources. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems and procedures. Our ability to effectively manage growth depends on our success in attracting and retaining highly qualified personnel, for which the competition may be intense. If we fail to manage these challenges effectively, our business could be harmed.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to obtain adequate product liability insurance.

Our business exposes us to a risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if our Maestro Rechargeable System, or any other products we may sell, causes, or appears to have caused, an injury. Claims may be made by consumers, healthcare providers, third-party strategic collaborators or others selling our products.

We have product liability insurance, which covers the use of our Maestro Rechargeable System and vBloc Therapy in our clinical trials and any commercial sales, in an amount we believe is appropriate. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost and on acceptable terms for an adequate coverage amount, or otherwise to protect against potential product liability claims, we could be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our Maestro Rechargeable System and vBloc Therapy in the market.

We may be subject to product liability claims even if it appears that the claimed injury is due to the actions of others. For example, we rely on the expertise of surgeons and other associated medical personnel to perform the medical procedure to implant and remove our Maestro Rechargeable System and to perform the related vBloc Therapy. If these medical personnel are not properly trained or are negligent, the therapeutic effect of vBloc Therapy may be diminished or the patient may suffer critical injury, which may subject us to liability. In addition, an injury that is caused by the negligence of one of our suppliers in supplying us with a defective component that injures a patient could be the basis for a claim against us. A product liability claim, regardless of its merit or eventual outcome, could result in decreased demand for our products; injury to our reputation; diversion of management's attention; withdrawal of clinical trial participants; significant costs of related litigation; substantial monetary awards to patients; product recalls or market withdrawals; loss of revenue; and the inability to commercialize our products under development.

Risks Related to Intellectual Property

If we are unable to obtain or maintain intellectual property rights relating to our technology and neuroblocking therapy, the commercial value of our technology and any future products will be adversely affected and our competitive position will be harmed.

Our commercial success depends in part on our ability to obtain protection in the United States and other countries for our Maestro Rechargeable System and vBloc Therapy by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. We own numerous U.S. and foreign patents and have numerous patent applications pending, most of which pertain to treating gastrointestinal disorders. We have also received or applied for patents in Europe, Australia, China, India and Japan. In addition, we are the exclusive licensee of three U.S. patents owned by the Mayo Foundation for Medical Education and Research, which are unrelated to our vBloc Therapy. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. We expect to incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third-party's products or patents in litigation or administrative proceedings, including patent interferences, re-examinations or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the loss of the entire patent or the relevant portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Even if we were to prevail in any litigation, we cannot assure you that we can obtain an injunction that prevents our competitors from practicing our patented technology. Our competitors may independently develop similar or alternative technologies or products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies.

We cannot assure you that we will obtain any patent protection that we seek, that any protection we do obtain will be found valid and enforceable if challenged or that it will confer any significant commercial advantage. U.S. patents and patent applications may also be subject to interference proceedings and U.S. patents may be subject to re-examination proceedings in the U.S. Patent and Trademark Office (USPTO), or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed, and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent offices, which proceedings could result in either loss of the patent or denial of the patent application, or loss or reduction in the scope of one or more of the claims of, the patent or patent application. In addition, such interference, re-examination and opposition proceedings may be costly. Moreover, the U.S. patent laws have recently changed with the adoption of the America Invents Act (AIA), possibly making it easier to challenge patents. Some of our technology was, and continues to be, developed in conjunction with third parties, and thus there is a risk that such third parties may claim rights in our intellectual property. Thus, any patents that we own or license from others may provide limited or no protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology.

Non-payment or delay in payment of patent fees or annuities, whether intentional or unintentional, may result in loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States, particularly in the field of medical products and procedures.

Many of our competitors have significant resources and incentives to apply for and obtain intellectual property rights that could limit or prevent our ability to commercialize our current or future products in the United States or abroad.

Many of our competitors who have significant resources and have made substantial investments in competing technologies may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets. Our current or future U.S. or foreign patents may be challenged, circumvented by competitors or others or may be found to be invalid, unenforceable or insufficient. In most cases in the United States patent applications are published 18 months after filing the application, or corresponding applications are published in other countries, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our pending patent applications, or that we were the first to file patent applications for such inventions.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Intellectual property litigation is a common tactic in the medical device industry to gain competitive advantage. If we become subject to a lawsuit, we may be required to expend significant financial and other resources and our management's attention may be diverted from our business.

There has been a history of frequent and extensive litigation regarding patent and other intellectual property rights in the medical device industry, and companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Accordingly, we may become subject to patent infringement claims or litigation in a court of law, or interference proceedings declared by the USPTO to determine the priority of inventions or an opposition to a patent grant in a foreign jurisdiction. We may also become subject to claims or litigation seeking payment of royalties based on sales of our product in connection with licensing or similar joint development arrangements with third parties or in connection with claims of patent infringement. The defense and prosecution of intellectual property suits, USPTO interference proceedings, reexamination proceedings, or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed, or opposition proceedings and related legal and administrative proceedings, are both costly and time consuming and could result in substantial uncertainty to us. Litigation or regulatory proceedings may also be necessary to enforce patent or other intellectual property rights of ours or to determine the scope and validity of other parties' proprietary rights. Any litigation, opposition or interference proceedings, with or without merit, may result in substantial expense to us, cause significant strain on our financial resources, divert the attention of our technical and management personnel and harm our reputation. We may not have the financial resources to defend our patents from infringement or claims of invalidity. An adverse determination in any litigation could subject us to significant liabilities to third parties, require us to seek licenses from or pay royalties to third parties or prevent us from manufacturing, selling or using our proposed products, any of which could have a material adverse effect on our business and prospects. We are not currently a party to any patent or other litigation.

Our vBloc Therapy or Maestro Rechargeable System may infringe or be claimed to infringe patents that we do not own or license, including patents that may issue in the future based on patent applications of which we are currently aware, as well as applications of which we are unaware. For example, we are aware of other companies that are investigating neurostimulation, including neuroblocking, and of patents and published patent applications held by companies in those fields. While we believe that none of such patents and patent applications are applicable to our products and technologies under development, third parties who own or control these patents and patent applications in the United States and abroad could bring claims against us that would cause us to incur substantial expenses and, if such claims are successfully asserted against us, they could cause us to pay substantial damages, could result in an injunction preventing us from selling, manufacturing or using our proposed products and would divert management's attention. Because patent applications in many countries such as the United States are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware and which may later result in issued patents that our products infringe. If a patent infringement suit were brought against us, we could be forced to stop our ongoing or planned clinical trials, or delay or abandon commercialization of the product that is subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third-party and be required to pay license fees or royalties, or both. A license may not be available at all or on commercially reasonable terms, and we may not be able to redesign our products to avoid infringement. Modification of our products or development of new products could require us to conduct additional clinical trials and to revise our filings with the FDA and other regulatory bodies, which would be time-consuming and expensive. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

Risks Relating to Ownership of Our Common Stock

The trading price of our common stock has been volatile and is likely to be volatile in the future.

The trading price of our common stock has been highly volatile. Further, our common stock has a limited trading history. Since our public offering in November 2007 through February 29, 2016 our stock price has fluctuated from a low of $0.82 to a high of $969.30, as adjusted for the 1-for-15 reverse split of our common stock that was effected on January 6, 2016. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory clearances or approvals of our product or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other product development milestones and to do so in accordance with the timing estimates we have publicly announced;
- changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
- changes in government regulations and standards affecting the medical device industry and our product;
- ability of our product to achieve market success;
- the performance of third-party contract manufacturers and component suppliers;
- our ability to develop sales and marketing capabilities;
- actual or anticipated variations in our results of operations or those of our competitors;
- announcements of new products, technological innovations or product advancements by us or our competitors;
- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- the trading volume of our common stock;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;
- public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products;
- decreases in market valuations of medical device companies; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

The stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company’s securities, securities class action litigation often has been initiated against a company. If class action litigation is initiated against us, we may incur substantial costs and our management’s attention may be diverted from our operations, which could significantly harm our business.

Our inability to comply with the listing requirements of the NASDAQ Stock Market could result in our common stock being delisted, which could affect its market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests (including a minimum closing bid price of $1.00 per share for our common stock) to maintain the listing of our common stock on the NASDAQ Stock Market. If we do not maintain compliance with the continued listing requirements for the NASDAQ Stock Market within specified periods and subject to permitted extensions, our common stock may be recommended for delisting (subject to any appeal we would file). If our common stock were delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting would also impair our ability to raise capital.

Our directors and executive officers hold a significant amount of our outstanding stock and could limit your ability to influence the outcome of key transactions, including changes in control.

Our executive officers and directors and entities affiliated with them beneficially own, in the aggregate (including options and warrants exercisable currently or within 60 days of December 31, 2015), approximately 14.5% of our outstanding common stock. Our executive officers, directors and affiliated entities, if acting together, could be able to influence significantly all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other significant corporate transactions. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may affect the market price of our common stock. This concentration of stock ownership may adversely affect the trading price of our common stock due to investors’ perception that conflicts of interest may exist or arise.

Sales of a substantial number of shares of our common stock in the public market by existing stockholders, or the perception that they may occur, could cause our stock price to decline.

Sales of substantial amounts of our common stock by us or by our stockholders, announcements of the proposed sales of substantial amounts of our common stock or the perception that substantial sales may be made, could cause the market price of our common stock to decline. We may issue additional shares of our common stock in follow-on offerings to raise additional capital, as amortizing payments under our outstanding senior amortizing convertible notes (the Notes), upon the exercise of options or warrants, or in connection with acquisitions or corporate alliances. We also plan to issue additional shares to our employees, directors or consultants in connection with their services to us. All of the currently outstanding shares of our common stock are freely tradable under federal and state securities laws, except for shares held by our directors, officers and certain greater than five percent stockholders, which may be subject to volume limitations. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time and could reduce the market price of our common stock.

In addition, certain of our stockholders, optionholders and warrantholders have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, to pay off our outstanding Notes, or for other corporate purposes, in the future we may offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the current price per share of our common stock. In addition, investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in prior offerings.

Our organizational documents and Delaware law make a takeover of our company more difficult, which may prevent certain changes in control and limit the market price of our common stock.

Our certificate of incorporation and bylaws and Section 203 of the Delaware General Corporation Law contain provisions that may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. These provisions include:

- the ability of our board of directors to create and issue preferred stock without stockholder approval, which could be used to implement anti-takeover devices;
- the authority for our board of directors to issue without stockholder approval up to the number of shares of common stock authorized in our certificate of incorporation, that, if issued, would dilute the ownership of our stockholders;
- the advance notice requirement for director nominations or for proposals that can be acted upon at stockholder meetings;
- a classified and staggered board of directors, which may make it more difficult for a person who acquires control of a majority of our outstanding voting stock to replace all or a majority of our directors;
- the prohibition on actions by written consent of our stockholders;
- the limitation on who may call a special meeting of stockholders;
- the prohibition on stockholders accumulating their votes for the election of directors; and
- the ability of stockholders to amend our bylaws only upon receiving a majority of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

These provisions also could discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. The existence of these provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. Some provisions in our certificate of incorporation and bylaws may deter third parties from acquiring us, which may limit the market price of our common stock.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of our common stock.

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. Our outstanding Notes also restrict our ability to pay dividends. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

Not applicable.

ITEM 2. ***PROPERTIES***

We lease approximately 28,388 square feet of lab and office space in St. Paul, Minnesota. The original lease agreement began October 1, 2008 and was set to expire September 30, 2015. On August 25, 2015 we entered into an amendment extending the term of the lease for three years until September 30, 2018.

ITEM 3. ***LEGAL PROCEEDINGS***

We are not currently a party to any litigation and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our business, operating results or financial condition. The medical device industry in which we operate is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, we may be involved in various legal proceedings from time to time.

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

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PART II.

ITEM 5. ***MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES***

Market For Our Common Stock

Our common stock has been traded on the NASDAQ Stock Market under the symbol "ETRM" since our initial public offering (IPO) on November 15, 2007. Prior to that date, there was no public market for our common stock. Our stock was traded on the NASDAQ Global Market from its initial listing at the time of our IPO until January 21, 2010. Subsequently, in anticipation of not curing our deficiencies with the continued listing requirements of the NASDAQ Global Market, we requested and were approved to transfer to the NASDAQ Capital Market, effective January 22, 2010.

As of February 29, 2016, there were approximately 50 holders of record of our common stock and 8,111,763 shares of common stock outstanding. No dividends have been paid on our common stock to date, and we do not anticipate paying any dividends in the foreseeable future.

The following table sets forth the high and low sales prices of our common stock as quoted on the NASDAQ Stock Market for the periods indicated. These prices have been adjusted to reflect the 1-for-15 reverse split of our common stock that was effected after trading on January 6, 2016.

Price Range of Common Stock

	Price Range	
	High	**Low**
Fiscal 2014		
First Quarter	$39.90	$25.20
Second Quarter	$32.55	$21.15
Third Quarter	$24.75	$16.50
Fourth Quarter	$22.05	$14.85
Fiscal 2015		
First Quarter	$30.75	$13.65
Second Quarter	$21.00	$ 8.85
Third Quarter	$ 9.90	$ 3.00
Fourth Quarter	$ 4.95	$ 1.50

The closing price for our common stock as reported by the NASDAQ Stock Market on February 29, 2016 was $1.08 per share.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Part III, Item 12 of this Annual Report on Form 10-K.

Unregistered Sales of Equity Securities

None.

Uses of Proceeds from Sale of Registered Securities

None.

Dividend Policy

We have never paid cash dividends on our common stock. The board of directors presently intends to retain all earnings for use in our business and does not anticipate paying cash dividends in the foreseeable future. We do not have a dividend reinvestment plan or a direct stock purchase plan.

Issuer Purchases of Equity Securities

None.

Stock Performance Graph

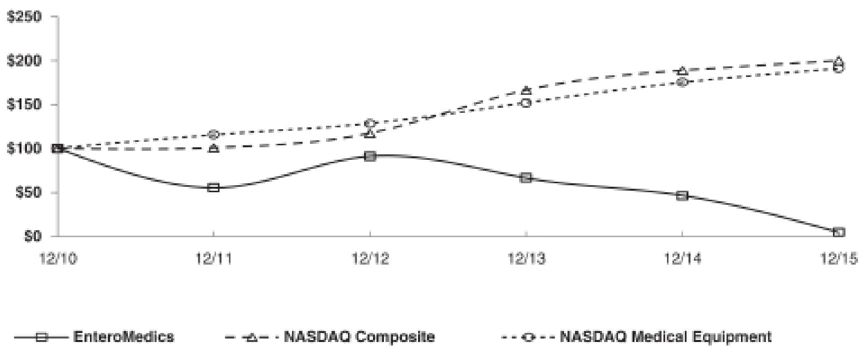
The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

The following graph shows a comparison of cumulative total return for our common stock, the NASDAQ Composite Index and the NASDAQ Medical Equipment Index. Such returns are based on historical results and are not intended to suggest future performance. The graph assumes $100 was invested in our common stock and in each of the indexes on December 31, 2010.

Data for the NASDAQ Composite Index and the NASDAQ Medical Equipment Index assume reinvestment of dividends. We have never paid dividends on our common stock and have no present plans to do so.

The stockholder return shown on the graph below is not necessarily indicative of future performance, and we do not make or endorse any predictions as to future stockholder returns.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among EnteroMedics, the NASDAQ Composite Index
and the NASDAQ Medical Equipment Index



* $100 invested on 12/31/10 in stock or index, including reinvestment of dividends. No dividends have been declared or paid on our common stock. Stock performance shown in the above chart for the common stock is historical and should not be considered indicative of future price performance. The graph was prepared by Research Data Group, Inc.

	December 31, 2010	December 31, 2011	December 31, 2012	December 31, 2013	December 31, 2014	December 31, 2015
EnteroMedics Inc.	$ 100.00	$ 55.19	$ 90.91	$ 66.23	$ 46.10	$ 4.22
NASDAQ Composite	100.00	100.53	116.92	166.19	188.78	199.95
NASDAQ Medical Equipment	100.00	115.55	128.17	151.89	175.17	190.80

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ITEM 6. ***SELECTED FINANCIAL DATA***

The following table sets forth certain financial data with respect to our business. The information set forth below is not necessarily indicative of results of future operations and should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7 and the consolidated financial statements and related notes thereto in Item 8 of this Annual Report on Form 10-K. Basic and diluted net loss per share and shares used to compute basic and diluted net loss per share have been adjusted to reflect the 1-for-15 reverse split of our common stock that was effected after trading on January 6, 2016.

	Fiscal Years				
	2015	2014	2013	2012	2011
	(In thousands, except per share data)				
Sales	$ 292	$ —	$ —	$ 311	$ —
Operations:					
Loss from operations	(28,034)	(25,593)	(24,734)	(22,549)	(25,257)
Net loss	(25,499)	(26,129)	(25,781)	(23,460)	(25,997)
Basic and diluted net loss per share	(4.27)	(5.78)	(7.03)	(8.90)	(12.91)
Shares used to compute basic and diluted net loss per share	5,970	4,524	3,667	2,636	2,014
Financial Position:					
Cash, cash equivalents, restricted cash and short-term investments	7,927	11,619	23,297	22,509	29,693
Working capital (current assets less current liabilities)	6,017	5,303	16,150	16,866	22,003
Total assets	11,587	14,386	26,388	26,096	32,486
Long-term debt, net of current portion and discounts	550	—	2,868	6,684	2,881
Accumulated deficit	(277,581)	(252,082)	(225,953)	(200,172)	(176,712)
Total stockholders’ equity	3,673	6,664	14,679	11,875	20,041

ITEM 7. ***MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS***

Except for the historical information contained herein, the matters discussed in this "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere in this Form 10-K are forward-looking statements that involve risks and uncertainties. The factors listed in Item 1A "Risk Factors," as well as any cautionary language in this Form 10-K, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from those projected. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

We are a medical device company with approvals to commercially launch our product, the Maestro Rechargeable System, in the United States, Australia, the European Economic Area and other countries that recognize the European CE Mark. We are focused on the design and development of devices that use neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders. Our proprietary neuroblocking technology, which we refer to as vBloc Therapy, is designed to intermittently block the vagus nerve using high frequency, low energy, electrical impulses. We have a limited operating history and only recently received U.S. Food and Drug Administration (FDA) approval to sell our product in the United States. In addition, we have regulatory approval to sell our product in Australia, the European Economic Area and other countries that recognize the European CE Mark and do not have any other source of revenue. We were incorporated in Minnesota on December 19, 2002 and later reincorporated in Delaware on July 22, 2004. We have devoted substantially all of our resources to the development and commercialization of our Maestro Rechargeable System.

The Maestro Rechargeable System, our initial product, uses vBloc Therapy to limit the expansion of the stomach, help control hunger sensations between meals, reduce the frequency and intensity of stomach contractions and produce a feeling of early and prolonged fullness. We believe the Maestro Rechargeable System offers obese patients a minimally-invasive treatment that can result in significant, durable and sustained weight loss. We believe that our Maestro Rechargeable System allows bariatric surgeons to offer a new option to obese patients who are concerned about the risks and complications associated with currently available anatomy-altering, restrictive or malabsorptive surgical procedures.

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, for the treatment of adult patients with obesity who have a Body Mass Index (BMI) of at least 40 to 45 kg/m2, or a BMI of at least 35 to 39.9 kg/m2 with a related health condition such as high blood pressure or high cholesterol levels, and who have tried to lose weight in a supervised weight management program and failed within the past five years. We have begun a controlled commercial launch at select bariatric centers of excellence in the United States and had our first commercial sales in 2015. During 2015, we started the process of building a sales force and a controlled expansion of our operations and recently hired three new executives in January 2016 to oversee this expansion. The direct sales force is supported by field technical managers who provide training, technical and other support services to our customers. Throughout 2015 our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven bariatric centers of excellence that met our certification criteria, which led to the training and certification of over 50 centers and 75 surgeons in implanting and administering vBloc Therapy. We plan to build on these efforts in 2016 through geography and self-pay patient focused direct-to-patient marketing, key opinion leader and center specific partnering, and a multi-faceted reimbursement strategy. To date, we have relied on, and anticipate that we will continue to rely on, third-party manufacturers and suppliers for the production of our Maestro Rechargeable System.

Data from our ReCharge trial was used to support the premarket approval (PMA) application for the Maestro Rechargeable System, submitted to the FDA in June 2013. The ReCharge trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial testing the effectiveness and safety of vBloc Therapy utilizing our Maestro Rechargeable System. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or sham control groups. The sham control group received a non-functional device during the trial period. All patients were expected to participate in a standard weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. As announced, the ReCharge trial met its primary safety endpoint with a 3.7% serious adverse event rate. The safety profile at 12 months was further supported by positive cardiovascular signals including a 5.5 mmHg drop in systolic blood pressure, a 2.8 mmHg drop in diastolic blood pressure and a 3.6 bpm drop in average heart rate.

Although the trial did not meet its predefined co-primary efficacy endpoints, it did demonstrate in the intent to treat (ITT) population (n=239) a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% (approximately 10% total body weight loss (TBL)) for vBloc Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. In the per protocol population, the trial demonstrated an EWL of 26.3% for vBloc Therapy-treated patients, with 56.8% of patients achieving at least 20% EWL.

In the ReCharge trial, two-thirds of vBloc Therapy-treated patients achieved at least 5% TBL at 12 months. According to the Centers for Disease Control and Prevention (CDC), 5% TBL can have significant health benefits on obesity related risk factors, or comorbidities, including reduction in blood pressure, improvements in Type 2 diabetes and reductions in triglycerides and cholesterol. Further analysis of our data at 12 months showed a meaningful impact on these comorbidities as noted in the below table showing the improvements seen at 10% TBL, the average weight loss in vBloc Therapy-treated patients.

Risk Factor	10% TBL
Systolic BP (mmHg)	-9
Diastolic BP (mmHg)	-6
Heart Rate (bpm)	-6
Total Cholesterol (mg/dL)	-15
LDL (mg/dL)	-9
Triglycerides (mg/dL)	-41
HDL (mg/dL)	3
Waist Circumference (inches)	-7
HbA1c (%)	-0.5

We subsequently announced that vBloc Therapy-treated patients were maintaining their weight loss at 18 months and 24 months with an EWL of 23.5% and 21.1%, respectively. The trial’s positive safety profile also continued throughout this reported time period.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011 for the treatment of obesity. The CE Mark approval for our Maestro Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. In January 2012, the final Maestro Rechargeable System components were listed on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA). The costs and resources required to successfully commercialize the Maestro Rechargeable System internationally are currently beyond our capability. Accordingly, we intend to devote our near-term efforts toward mounting a successful system launch in the United States. We intend to explore select international markets to commercialize the Maestro Rechargeable System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates.

To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in our human clinical trials. We have also not observed any long-term problematic clinical side effects in any patients. In addition, data from our VBLOC-DM2 ENABLE trial outside the United States demonstrate that vBloc Therapy may hold promise in improving obesity-related comorbidities such as diabetes and hypertension. We are conducting, or plan to conduct, further studies in each of these comorbidities to assess vBloc Therapy’s potential in addressing multiple indications.

We recently commenced commercial operations in the United States, deriving revenues from our primary business activity in 2015. We expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our selling, general and administrative expenses to increase as we continue to add the infrastructure necessary to support our initial commercial sales, operate as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur operating losses for the next several years. We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments.

Our board of directors and stockholders approved a 1-for-15 reverse split of the Company's outstanding common stock that became effective after trading on January 6, 2016 (the Reverse Stock Split). The Reverse Stock Split did not change the par value of our stock or the number of preferred shares authorized by our Fifth Amended and Restated Certificate of Incorporation. An amendment to the Certificate of Incorporation was also approved in connection with the Reverse Stock Split to increase the number of shares of our common stock authorized for issuance to 150 million shares, effective January 6, 2016. All share and per share amounts have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, title or risk of loss has passed, the selling price is fixed or determinable and collection is reasonably assured. Products are sold through direct sales or medical device distributors and revenue is recognized upon sale to a bariatric center of excellence or a medical device distributor when no right of return or price protection exists. Terms of sales to international distributors are generally EXW, reflecting that goods are shipped "ex works," in which risk of loss is assumed by the distributor at the shipping point. A provision for returns is recorded only if product sales provide for a right of return. No provision for returns was recorded for the year ended December 31, 2015, as the product sales recorded did not provide for rights of return.

Inventory

From inception, inventory related purchases had been used for research and development related activities and had accordingly been expensed as incurred. In December 2011, we began receiving ARTG listings for components of the Maestro Rechargeable System from the Australian TGA, with the final components being listed on the ARTG in January 2012. As a result, we determined certain assets were recoverable as inventory beginning in December 2011 and have recorded a current inventory balance of $1,686,000 and $981,000 as of December 31, 2015 and 2014, respectively. We account for inventory at the lower of cost or market and record any long-term inventory as other assets in the consolidated balance sheets. There was $519,000 and $825,000 of long-term inventory as of December 31, 2015 and 2014, respectively.

Senior Amortizing Convertible Notes

The senior amortizing convertible notes issued in November 2015 (the Notes) include a conversion feature which requires bifurcation and liability classification and measurement, at fair value, and requires evaluation at each reporting period. Under Accounting Standards Codification (ASC) 825, Financial Instruments, the Financial Accounting Standards Board (FASB) provides an alternative to bifurcation and companies may instead elect fair value measurement for the entire instrument, including the debt and conversion feature. We have elected the fair value alternative in order to simplify our accounting and reporting of the senior amortizing convertible notes upon issuance. The fair value of these senior amortizing convertible notes is re-measured at each financial reporting period, with any changes in fair value being recognized as a component of other income (expense) in the consolidated statements of operations.

We have concluded that the fair value of the Notes at issuance is equal to the gross proceeds received less the fair value of the warrants issued in conjunction with the Notes. The fair value of the warrants is recorded as a discount to the Notes and amortized to interest expense following the effective interest rate method over the term of the Notes.

On December 31, 2015, the fair value of the outstanding Notes was determined to be $1.3 million using a Binomial Lattice model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 57.5%; (3) risk-free interest rate of 1.11%; (4) remaining contractual term of 1.86 years; and (5) fair value of our common stock of $1.95 per share.

Common Stock Warrant Liability

Common stock warrants that were issued in connection with the July 8, 2015 public offering and the Notes are classified as a liability in the consolidated balance sheets, as the common stock warrants issued provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair value of these common stock warrants is re-measured at each financial reporting period and immediately before exercise, with any changes in fair value being recognized as a component of other income (expense) in the consolidated statements of operations.

The fair value of our common stock warrant liability is calculated using a Black-Scholes valuation model. The common stock warrants issued July 8, 2015 had a fair value of $2.8 million and $6.0 million on December 31, 2015 and July 8, 2015, respectively. The common stock warrants issued November 9, 2015 had a fair value of $118,000 and $169,000 on December 31, 2015 and November 9, 2015, respectively. The fair value was calculated using the following assumptions:

	July 2015 Warrants		November 2015 Warrants	
	December 31, 2015	July 8, 2015	December 31, 2015	November 9, 2015
Risk-free interest rates	1.31%	0.91%	1.76%	1.75%
Expected life	36 months	42 months	58 months	60 months
Expected dividends	0%	0%	0%	0%
Expected volatility	97.94%	89.89%	86.27%	84.85%

Stock-Based Compensation

We account for share-based payments using the fair value method, which requires compensation expense to be recognized using a fair-value-based method for costs related to all share-based payments including stock options. Companies are required to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. Calculating stock-based compensation expense requires the input of highly subjective assumptions, which represent our best estimates and involve inherent uncertainties and the application of management's judgment. Estimates of stock-based compensation expenses are significant to our consolidated financial statements, but these expenses are based on the Black-Scholes pricing model and will never result in the payment of cash by us. All option grants are expensed on a straight-line basis over the vesting period.

The application of share-based payment principles may be subject to further interpretation and refinement over time. There are significant differences among option valuation models, and this may result in a lack of comparability with other companies that use different models, methods and assumptions. If factors change and we employ different assumptions in the application of share-based payment accounting in future periods, or if we decide to use a different valuation model, the compensation expense that we record in the future may differ significantly from what we have recorded in the current period and could materially affect our operating loss, net loss and net loss per share.

The fair value method is applied to all share-based payment awards issued to employees and where appropriate, nonemployees, unless another source of literature applies. When determining the measurement date of a nonemployee's share-based payment award, the Company measures the stock options at fair value and remeasures such stock options to the current fair value until the performance date has been reached. For stock options granted to nonemployees, the fair value of the stock options is estimated using the Black-Scholes valuation model. This model utilizes the estimated fair value of common stock and requires that, at the date of grant and each subsequent reporting period until the services are completed or a significant disincentive for nonperformance occurs, we make assumptions with respect to the expected term of the option, the volatility of the fair value of our common stock, risk free interest rates and expected dividend yields of our common stock. Different estimates of volatility and expected life of the option could materially change the value of an option and the resulting expense.

Net Operating Losses and Tax Credit Carryforwards

At December 31, 2015, we had federal net operating loss carryforwards of approximately $117.0 million. These net operating loss carryforwards will expire in varying amounts from 2022 through 2035, if not utilized. The Internal Revenue Code (IRC) imposes restrictions on the utilization of various carryforward tax attributes in the event of a change in ownership of the Company, as defined by IRC Section 382. In addition, IRC Section 382 may limit our built-in items of deduction, including capitalized start-up costs and research and development costs. During 2011, we completed an IRC Section 382 review and the results of this review indicate ownership changes have occurred which would cause a limitation on the utilization of carryforward attributes. Our gross net operating loss carryforwards, start-up costs and research and development credits are all subject to limitation. Under these tax provisions, the limitation is applied first to any built-in losses, then to any net operating losses and then to any general business credits. It is likely that ownership changes have occurred since we completed our IRC Section 382 review in 2011 and could result in further limitations on the utilization of carryforward attributes. A valuation allowance has been established to reserve for the potential benefits of the remaining carryforwards and tax credits in our consolidated financial statements to reflect the uncertainty of future taxable income required to utilize available tax loss carryforwards and other deferred tax assets.

Financial Overview

Revenue

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, and have begun a controlled commercial launch at select bariatric centers of excellence in the United States. In 2015 we trained and certified over 50 centers and 75 surgeons in implanting and administering vBloc Therapy. We had our first commercial sales within the United States in 2015 and for the year ended December 31, 2015 we recognized $292,000 in revenue.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011 for the treatment of obesity, which enables commercialization in the European Economic Area and other countries that recognize the European CE Mark. The CE Mark approval for our Maestro Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. In January 2012, the final Maestro Rechargeable System components were listed on the ARTG by the Australian TGA. We have entered into exclusive, multi-year agreements with Device Technologies Australia Pty Limited and Bader Sultan & Brothers

Co. W.L.L., for commercialization and distribution of the Maestro Rechargeable System in Australia and the Gulf Coast Countries of the Middle East, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates, respectively. We made our first commercial shipments to Device Technologies Australia Pty Limited and Bader Sultan & Brothers Co. W.L.L. during the year ended December 31, 2012 and recognized $311,000 in revenue. We have not generated revenue from commercial sales outside of the United States since 2012.

Any revenue from initial sales of a new product in the United States or internationally is difficult to predict and in any event will only modestly reduce our continued losses resulting from our research and development and other activities.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of compensation for executive, finance, market development and administrative personnel, including stock-based compensation. Other significant expenses include costs associated with attending medical conferences, professional fees for legal services, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, and accounting services, cash management fees, consulting fees and travel expenses.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development, quality assurance and clinical and regulatory expenses, incurred in the development of our Maestro Rechargeable System. Research and development expenses also include employee compensation, including stock-based compensation, consulting services, outside services, materials, clinical trial expenses, including supplies, devices, explants and revisions, depreciation and travel. We expense research and development costs as they are incurred.

Results of Operations

Comparison of the Years Ended December 31, 2015 and 2014

Sales. Sales were $292,000 for the year ended December 31, 2015, compared to no sales for the year ended December 31, 2014. The increase of $292,000 is the result of receiving FDA approval on January 14, 2015 and commencing a controlled commercial launch of the Maestro Rechargeable System at select bariatric centers of excellence in the United States.

Cost of Goods Sold. Cost of goods sold were $125,000 for the year ended December 31, 2015, compared to no cost of goods sold for the year ended December 31, 2014. Gross margin was 57.2% for the year ended December 31, 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $19.9 million for the year ended December 31, 2015, compared to $14.6 million for the year ended December 31, 2014. The increase of $5.3 million, or 36.6%, was primarily due to increases of $2.1 million, $1.7 million, $1.0 million and $505,000 in payroll-related expenses, professional services, employee stock-based compensation and travel, respectively. The increases in payroll-related expenses, professional services and travel are primarily the result of receiving FDA approval on January 14, 2015 and beginning a controlled commercial launch at select bariatric centers of excellence in the United States. The increase in payroll-related expenses is also the result of a special one-time bonus and an increase in the 2014 management incentive plan accrual in recognition of achieving FDA approval on January 14, 2015. The increase in employee stock-based compensation is also a result of stock option grants made in recognition of the receipt of FDA approval and in connection with new hires in 2015.

Research and Development Expenses. Research and development expenses were $8.1 million for the year ended December 31, 2015, compared to $11.0 million for the year ended December 31, 2014. The decrease of

$2.9 million, or 26.2%, was primarily due to decreases of $2.3 million, $254,000, $171,000 and $160,000 in professional services, payroll-related expenses, devices and travel. Professional services in 2014 were primarily related to preparation for the advisory panel meeting with the FDA, which was held June 17, 2014. Decreases in payroll-related expenses, devices and travel were primarily the result of decreased emphasis in research and development as efforts were focused on the commercial launch as a result of receiving FDA approval on January 14, 2015.

Interest Expense. Interest expense was $939,000 for the year ended December 31, 2015, compared to $530,000 for the year ended December 31, 2014. The increase of $409,000, or 77.1%, is primarily due to $532,000 and $33,000 of financing costs that were assigned to the common stock warrants issued with the July 8, 2015 financing and the Notes, respectively, both being recognized immediately as interest expense as the warrants are exercisable upon issuance, together with a $187,000 success fee paid to Silicon Valley Bank as a result of achieving FDA approval on January 14, 2015. These increases were offset by a reduction of interest expense due to the declining principal balance through monthly principal and interest loan payments that began on April 1, 2013.

Change in Value of Warrant Liability. The value of the common stock warrant liability decreased $3.3 million for the year ended December 31, 2015, compared to no change for the year ended December 31, 2014. Common stock warrant liabilities were recorded on July 8, 2015 and November 9, 2015 as the common stock warrants issued with the July 8, 2015 public offering and with the Notes provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair market value was calculated using the Black-Scholes valuation model, which resulted in $3.2 million and $51,000 decreases for the year ended December 31, 2015 for the common stock warrants issued with the July 8, 2015 public offering and the Notes, respectively as our stock price decreased from $5.55 on July 8, 2015 and $2.55 on November 9, 2015 to $1.95 on December 31, 2015.

Comparison of the Years Ended December 31, 2014 and 2013

Sales. There were no sales for the years ended December 31, 2014 and 2013, which was primarily the result of focusing our resources on the U.S. regulatory approval process.

Cost of Goods Sold. There were no cost of goods sold for the years ended December 31, 2014 and 2013.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $14.6 million for the year ended December 31, 2014, compared to $13.7 million for the year ended December 31, 2013. The increase of $903,000, or 6.6%, was primarily due to increases of $586,000, $214,000 and $49,000 in payroll-related expenses, employee stock-based compensation and travel costs, respectively. The increase in payroll-related expenses was primarily the result of a special one-time bonus in recognition of the Advisory Panel vote regarding the safety, efficacy and benefit/risk profile of our Maestro Rechargeable System that occurred on June 17, 2014 (the Special Bonus). The increase in employee stock-based compensation was primarily the result of stock option grants made to management on May 31, 2013 and new hires in 2014. The increase in travel costs was primarily related to preparation for the Advisory Panel meeting.

Research and Development Expenses. Research and development expenses were $11.0 million for the year ended December 31, 2014, compared to $11.1 million for the year ended December 31, 2013. The decrease of $44,000, or 0.4%, was primarily due to decreases of $1.1 million in professional services offset by increases of $458,000, $202,000, $180,000 and $136,000 in payroll-related expenses, device costs, travel costs and employee stock-based compensation expense, respectively. The decrease in professional services was primarily related to costs associated with the 2013 unblinding of the ReCharge trial and the use of engineering consultants in 2013 during the PMA submission process that were not required in 2014. The increase in payroll-related expenses was primarily the result of the Special Bonus. The increase in device costs was primarily related to conversions to active devices, on-going clinical trial support, inventory valuation adjustments and commercialization process development and validation efforts. The increase in travel costs was primarily related to preparation for the Advisory Panel meeting. The increase in employee stock-based compensation was primarily the result of stock option grants made to management on May 31, 2013.

Interest Expense. Interest expense was $530,000 for the year ended December 31, 2014, compared to $932,000 for the year ended December 31, 2013. The decrease of $402,000, or 43.1%, was the result of a reduction in the loan principal balance through monthly principal and interest loan payments beginning April 1, 2013.

Liquidity and Capital Resources

As of December 31, 2015, we had $7.9 million in cash and cash equivalents. Of this amount $2.8 million was invested in short-term money market funds that are not considered to be bank deposits and are not insured or guaranteed by the Federal Deposit Insurance Company or other government agency. These money market funds seek to preserve the value of the investment at $1.00 per share; however, it is possible to lose money investing in these funds. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. At times, such deposits may be in excess of insured limits. We have not experienced any losses on our deposits of cash and cash equivalents.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of December 31, 2015, we had $7.9 million of cash and cash equivalents to fund our anticipated operations through 2016. On November 4, 2015 we entered into a securities purchase agreement with institutional investors to issue $25.0 million of the Notes along with the accompanying warrants. $1.5 million of the Notes was funded at the initial closing on November 9, 2015. An additional $11.0 million of the Notes was funded at the second closing on January 11, 2016, with the remaining $12.5 million to be funded at the third closing. Additionally, we have agreed that we will not, for a period of one year after the first closing, issue any further securities, other than certain excluded securities (further described below). Our anticipated operations include plans that consider the controlled commercial launch of vBloc Therapy, delivered via the Maestro Rechargeable System, which was approved by the FDA on January 14, 2015. We believe that we have the flexibility to manage the growth of our expenditures and operations. In order to accelerate the execution of our business plans we may need to raise additional funds.

Loan and Security Agreement

On April 16, 2012, we entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank (SVB) pursuant to which SVB agreed to make term loans in an aggregate principal amount of up to $20.0 million ($10.0 million of which was not available as we did not meet the predefined primary efficacy measures of the ReCharge trial and did not meet certain financial objectives for 2012), on the terms and conditions set forth in the Loan Agreement.

Pursuant to the Loan Agreement, a term loan was funded in the aggregate principal amount of $10.0 million on April 23, 2012, a portion of which was used to repay in full outstanding debt of approximately $4.7 million. The term loan required interest only payments monthly through March 31, 2013, followed by 30 equal payments of principal in the amount of $333,333 plus accrued interest beginning on April 1, 2013 and ending on September 1, 2015, payable monthly. Amounts borrowed under the Loan Agreement bear interest at a fixed annual rate equal to 8.0%. We entered into a First Amendment (the First Amendment) to the Loan Agreement on May 9, 2013 pursuant to which we agreed to new financial covenants.

The First Amendment eliminated the financial covenants that required us to generate certain minimum amounts of revenue from the sale of our Maestro Rechargeable System and to implant certain minimum numbers of Maestro Rechargeable Systems during cumulative quarterly measurement periods beginning with the period ended March 31, 2013 and ending with the period ended June 30, 2015. It also removed SVB’s ability to require us to maintain a restricted cash balance of $7.5 million in an SVB account as a result of not meeting the predefined primary efficacy measures of the ReCharge trial.

The First Amendment added two new financial covenants, one of which required us to receive cumulative aggregate proceeds of at least $5.0 million by November 15, 2013 and $10.0 million by April 15, 2014 from new capital transactions, both of which were fulfilled. The second financial covenant required us to maintain a liquidity ratio (unrestricted cash divided by outstanding debt) of at least 1.25:1.00 until we received FDA approval for the Maestro Rechargeable System on January 14, 2015, at which point it was reduced to 0.75:1.00. The First Amendment did not change the interest rate or the amortization structure. A 5.0% final payment fee of $500,000 was due and paid on September 1, 2015. We also paid SVB a $187,000 success fee as a result of receiving FDA approval for the Maestro Rechargeable System. The final payment related to the Loan Agreement, as amended, was paid on September 1, 2015.

Equity Distribution Agreement—July 2013

On July 31, 2013, we entered into an equity distribution agreement with Canaccord Genuity Inc. (Canaccord) to sell shares of our common stock having aggregate gross sales proceeds of up to $20.0 million, from time to time, through an ATM under which Canaccord acted as our sales agent (the Canaccord ATM). We determined, at our sole discretion, the timing and number of shares sold under the Canaccord ATM. We paid Canaccord a commission for its services in acting as agent in the sale of common stock equal to 2.0% of the gross sales price per share of all shares sold through it as agent under the equity distribution agreement. The equity distribution agreement with Canaccord was terminated effective June 10, 2014. As of the termination date, we had sold a total of 794,933 shares under the Canaccord ATM at a weighted-average selling price of $25.01 per share for gross proceeds of $19.9 million before deducting offering expenses.

Sales Agreement—June 2014

On June 13, 2014, we entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of our common stock having aggregate gross sales proceeds of up to $25.0 million, from time to time, through an ATM under which Cowen will act as our sales agent (the Cowen ATM). We will determine, at our sole discretion, the timing and number of shares to be sold under the Cowen ATM. We will pay Cowen a commission for its services in acting as agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of December 31, 2015, we have sold 367,903 shares under the Cowen ATM at a weighted-average selling price of $20.60 per share for gross proceeds of $7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM subsequent to December 31, 2015 through March 28, 2016. We are restricted from issuing shares under the Cowen ATM per the terms of the Notes (further described below).

Sales Agreement—July 2015

On July 8, 2015, we closed a public offering, where we sold 2,133,333 units at an aggregate price of $7.50 per unit, for gross proceeds of $16.0 million, before deducting estimated offering expenses of approximately $1.4 million, of which $532,000 was assigned to the warrants. Each unit consisted of: (A)(i) one share of common stock or (ii) one pre-funded Series C warrant to purchase one share of common stock at an exercise price equal to $7.50 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price equal initially to $9.00 per share (Series A Warrant). Each purchaser of a unit could elect to receive a Series C Warrant in lieu of a share of common stock. No Series C Warrants were issued.

The Series A Warrants are exercisable for a period of 42 months from the closing date of the public offering. The exercise price and number of shares of common stock issuable on the exercise of the Series A Warrants are subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of the Series A Warrant does not have the right to exercise any portion of the Series A Warrant if the holder, together with its affiliates, would, subject to certain limited exceptions, beneficially own in excess of 9.99% of our common stock outstanding immediately after the exercise or 4.99% as may be elected by the purchaser.

The exercise price of the Series A Warrants issued July 8, 2015 was reduced to $2.40 per share on November 9, 2015 as a result of the issuance of the Notes and was further reduced to $1.50 per share on December 31, 2015 and $0.97 per share on January 29, 2016 after the first and second installment payments on the Notes were made.

Senior Amortizing Convertible Notes

On November 4, 2015, we entered into a securities purchase agreement (the Purchase Agreement) to issue and sell to four institutional investors 7% senior convertible notes due 2017 that are convertible into shares of our common stock at a price equal to $4.35 per share with an aggregate principal amount of $25.0 million. Each Note was sold with a warrant to purchase a share of common stock (the Warrants) with an exercise price of $4.65 per share. We issued and sold Notes and Warrants for aggregate total proceeds of $12.5 million in two separate closings and will issue and sell Notes and Warrants for aggregate total proceeds of $12.5 million in the third and final closing.

Description of the Notes

The Notes are payable in monthly installments, accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the First Closing (defined below), unless converted or redeemed earlier. The Notes may be repaid, at our election, in either cash or shares of our common stock at a discount to the then-current market price. The Notes are also convertible from time to time, at the election of the holders, into shares of our common stock at an initial conversion price of $4.35 per share. The conversion price was adjusted to $1.09 per share on January 29, 2016, the 16th trading day following the Reverse Stock Split, per the terms of the Notes.

The holder of each Note has the right to convert any portion of such Note unless the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the conversion, as such percentage ownership is determined in accordance with the terms of the Notes. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing us notice.

The first of the three closings (the First Closing) occurred on November 9, 2015. At the First Closing, we issued and sold Notes with an aggregate principal amount of $1.5 million, along with Warrants exercisable for 117,520 shares.

The second of the three closings (the Second Closing) occurred on January 11, 2016 after we received approval of the offering by our stockholders and the satisfaction of certain customary closing conditions. At the Second Closing, we issued and sold Notes with an aggregate principal amount of $11.0 million, along with Warrants exercisable for 861,842 shares.

At the final of the three closings (the Third Closing) we will issue and sell Notes with an aggregate principal amount of $12.5 million, along with Warrants exercisable for 979,366 shares.

The following table summarizes the installment amounts and additional conversions by the holders of the Notes through December 31, 2015:

	Principal	Interest	Total	Common Shares
Installment amount at December 31, 2015	$65,217	$23,651	$ 88,868	56,967
Holder conversions during the quarter ended December 31, 2015	18,261	2,375	20,636	13,228
	$83,478	$26,026	$109,504	70,195

Description of the Warrants

Each Warrant is exercisable immediately and for a period of 60 months from the date of the issuance of the Warrant. The Warrants entitle the holders of the Warrants to purchase, in aggregate, 1,958,728 shares of our common stock upon the completion of the Third Closing, subject to certain adjustments. The Warrants are initially exercisable at an exercise price equal to $4.65, subject to adjustment on the eighteen month anniversary of issuance, and certain other adjustments. The exercise price and number of shares of common stock issuable on the exercise of the Warrants is subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of each Warrant does not have the right to exercise any portion of such Warrant if the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing us notice.

The exercise price of the Warrants issued November 9, 2015 was reduced to $1.09 per share on January 29, 2016, the 16th trading day following the Reverse Stock Split, per the terms of the Warrants. The exercise price of the Warrants issued January 11, 2016 remains $4.65 per share per the terms of the Warrants. All of the Warrants issued with the Notes remain subject to adjustment on the eighteen month anniversary of issuance.

Net Cash Used in Operating Activities

Net cash used in operating activities was $22.6 million, $19.4 million and $18.4 million for the years ended December 31, 2015, 2014 and 2013, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, less noncash expenses for stock-based compensation, depreciation and amortization, change in value of warrant liability, and partially offset by changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities was $39,000, $89,000 and $216,000 for the years ended December 31, 2015, 2014 and 2013, respectively. Net cash used in investing activities is primarily related to the purchase of property and equipment. For the year ended December 31, 2013, net cash used in investing activities also consisted of a decrease in restricted cash of $200,000 due to the expiration of the requirement in our lease agreement with Roseville Properties Management Company to maintain an irrevocable, unconditional, standby letter of credit until October 1, 2013.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $19.0 million, $7.8 million and $19.6 million for the years ended December 31, 2015, 2014 and 2013, respectively. For the year ended December 31, 2015, net cash provided by financing activities was primarily the result of gross proceeds of $16.0 million from the July 8, 2015 public offering, ATM draws of $6.7 million and $1.5 million in gross proceeds from the issuance of the Notes on November 9, 2015. These increases were offset by $1.7 million in financing costs, $477,000 of debt issuance costs and principal repayments of $3.0 million on our long-term debt.

For the year ended December 31, 2014, net cash provided by financing activities was primarily the result of gross proceeds from ATM draws of $9.8 million and proceeds of $2.2 million from the exercise of common stock warrants. These increases were offset by $285,000 in financing costs and $4.0 million in principal repayments on our long-term debt.

For the year ended December 31, 2013, net cash provided by financing activities was primarily the result of a public offering that resulted in gross proceeds of $13.1 million for the issuance of common stock and common stock warrants and gross proceeds from ATM draws of $11.0 million, offset by $1.4 million in financing costs and principal repayments of $3.0 million on our long-term debt.

Operating Capital and Capital Expenditure Requirements

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, and have begun a controlled commercial launch at select bariatric centers of excellence in the United States. We had our first commercial sales within the United States in 2015 and for the year ended December 31, 2015 we recognized $292,000 in revenue. We anticipate that we will continue to incur net losses for the next several years as we develop our products, commercialize our Maestro Rechargeable System, develop the corporate infrastructure required to sell our products, operate as a publicly-traded company and pursue additional applications for our technology platform.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of December 31, 2015, we had $7.9 million of cash and cash equivalents to fund our anticipated operations through 2016. On November 4, 2015 we entered into a securities purchase agreement with institutional investors to issue $25.0 million of Notes along with the accompanying warrants. $1.5 million of the Notes was funded at the initial closing on November 9, 2015. An additional $11.0 million of the Notes was funded at the second closing on January 11, 2016, with the remaining $12.5 million to be funded at the third closing. Additionally, we have agreed that we will not, for a period of one year after the first closing, issue any further securities, other than certain excluded securities. Our anticipated operations include plans that consider the controlled commercial launch of vBloc Therapy, delivered via the Maestro Rechargeable System, which was approved by the FDA on January 14, 2015. We believe that we have the flexibility to manage the growth of our expenditures and operations. In order to accelerate the execution of our business plans we may need to raise additional funds. Obtaining funds through the sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. The sale of additional equity may require us to obtain approval from our stockholders to increase the number of shares of common stock we have authorized under our certificate of incorporation. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to products or proprietary technologies, or grant licenses on terms that are not favorable.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of products and the cost to commercialize our products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part I, Item 1A, *Risk Factors*, of our Annual Report on Form 10-K. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our Maestro Rechargeable System, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete the development of the products and successfully deliver a commercial product to the market. Our future capital requirements will depend on many factors, including, but not limited to, the following:

- the cost and timing of establishing sales, marketing and distribution capabilities;

- the cost of establishing clinical and commercial supplies of our Maestro Rechargeable System and any products that we may develop;
- the rate of market acceptance of our Maestro Rechargeable System and vBloc Therapy and any other product candidates;
- the cost and timing of obtaining adequate coding, coverage or payment levels for our Maestro Rechargeable System and vBloc Therapy by government healthcare programs and other third-party payors;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the effect of competing products and market developments;
- the cost of explanting clinical devices;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- any revenue generated by sales of our Maestro Rechargeable System or our future products;
- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals;
- the cost of any recalls or other field actions required either by us or by regulatory bodies in those countries in which we market our products; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Contractual Obligations

On August 25, 2015, we entered into an amendment extending the term of our operating lease for three years until September 30, 2018, with monthly base rent ranging from $18,925 to $20,345. The following table summarizes our contractual obligations as of December 31, 2015 and the effect those obligations are expected to have on our financial condition and liquidity position in future periods:

	Payments Due By Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Operating lease	$650,085	$ 229,233	$420,852	$ —	$ —
Total contractual cash obligations	$650,085	$ 229,233	$420,852	$ —	$ —

The table above reflects only payment obligations that are fixed and determinable based on our current agreements. Our operating lease commitment relates to our corporate headquarters in St. Paul, Minnesota. The above table does not include the Notes due to the variability in timing and the option to settle the Notes through the issuance of shares.

Off-balance-sheet Arrangements

Since our inception, we have not engaged in any off-balance-sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities as defined by rules enacted by the SEC and FASB, and accordingly, no such arrangements are likely to have a current or future effect on our financial position, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

In April 2015, FASB issued *Simplifying the Presentation of Debt Issuance Costs, (Accounting Standards Update No. 2015-03 (ASU 2015-03))*, which changes the presentation of debt issuance costs in the financial statements. Under the ASU, an entity presents such costs in the balance sheet as a direct deduction from the recognized debt liability rather than as an asset. Amortization of the costs is reported as interest expense. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2015. We have evaluated the impact of adopting ASU 2015-03 and do not believe the new guidance will have a material effect on our financial position, results of operations or cash flows.

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))*, which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2017. We are currently evaluating the impact of adopting ASU 2014-09 on our consolidated financial statements.

Various other accounting standards and interpretations have been issued with 2015 effective dates and effective dates subsequent to December 31, 2015. We have evaluated the recently issued accounting pronouncements that are currently effective or will be effective in 2015 and believe that none of them have had or will have a material effect on our financial position, results of operations or cash flows.

ITEM 7A. ***QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK***

Our exposure to market risk is confined to our cash and cash equivalents. As of December 31, 2015 we had $7.9 million in cash and cash equivalents. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio, if any, are not leveraged, are classified as either available for sale or held-to-maturity and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk.

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ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA***

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
EnteroMedics Inc.
St. Paul, Minnesota

We have audited the accompanying consolidated balance sheets of EnteroMedics Inc. and subsidiary (the “Company”) as of December 31, 2015 and 2014 and the related consolidated statements of operations, comprehensive loss, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota
March 28, 2016

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ENTEROMEDICS INC.

Consolidated Balance Sheets

	December 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,927,240	$ 11,619,167
Accounts receivable	57,928	2,812
Inventory	1,686,324	980,519
Prepaid expenses and other current assets	831,495	421,673
Total current assets	10,502,987	13,024,171
Property and equipment, net	326,296	481,522
Other assets	757,802	879,905
Total assets	$ 11,587,085	$ 14,385,598
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable (net of discounts of $23,836 at December 31, 2014)	$ —	$ 2,976,164
Current portion of convertible notes payable	717,391	—
Accounts payable	172,050	399,336
Accrued expenses	3,595,415	3,830,766
Accrued interest payable	1,172	514,937
Total current liabilities	4,486,028	7,721,203
Convertible notes payable, less current portion (net of discounts of $149,340 at December 31, 2015)	549,791	—
Common stock warrant liability	2,877,817	—
Total liabilities	7,913,636	7,721,203
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, $0.01 par value; 13,333,333 shares authorized; 7,163,820 and 4,638,030 shares issued and outstanding at December 31, 2015 and 2014, respectively	71,638	46,380
Additional paid-in capital	281,182,349	258,699,806
Accumulated deficit	(277,580,538)	(252,081,791)
Total stockholders' equity	3,673,449	6,664,395
Total liabilities and stockholders' equity	$ 11,587,085	$ 14,385,598

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

Consolidated Statements of Operations

	Years ended December 31, 2015	2014	2013
Sales	$ 292,000	$ —	$ —
Cost of goods sold	125,047	—	—
Gross profit	166,953	—	—
Operating expenses:			
Selling, general and administrative	19,892,424	14,561,656	13,658,824
Research and development	8,141,323	11,031,619	11,075,493
Total operating expenses	28,033,747	25,593,275	24,734,317
Operating loss	(27,866,794)	(25,593,275)	(24,734,317)
Other income (expense):			
Interest income	1,819	3,331	5,717
Interest expense	(939,182)	(530,222)	(932,364)
Change in value of warrant liability	3,295,536	—	—
Other, net	9,874	(8,554)	(119,695)
Net loss	$ (25,498,747)	$ (26,128,720)	$ (25,780,659)
Net loss per share—basic and diluted	$ (4.27)	$ (5.78)	$ (7.03)
Shares used to compute basic and diluted net loss per share	5,970,282	4,524,428	3,667,328

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

Consolidated Statements of Comprehensive Loss

	Years ended December 31, 2015	2014	2013
Net loss	$ (25,498,747)	$ (26,128,720)	$ (25,780,659)
Comprehensive loss	$ (25,498,747)	$ (26,128,720)	$ (25,780,659)

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance, December 31, 2012	2,789,551	$ 27,896	$ 212,019,187	$ (200,172,412)	$ 11,874,671
Net loss	—	—	—	(25,780,659)	(25,780,659)
Employee stock-based compensation expense	—	—	5,788,249	—	5,788,249
Nonemployee stock-based compensation expense	—	—	166,679	—	166,679
Issuance of common stock and warrants to purchase approximately 367,175 shares of common stock in registered public offering in February 2013 for cash at an aggregate price of $14.25 per share and corresponding warrant, net of financing costs of $1,066,200	918,000	9,180	12,006,120	—	12,015,300
Issuance of common stock through "at-the-market" equity offerings beginning in September 2013 for cash from $16.50 to $31.54 per share, net of financing costs of $381,981	527,853	5,279	10,581,838	—	10,587,117
Exercise of 1,353 warrants in 2013 for cash from $17.10 to $28.50 per share	1,353	14	28,006	—	28,020
Balance, December 31, 2013	4,236,757	$ 42,369	$ 240,590,079	$ (225,953,071)	$ 14,679,377
Net loss	—	—	—	(26,128,720)	(26,128,720)
Employee stock-based compensation expense	—	—	6,138,384	—	6,138,384
Nonemployee stock-based compensation expense	—	—	181,323	—	181,323
Issuance of common stock through "at-the-market" equity offerings in 2014 for cash from $16.54 to $38.06 per share, net of financing costs of $284,698	312,731	3,126	9,548,640	—	9,551,766
Exercise of 88,542 warrants in 2014 for cash from $17.10 to $32.85 per share	88,542	885	2,241,380	—	2,242,265
Balance, December 31, 2014	4,638,030	$ 46,380	$ 258,699,806	$ (252,081,791)	$ 6,664,395
Net loss	—	—	—	(25,498,747)	(25,498,747)
Employee stock-based compensation expense	—	—	6,974,489	—	6,974,489
Nonemployee stock-based compensation expense	—	—	(34,712)	—	(34,712)
Issuance of common stock through "at-the-market" equity offerings in 2015 for cash from $16.60 to $22.70 per share, net of financing costs of $259,560	322,262	3,223	6,389,149	—	6,392,372
Issuance of common stock, net of warrants to purchase approximately 2,133,316 shares of common stock valued at $6,003,932, in registered public offering in July 2015 for cash at an aggregate price of $7.50 per unit, net of financing costs of $929,920	2,133,333	21,333	9,044,815	—	9,066,148
Issuance of common stock for payments made in shares on convertible notes payable	70,195	702	108,802	—	109,504
Balance, December 31, 2015	7,163,820	$ 71,638	$ 281,182,349	$ (277,580,538)	$ 3,673,449

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

Consolidated Statements of Cash Flows

	Years ended December 31,		
	2015	2014	2013
Cash flows from operating activities:			
Net loss	$ (25,498,747)	$ (26,128,720)	$ (25,780,659)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	188,606	188,904	174,629
Loss on sale of equipment	885	—	—
Stock-based compensation	6,939,777	6,319,707	5,954,928
Amortization of commitment fees, debt issuance costs and original issue discount	825,735	123,068	199,592
Change in value of warrant liability	(3,295,536)	—	—
Other, net	—	—	8,030
Change in operating assets and liabilities:			
Accounts receivable	(55,116)	14,930	26,634
Inventory	(705,805)	147,422	143,266
Prepaid expenses and other current assets	(409,822)	125,071	24,910
Other assets	349,709	(74,372)	246,764
Accounts payable	(222,636)	267,356	60,732
Accrued expenses	(235,351)	(355,294)	512,451
Accrued interest payable	(487,739)	(11,735)	2,994
Net cash used in operating activities	(22,606,040)	(19,383,663)	(18,425,729)
Cash flows from investing activities:			
Decrease in restricted cash	—	—	200,000
Purchases of property and equipment	(38,915)	(88,680)	(416,010)
Net cash used in investing activities	(38,915)	(88,680)	(216,010)
Cash flows from financing activities:			
Proceeds from warrants exercised	—	2,242,265	28,020
Proceeds from sale of common stock and warrants for purchase of common stock	22,651,932	9,836,464	24,050,598
Common stock financing costs	(1,721,794)	(284,698)	(1,448,181)
Proceeds from convertible notes payable	1,500,000	—	—
Repayments on notes payable	(3,000,000)	(4,000,000)	(3,000,000)
Debt issuance costs	(477,110)	—	—
Net cash provided by financing activities	18,953,028	7,794,031	19,630,437
Net (decrease) increase in cash and cash equivalents	(3,691,927)	(11,678,312)	988,698
Cash and cash equivalents:			
Beginning of period	11,619,167	23,297,479	22,308,781
End of period	$ 7,927,240	$ 11,619,167	$ 23,297,479
Supplemental disclosure:			
Interest paid	$ 601,185	$ 418,889	$ 729,778
Noncash investing and financing activities:			
Conversion of convertible notes and interest payable	$ 109,504	$ —	—

See accompanying notes to consolidated financial statements.

EnteroMedics Inc.

Notes to Consolidated Financial Statements

(1) Formation and Business of the Company

EnteroMedics Inc. (EnteroMedics or the Company) is developing implantable systems to treat obesity, metabolic diseases and other gastrointestinal disorders. The Company was incorporated in the state of Minnesota on December 19, 2002, originally as two separate legal entities, Alpha Medical, Inc. and Beta Medical, Inc., both of which were owned 100% by a common stockholder. Effective October 1, 2003, the two entities were combined and the combined entity changed its name to EnteroMedics Inc. The Company reincorporated in Delaware on July 22, 2004. The Company has devoted substantially all of its resources to recruiting personnel, developing its product technology, obtaining patents to protect its intellectual property, commercialization activities and raising capital and has recently commenced commercial operations in the United States deriving revenues from its primary business activity in 2015. The Company is headquartered in St. Paul, Minnesota.

EnteroMedics Europe Sárl (EnteroMedics Europe), a wholly owned subsidiary of the Company, was formed in January 2006. EnteroMedics Europe is a Swiss entity established as a means to conduct clinical trials in Switzerland. Upon establishment there were 20 shares of EnteroMedics Europe issued and outstanding with a par value of 1,000 Swiss Francs. EnteroMedics purchased 100% of the shares and then issued one share to a fiduciary agent. The one share is the property of EnteroMedics and is held by the fiduciary in a fiduciary capacity under terms of the Fiduciary Agreement. The functional currency of EnteroMedics Europe has been determined to be the U.S. Dollar.

The Company’s board of directors and stockholders approved a 1-for-15 reverse split (the Reverse Stock Split) of the Company’s outstanding common stock that became effective after trading on January 6, 2016. The Reverse Stock Split did not change the par value of the Company’s stock or the number of preferred shares authorized by the Company’s Fifth Amended and Restated Certificate of Incorporation. An amendment to the Certificate of Incorporation was also approved in connection with the Reverse Stock Split to increase the number of shares of the Company’s common stock authorized for issuance to 150 million shares, effective January 6, 2016. All share and per share amounts have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

EnteroMedics has incurred losses through December 31, 2015 and has not generated positive cash flows from operations. The Company expects such losses to continue into the foreseeable future as it continues to develop and commercialize its technologies. The Company may need to obtain additional financing and there can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. If adequate funds are not available, the Company may have to delay development or commercialization of products or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to commercialize.

(2) Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America. The Company’s fiscal year ends on December 31.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

EnteroMedics Inc.

Notes to Consolidated Financial Statements (Continued)

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany transactions and accounts have been eliminated in consolidation.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are primarily deposited in demand and money market accounts. At times, such deposits may be in excess of insured limits. Investments in money market funds are not considered to be bank deposits and are not insured or guaranteed by the federal deposit insurance company or other government agency. These money market funds seek to preserve the value of the investment at $1.00 per share; however, it is possible to lose money investing in these funds. The Company has not experienced any losses on its deposits of cash and cash equivalents.

The Company's products require approval from the U.S. Food and Drug Administration (FDA) or corresponding foreign regulatory agencies prior to commercial sales. The Company received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, and has begun a controlled commercial launch at select bariatric centers of excellence in the United States. The Maestro Rechargeable System has also received CE Mark and is listed on the Australian Register of Therapeutic Goods.

The medical device industry is characterized by frequent and extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often difficult to predict, and the outcome may be uncertain until the court has entered final judgment and all appeals are exhausted. The Company's competitors may assert that its products or the use of the Company's products are covered by U.S. or foreign patents held by them.

The Company's activities are subject to significant risk and uncertainties, including the ability to obtain additional financing and there can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. If adequate funds are not available, the Company may have to delay development or commercialization of products or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to commercialize.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. The Company's common stock warrants are required to be reported at fair value and the Company has elected to report its senior amortizing convertible notes at fair value. The fair values of common stock warrants and investments in debt and equity securities, if any, are disclosed in Note 4. The fair value of the Company's senior amortizing convertible notes is disclosed in Notes 4 and 9.

Common Stock Warrant Liability

Common stock warrants that were issued in connection with the July 8, 2015 public offering and the November 9, 2015 senior amortizing convertible notes are classified as a liability in the consolidated balance sheets, as the common stock warrants issued provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair value of these common stock warrants is re-measured at each financial reporting period and immediately before exercise, with any changes in fair value being recognized as a component of other income (expense) in the consolidated statements of operations.

Cash and Cash Equivalents

The Company considers highly liquid investments generally with maturities of 90 days or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates market value. The Company's cash equivalents are primarily in money market funds and certificates of deposit. The Company deposits its cash and cash equivalents in high-quality credit institutions.

Restricted Cash

The Company had $200,000 in a cash collateral money market account as of December 31, 2012. Pursuant to the Lease Agreement the Company entered into with Roseville Properties Management Company in July 2008, the Company was required to deliver to Roseville Properties an irrevocable, unconditional, standby letter of credit in the amount of $200,000 on the second anniversary of the commencement of lease payments. The irrevocable standby letter of credit was issued by Silicon Valley Bank, who required the Company to set up a restricted cash collateral money market account to fully secure the standby letter of credit. The fully secured standby letter of credit was maintained through October 1, 2013, per the terms of the lease agreement.

Short-Term Investments

The Company considers all investments with maturities greater than three months and less than one year at the time of purchase as short-term investments and classifies them as either available for sale or held to maturity. The Company also considers certain investments with maturities greater than one year but which are also held for liquidity purposes and are available for sale as short-term investments.

Available-for-sale securities are carried at fair value based on quoted market prices, with the unrealized gains and losses included in other comprehensive income within stockholders' equity in the consolidated balance sheets. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest and other income. Interest and dividends on securities classified as available for sale are included in interest income. The cost of securities sold is based on the specific identification method.

Short-term investments in debt securities which the Company has the positive intent and ability to hold to maturity are reported at cost, adjusted for premiums and discounts that are recognized in interest income, using the interest method, over the period to maturity. Unrealized losses on held-to-maturity securities reflecting a decline in value determined to be other than temporary are charged to income.

Inventory

The Company accounts for inventory at the lower of cost or market and records any long-term inventory as other assets in the consolidated balance sheets.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over their estimated useful lives of five to seven years for furniture and equipment and three to five years for computer hardware and software. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Upon retirement or sale, the cost and related accumulated depreciation or amortization are removed from the consolidated balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations. Repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value or estimates of future discounted cash flows. The Company has not identified any such impairment losses to date.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The Company has provided a full valuation allowance against the gross deferred tax assets as of December 31, 2015 and 2014 (see Note 12). The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the consolidated statements of operations.

Medical Device Excise Tax

On January 14, 2015, the Company received FDA approval for vBloc Therapy, delivered via the Maestro Rechargeable System, and starting in the second quarter of 2015 revenues were generated from sales in the United States. As a result, the Company is now required to pay a quarterly Medical Device Tax which is a part of the Affordable Care Act, which imposes a 2.3% excise tax on the sale of certain medical devices by device manufactures, producers or importers. The excise tax was effective on sales of devices made after December 31, 2012. The Company records the Medical Device Tax as an operating expense in the consolidated statements of operations. A moratorium was placed on the Medical Device Tax for 2016 and 2017.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a company during a period from transactions and other events and circumstances excluding transactions resulting from investment owners and distributions to owners. There was no difference from reported net loss for the years ended December 31, 2015, 2014 and 2013.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, title or risk of loss has passed, the selling price is fixed or determinable and collection is reasonably assured. Products are sold through direct sales or medical device distributors and revenue is recognized upon sale to a bariatric center of excellence or a medical device distributor when no right of return or price protection exists. Terms of sales to international distributors are generally EXW, reflecting that goods are shipped "ex works," in which risk of loss is assumed by the distributor at the shipping point. A provision for returns is recorded only if product sales provide for a right of return. No provision for returns was recorded for the year ended December 31, 2015, as the product sales recorded did not provide for rights of return.

EnteroMedics Inc.

Notes to Consolidated Financial Statements (Continued)

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses include, but are not limited to, product development, clinical trial expenses, including supplies, devices, explants and revisions, quality assurance, regulatory expenses, payroll and other personnel expenses, materials and consulting costs.

Patent Costs

Costs associated with the submission of a patent application are expensed as incurred given the uncertainty of the patents resulting in probable future economic benefits to the Company. Patent-related legal expenses included in general and administrative costs were $202,381, $338,055 and $296,575 for the years ended December 31, 2015, 2014 and 2013, respectively.

Derivative Instruments

The Company accounts for outstanding warrants that are not indexed to the Company's stock or warrants issued when the Company has insufficient authorized and unissued stock available to share settle the outstanding warrants as derivative instruments, which require that the warrants be classified as a liability and measured at fair value with changes in fair value recognized currently in earnings and recorded separately in the consolidated statements of operations. The Company did not have any such instruments during the years ended December 31, 2015, 2014 and 2013.

Stock-Based Compensation

The fair value method is applied to all share-based payment awards issued to employees and where appropriate, nonemployees, unless another source of literature applies. When determining the measurement date of a nonemployee's share-based payment award, the Company measures the stock options at fair value and remeasures such stock options to the current fair value until the performance date has been reached. All option grants are expensed on a straight-line basis over the vesting period.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is based on the weighted-average common shares outstanding during the period plus dilutive potential common shares calculated using the treasury stock method. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share. The Company's potential dilutive shares, which include outstanding common stock options and warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share for the years ended December 31, 2015, 2014 and 2013:

	Years ended December 31,		
	2015	2014	2013
Numerator:			
Net loss	$ (25,498,747)	$ (26,128,720)	$ (25,780,659)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares outstanding	5,970,282	4,524,428	3,667,328
Net loss per share—basic and diluted	$ (4.27)	$ (5.78)	$ (7.03)

EnteroMedics Inc.

Notes to Consolidated Financial Statements (Continued)

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	December 31,		
	2015	2014	2013
Stock options outstanding	1,535,418	843,563	778,998
Warrants to purchase common stock	3,841,276	1,613,133	1,703,183

Recently Issued Accounting Standards

In April 2015, the Financial Accounting Standards Board (FASB) issued *Simplifying the Presentation of Debt Issuance Costs*, *(Accounting Standards Update No. 2015-03 (ASU 2015-03))*, which changes the presentation of debt issuance costs in the financial statements. Under the ASU, an entity presents such costs in the balance sheet as a direct deduction from the recognized debt liability rather than as an asset. Amortization of the costs is reported as interest expense. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2015. The Company has evaluated the impact of adopting ASU 2015-03 and does not believe the new guidance will have a material effect on the Company's financial position, results of operations or cash flows.

In May 2014, FASB issued *Revenue from Contracts with Customers*, *Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))*, which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

Various other accounting standards and interpretations have been issued with 2015 effective dates and effective dates subsequent to December 31, 2015. The Company has evaluated the recently issued accounting pronouncements that are currently effective or will be effective in 2015 and believe that none of them have had or will have a material effect on the Company's financial position, results of operations or cash flows.

(3) Liquidity and Management's Plans

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has financed its operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of December 31, 2015, the Company had $7.9 million of cash and cash equivalents to fund its anticipated operations through 2016. On November 4, 2015 the Company entered into a securities purchase agreement with institutional investors to issue $25.0 million of senior amortizing convertible notes (the Notes) along with the accompanying warrants. $1.5 million of the Notes was funded at the first closing on November 9, 2015. An additional $11.0 million of the Notes was funded at the second closing on January 11, 2016, with the remaining $12.5 million to be funded at the third closing. Additionally, we have agreed that we will not, for a period of one year after the first closing, issue any further securities, other than certain excluded securities (further described in Note 9). The Company's anticipated operations include plans that consider the controlled commercial launch of vBloc Therapy, delivered via the Maestro Rechargeable System, which was approved by the FDA on January 14, 2015. The Company believes that it has the flexibility to manage the growth of its expenditures and operations.

EnteroMedics Inc.

Notes to Consolidated Financial Statements (Continued)

(4) Short-term Investments and Fair Value Measurements

Fair value of financial assets and liabilities is defined as the price that would be received to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy has been established that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

- Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active or model-derived valuations for which all significant inputs are observable, either directly or indirectly.
- Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable.

The Company's assets that are measured at fair value on a recurring basis are classified within Level 1 or Level 2 of the fair value hierarchy. The Company does not hold any assets that are measured at fair value using Level 3 inputs. The types of instruments the Company invests in that are valued based on quoted market prices in active markets may include U.S. treasury securities and money market funds. Such instruments are classified by the company within Level 1 of the fair value hierarchy. U.S. treasuries are valued using unadjusted quoted prices for identical assets in active markets that the Company can access.

The types of instruments the Company invests in that are valued based on quoted prices in less active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency include the Company's U.S. agency securities, commercial paper, U.S. corporate bonds and municipal obligations. Such instruments are classified by the Company within Level 2 of the fair value hierarchy. The Company values these types of assets using consensus pricing or a weighted average price, which is based on multiple pricing sources received from a variety of industry standard data providers (e.g. Bloomberg), security master files from large financial institutions, and other third-party sources. The multiple prices obtained are then used as inputs into a distribution-curve-based algorithm to determine the daily market price.

The Company did not hold any short-term investments classified as available for sale or held to maturity as of December 31, 2015 and 2014.

The fair value of the Company's common stock warrant liability is calculated using a Black-Scholes valuation model and is classified as Level 2 in the fair value hierarchy. The common stock warrants issued July 8, 2015 had a fair value of $2,759,583 and $6,003,932 on December 31, 2015 and July 8, 2015, respectively. The common stock warrants issued November 9, 2015 had a fair value of $118,234 and $169,421 on December 31, 2015 and November 9, 2015, respectively. The fair value was calculated using the following assumptions:

	July 2015 Warrants		November 2015 Warrants	
	December 31, 2015	July 8, 2015	December 31, 2015	November 9, 2015
Risk-free interest rates	1.31%	0.91%	1.76%	1.75%
Expected life	36 months	42 months	58 months	60 months
Expected dividends	0%	0%	0%	0%
Expected volatility	97.94%	89.89%	86.27%	84.85%

EnteroMedics Inc.

Notes to Consolidated Financial Statements (Continued)

The following table summarizes fair value measurements of the senior amortizing convertible notes and the common stock warrants issued in 2015 by level at December 31, 2015:

	Level 1	Level 2	Level 3	Total
Senior amortizing convertible notes (net of discounts of $149,340)	$ —	$ —	$1,267,182	$1,267,182
Common stock warrants	—	2,877,817	—	2,877,817
Total	$ —	$2,877,817	$1,267,182	$4,144,999

As of December 31, 2015 the Company converted $109,504 of senior amortizing convertible notes principal and interest into shares of common stock. There were no gains or losses resulting from the senior amortizing convertible notes recognized in the consolidated statements of operations for the year ended December 31, 2015.

(5) Inventory

From inception, inventory related purchases had been used for research and development related activities and had accordingly been expensed as incurred. In December 2011, the Company began receiving Australian Register of Therapeutic Goods (ARTG) listings for components of the Maestro Rechargeable System from the Australian Therapeutic Goods Administration, with the final components being listed on the ARTG in January 2012. As a result, the Company determined certain assets were recoverable as inventory beginning in December 2011. The Company accounts for inventory at the lower of cost or market and records any long-term inventory as other assets in the consolidated balance sheets. There was approximately $519,000 and $825,000 of long-term inventory, primarily consisting of raw materials, as of December 31, 2015 and 2014, respectively.

Current inventory consists of the following as of:

	December 31,	
	2015	2014
Raw materials	$ 576,898	$ 322,157
Work-in-process	1,066,345	632,615
Finished goods	43,081	25,747
Inventory	$ 1,686,324	$ 980,519

(6) Property and Equipment

Property and equipment consists of the following as of:

	December 31,	
	2015	2014
Furniture and equipment	$ 2,299,290	$ 2,295,433
Computer hardware and software	585,880	556,556
Leasehold improvements	62,651	62,651
	2,947,821	2,914,640
Less accumulated depreciation and amortization	(2,621,525)	(2,433,118)
Property and equipment, net	$ 326,296	$ 481,522

EnteroMedics Inc.

Notes to Consolidated Financial Statements (Continued)

(7) Accrued Expenses

Accrued expenses consist of the following as of:

	December 31, 2015	December 31, 2014
Professional service related expenses	$ 1,912,775	$ 2,107,712
Payroll related expenses	1,270,208	1,267,141
Other expenses	412,432	455,913
Accrued expenses	$ 3,595,415	$ 3,830,766

(8) Notes Payable

Notes payable consists of the following as of:

	December 31, 2015	December 31, 2014
Growth capital loan dated April 16, 2012 (net of discounts of $0 and $23,836 at December 31, 2015 and 2014, respectively)	$—	$ 2,976,164
Less current portion	—	(2,976,164)
Total long-term debt	$—	$ —

On April 16, 2012, the Company entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank (SVB) pursuant to which SVB agreed to make term loans in an aggregate principal amount of up to $20.0 million ($10.0 million of which was not available as the Company did not meet the predefined primary efficacy measures of the ReCharge trial and did not meet certain financial objectives for 2012), on the terms and conditions set forth in the Loan Agreement.

Pursuant to the Loan Agreement, a term loan was funded in the aggregate principal amount of $10.0 million on April 23, 2012, a portion of which was used to repay in full outstanding debt of approximately $4.7 million. The term loan required interest only payments monthly through March 31, 2013 followed by 30 equal payments of principal in the amount of $333,333 plus accrued interest beginning on April 1, 2013 and ending on September 1, 2015, payable monthly. Amounts borrowed under the Loan Agreement bear interest at a fixed annual rate equal to 8.0%. The Company entered into a First Amendment (the First Amendment) to the Loan Agreement on May 9, 2013 pursuant to which the Company and SVB agreed to new financial covenants.

The First Amendment eliminated the financial covenants that required the Company to generate certain minimum amounts of revenue from the sale of its Maestro Rechargeable System and to implant certain minimum numbers of Maestro Rechargeable Systems during cumulative quarterly measurement periods beginning with the period ended March 31, 2013 and ending with the period ended June 30, 2015. It also removed SVB's ability to require the Company to maintain a restricted cash balance of $7.5 million in an SVB account as a result of the Company not meeting the predefined primary efficacy measures of the ReCharge trial.

The First Amendment added two new financial covenants, one of which required the Company to receive cumulative aggregate net proceeds of at least $5.0 million by November 15, 2013 and $10.0 million by April 15, 2014 from new capital transactions, both of which were fulfilled. The second financial covenant required the Company to maintain a liquidity ratio (unrestricted cash divided by outstanding debt) of at least 1.25:1.00 until it received FDA approval for the Maestro Rechargeable System on January 14, 2015, at which point it was reduced

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Notes to Consolidated Financial Statements (Continued)

to 0.75:1.00. The First Amendment did not change the interest rate or the amortization structure. A 5.0% final payment fee of $500,000 was due and paid on September 1, 2015. The Company also paid SVB a $187,000 success fee as a result of receiving FDA approval for the Maestro Rechargeable System.

The Company had granted SVB a security interest in all of the Company's assets, excluding intellectual property except with respect to all license, royalty fees and other revenues and income arising out of or relating to any of the intellectual property and all proceeds of the intellectual property. The Company also had entered into a negative pledge arrangement with SVB pursuant to which it had agreed not to encumber any of its intellectual property without SVB's prior written consent.

Pursuant to the Loan Agreement, on April 16, 2012, the Company issued SVB a warrant to purchase 7,116 shares of common stock, exercisable for ten years from the date of grant, at an exercise price of $35.10 per share.

The final payment related to the Loan Agreement, as amended, was paid on September 1, 2015.

(9) Senior Amortizing Convertible Notes

On November 4, 2015, the Company entered into a securities purchase agreement (the Purchase Agreement) to issue and sell to four institutional investors 7% senior convertible notes due 2017 that are convertible into shares of the Company's common stock at a price equal to $4.35 per share with an aggregate principal amount of $25.0 million. Each Note was sold with a warrant to purchase a share of common stock (the Warrants) with an exercise price of $4.65 per share. The Company issued and sold Notes and Warrants for aggregate total proceeds of $12.5 million in two separate closings and will issue and sell Notes and Warrants for aggregate total proceeds of $12.5 million in the third and final closing.

Description of the Notes

The Notes are payable in monthly installments, accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the First Closing (defined below), unless converted or redeemed earlier. The Notes may be repaid, at the Company's election, in either cash or shares of the Company's common stock at a discount to the then-current market price. The Notes are also convertible from time to time, at the election of the holders, into shares of the Company's common stock at an initial conversion price of $4.35 per share. The conversion price was adjusted to $1.09 per share on January 29, 2016, the 16^{th} trading day following the Reverse Stock Split, per the terms of the Notes.

The holder of each Note has the right to convert any portion of such Note unless the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the conversion, as such percentage ownership is determined in accordance with the terms of the Notes. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing notice to the Company.

The Company has determined that the conversion feature in the Notes requires bifurcation and liability classification and measurement, at fair value, and requires evaluation at each reporting period. Under Accounting Standards Codification (ASC) 825, Financial Instruments, the FASB provides an alternative to bifurcation and companies may instead elect fair value measurement for the entire instrument, including the debt and conversion feature. The Company has elected the fair value alternative in order to simplify its accounting and reporting of the Notes upon issuance. The Company has also concluded that the fair value of the Notes at issuance is equal to the gross proceeds received less the fair value of the Warrants issued in conjunction with the Notes. The fair value of the Warrants is recorded as a discount to the Notes and amortized to interest expense following the effective interest rate method over the term of the Notes.

The first of the three closings (the First Closing) occurred on November 9, 2015. At the First Closing, the Company issued and sold Notes with an aggregate principal amount of $1.5 million, along with Warrants exercisable for 117,520 shares. The fair value of the Warrants issued on November 9, 2015 was determined to be $169,000 using a Black-Scholes valuation model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 84.85%; (3) weighted average risk –free interest rate of 1.75%; and (4) expected life of 5.0 years.

The second of the three closings (the Second Closing) occurred on January 11, 2016 after the Company received approval of the offering by the Company's stockholders and the satisfaction of certain customary closing conditions. At the Second Closing, the Company issued and sold Notes with an aggregate principal amount of $11.0 million, along with Warrants exercisable for 861,842 shares. The fair value of the Warrants issued on January 11, 2016 was determined to be $515,000 using a Black-Scholes valuation model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 85.90%; (3) weighted average risk –free interest rate of 1.58%; and (4) expected life of 5.0 years.

At the final of the three closings (the Third Closing) the Company will issue and sell Notes with an aggregate principal amount of $12.5 million, along with Warrants exercisable for 979,366 shares.

On December 31, 2015, the fair value of the outstanding Notes was determined to be $1.3 million using a Binomial Lattice model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 57.5%; (3) risk-free interest rate of 1.11%; (4) remaining contractual term of 1.86 years; and (5) fair value of the Company's common stock of $1.95 per share.

The following table summarizes the installment amounts and additional conversions by the holders of the Notes through December 31, 2015:

	Principal	Interest	Total	Common Shares
Installment amount at December 31, 2015	$65,217	$23,651	$ 88,868	56,967
Holder conversions during the quarter ended December 31, 2015	18,261	2,375	20,636	13,228
	$83,478	$26,026	$109,504	70,195

Description of the Warrants

Each Warrant is exercisable immediately and for a period of 60 months from the date of the issuance of the Warrant. The Warrants entitle the holders of the Warrants to purchase, in aggregate, 1,958,728 shares of the Company's common stock upon the completion of the Third Closing, subject to certain adjustments. The Warrants are initially exercisable at an exercise price equal to $4.65, subject to adjustment on the eighteen month anniversary of issuance, and certain other adjustments. The exercise price and number of shares of common stock issuable on the exercise of the Warrants is subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of each Warrant does not have the right to exercise any portion of such Warrant if the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing notice to the Company.

The exercise price of the Warrants issued November 9, 2015 was reduced to $1.09 per share on January 29, 2016, the 16th trading day following the Reverse Stock Split, per the terms of the Warrants. The exercise price of the Warrants issued January 11, 2016 remains $4.65 per share per the terms of the Warrants. All of the Warrants issued with the Notes remain subject to adjustment on the eighteen month anniversary of issuance.

(10) Preferred Stock

The Company's Amended and Restated Certificate of Incorporation currently authorizes 5,000,000 shares of $0.01 par value preferred stock. As of December 31, 2015 and 2014, there were no shares of preferred stock issued or outstanding.

(11) Stock Sales

Sales Agreement—July 2015

On July 8, 2015, the Company closed a public offering, where it sold 2,133,333 units at an aggregate price of $7.50 per unit, for gross proceeds of $16.0 million before deducting estimated offering expenses of approximately $1.4 million, of which $532,000 was assigned to the warrants issued with each unit sold and was recognized immediately as interest expense in the consolidated statements of operations as the warrants are exercisable upon issuance. Each unit consisted of: (A)(i) one share of common stock or (ii) one pre-funded Series C warrant to purchase one share of common stock at an exercise price equal to $7.50 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price initially equal to $9.00 per share (Series A Warrant). Each purchaser of a unit could elect to receive a Series C Warrant in lieu of a share of common stock. No Series C Warrants were issued.

The Series A Warrants are exercisable for a period of 42 months from the closing date of the public offering. The exercise price and number of shares of common stock issuable on the exercise of the Series A Warrants are subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of the Series A Warrant does not have the right to exercise any portion of the Series A Warrant if the holder, together with its affiliates, would, subject to certain limited exceptions, beneficially own in excess of 9.99% of the Company's common stock outstanding immediately after the exercise or 4.99% as may be elected by the purchaser.

The exercise price of the Series A Warrants issued July 8, 2015 was reduced to $2.40 per share on November 9, 2015 as a result of the issuance of the Notes and was further reduced to $1.50 per share on December 31, 2015 and $0.97 per share on January 29, 2016 after the first and second installment payments on the Notes were made.

Sales Agreement—June 2014

On June 13, 2014, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of the Company's common stock having aggregate gross sales proceeds of up to $25.0 million, from

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Notes to Consolidated Financial Statements (Continued)

time to time, through an ATM under which Cowen will act as the Company's sales agent (the Cowen ATM). The Company will determine, at its sole discretion, the timing and number of shares to be sold under the Cowen ATM. The Company will pay Cowen a commission for its services in acting as agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of December 31, 2015, the Company had sold 367,903 shares under the Cowen ATM at a weighted-average selling price of $20.60 per share for gross proceeds of $7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM subsequent to December 31, 2015 through March 28, 2016. The Company is restricted from issuing shares under the Cowen ATM per the terms of the Notes (see Note 9).

Equity Distribution Agreement—July 2013

On July 31, 2013, the Company entered into an equity distribution agreement with Canaccord Genuity Inc. (Canaccord) to sell shares of the Company's common stock having aggregate gross sales proceeds of up to $20.0 million, from time to time, through an ATM under which Canaccord acted as the Company's sales agent (the Canaccord ATM). The Company determined, at its sole discretion, the timing and number of shares sold under the Canaccord ATM. The Company paid Canaccord a commission for its services in acting as agent in the sale of common stock equal to 2.0% of the gross sales price per share of all shares sold through it as agent under the equity distribution agreement. The equity distribution agreement with Canaccord was terminated effective June 10, 2014. As of the termination date, the Company had sold a total of 794,933 shares under the Canaccord ATM at a weighted-average selling price of $25.01 per share for gross proceeds of $19.9 million before deducting offering expenses.

Public Offering—February 2013

On February 27, 2013, the Company closed a public offering, selling 918,000 shares of common stock, together with warrants to purchase approximately 367,175 shares of common stock at an aggregate price of $14.25 per share and corresponding warrant, for gross proceeds of $13.1 million before deducting offering expenses. Certain directors of the Company participated in the public offering (see Note 15).

The warrants have an exercise price of $17.10 per share of common stock and are exercisable for a period of five years from February 27, 2013. Holders of the warrants are not permitted to exercise those warrants for an amount of common stock that would result in the holder owning more than 19.99% of the Company's common stock.

(12) Income Taxes

The Company has incurred net operating losses (NOLs) since inception. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying consolidated financial statements.

The income tax expense benefit differed from the amount computed by applying the U.S. federal income tax rate of 34% to income before income taxes as a result of the following:

	2015	2014	2013
Computed 'expected' tax benefit	34.0%	34.0%	34.0%
Other permanent adjustments	1.6%	-2.3%	-2.3%
Research and development credit	0.9%	0.3%	3.5%
Federal valuation allowance	-36.5%	-32.0%	-35.2%
	0.0%	0.0%	0.0%

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Notes to Consolidated Financial Statements (Continued)

The tax effect of temporary differences that give rise to significant portions of the deferred tax assets as of December 31 is presented below:

	2015	2014
Deferred tax assets (liabilities):		
Start-up costs	$ 8,886,000	$ 8,739,000
Capitalized research and development costs	29,781,000	30,276,000
Reserves and accruals	8,121,000	6,052,000
Property and equipment	107,000	94,000
Research and development credit	1,972,000	1,636,000
Net operating loss carryforwards	25,695,000	16,656,000
Total gross deferred tax assets	74,562,000	63,453,000
Valuation allowance	(74,562,000)	(63,453,000)
Net deferred tax assets	$ —	$ —

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. In addition, certain limitations imposed under the Internal Revenue Code (IRC) could further limit the Company's realization of these deferred tax assets in the event of changes in ownership of the Company, as defined by IRC Section 382. Based on the level of historical taxable losses and projections of future taxable income (losses) over the periods in which the deferred tax assets can be realized, management currently believes that it is more likely than not that the Company will not realize the benefits of these deductible differences. Accordingly, the Company has provided a valuation allowance against the gross deferred tax assets as of December 31, 2015 and 2014.

The Company's ability to utilize its net operating loss carryforwards and built-in items of deduction, including capitalized start-up costs and research and development costs, may be substantially limited due to ownership changes that may have occurred or that could occur in the future. These ownership changes may limit the amount of net operating loss carryforwards and built-in items of deduction that can be utilized annually to offset future taxable income. In general, an ownership change, as defined in IRC Section 382, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups. During 2011, the Company completed an IRC Section 382 review and the results of the review indicated that ownership changes had occurred. While the Company has not completed an IRC Section 382 review since 2011, it believes that it is likely that additional ownership changes have occurred since then. Since the Company has experienced an ownership change, utilization of carryforward attributes are subject to an annual limitation, which is determined by first multiplying the value of the Company's common stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any such limitation may result in the expiration of a significant portion of the carryforward attributes before utilization and the permanent loss of built-in items of deduction. Any carryforward attributes that expire prior to utilization or permanent loss of built-in items of deduction as a result of such limitations will be removed from deferred tax assets with a corresponding adjustment to the valuation allowance.

As of December 31, 2015, the Company has generated U.S. federal net operating loss carryforwards of approximately $117.0 million. Of the total federal net operating loss, $221,000 would result in tax benefits recorded to additional paid-in capital. The federal net operating loss carryforwards expire in the years 2022 through 2035.

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Notes to Consolidated Financial Statements (Continued)

As of December 31, 2015 and 2014, there were no unrecognized tax benefits. Accordingly, a tabular reconciliation from beginning to ending periods is not provided. The Company will classify any future interest and penalties as a component of income tax expense if incurred. To date, there have been no interest or penalties charged or accrued in relation to unrecognized tax benefits.

The Company does not anticipate that the total amount of unrecognized tax benefits will change significantly in the next twelve months.

Net operating loss carryforwards of the Company are subject to review and possible adjustment by the taxing authorities. In addition, the Company is subject to U.S. federal examinations for the years 2012 forward. With certain exceptions (e.g. the net operating loss carryforwards), the Company is no longer subject to U.S. federal, state or local examinations by tax authorities for years prior to 2012. There are no U.S. federal tax examinations currently in progress.

The Company's Minnesota Corporation Franchise Tax returns for tax years ending December 31, 2011 through December 31, 2013, are currently under review.

(13) Stock Options

The Company has adopted the Amended and Restated 2003 Stock Incentive Plan (the Plan) that includes both incentive stock options and nonqualified stock options to be granted to employees, officers, consultants, independent contractors, directors and affiliates of the Company. At December 31, 2015 and 2014, according to the Plan 1,320,000 shares have been authorized and reserved. The board of directors establishes the terms and conditions of all stock option grants, subject to the Plan and applicable provisions of the IRC. Incentive stock options must be granted at an exercise price not less than the fair market value of the common stock on the grant date. The options granted to participants owning more than 10% of the Company's outstanding voting stock must be granted at an exercise price not less than 110% of fair market value of the common stock on the grant date. The options expire on the date determined by the board of directors, but may not extend more than 10 years from the grant date, while incentive stock options granted to participants owning more than 10% of the Company's outstanding voting stock expire five years from the grant date. The vesting period for employees is generally over four years. The vesting period for nonemployees is determined based on the services being provided.

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Notes to Consolidated Financial Statements (Continued)

Stock option activity for the Plan is as follows:

	Shares Available For Grant	Outstanding Options: Number of Shares	Outstanding Options: Weighted-Average Exercise Price	Aggregate Intrinsic Value
Balance, December 31, 2012	293,106	522,225	$ 49.16	
Shares reserved	—	—	—	
Options granted	(289,710)	289,710	19.85	
Options exercised	—	—	—	
Options cancelled	32,937	(32,937)	45.00	
Balance, December 31, 2013	36,333	778,998	38.00	
Shares reserved	500,000	—	—	
Options granted	(83,823)	83,823	24.45	
Options exercised	—	—	—	
Options cancelled	19,258	(19,258)	36.11	
Balance, December 31, 2014	471,768	843,563	37.10	$519,546
Shares reserved	—	—	—	
Options granted	(226,631)	226,631	15.77	
Options exercised	—	—	—	
Options cancelled	51,442	(51,442)	27.74	
Balance, December 31, 2015	296,579	1,018,752	$ 32.83	$ —

On November 2, 2015, the Company announced that Dan W. Gladney would become the Company's President and Chief Executive Officer (CEO) effective November 16, 2015, and would join the Company on November 2, 2015 as President-Elect and a member of the Board of Directors. In connection with the appointment of Mr. Gladney to the position of President and CEO, on October 28, 2015, Mr. Gladney was also granted an option to purchase 516,666 shares of the Company's common stock as an inducement grant, with an exercise price of $3.75 per share, the closing price of the Company's common stock on October 28, 2015. Mr. Gladney's option will vest as follows: 25% of the shares will vest as of one year from the date of his employment agreement, and the remaining 75% of the shares will then vest in equal 2.0833% installments each month thereafter over the following 36 months.

The options outstanding, vested and currently exercisable for the Plan and the inducement grant by exercise price at December 31, 2015:

	Outstanding Options and Expected to Vest			Options Exercisable and Vested		
Exercise Price	Number of Shares Outstanding	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value
$0.01 to $10.00	536,529	9.7	$ —	6,145	$ 3.57	$ —
$10.01 to $20.00	450,016	8.2	—	247,800	19.09	—
$20.01 to $30.00	136,713	6.4	—	96,672	27.52	—
$30.01 to $40.00	79,313	5.0	—	79,310	38.80	—
$40.01 to $50.00	57,058	5.4	—	57,058	40.34	—
> $50.00	275,789	6.3	—	251,474	59.06	—
	1,535,418		$ —	738,459	$ 37.44	$ —

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Notes to Consolidated Financial Statements (Continued)

Stock-Based Compensation for Nonemployees

Stock-based compensation expenses related to stock options granted to nonemployees is recognized as the stock options are earned. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The fair value of the stock options granted is calculated at each reporting date, using the Black-Scholes option-pricing model, until the award vests or there is a substantial disincentive for the nonemployee not to perform the required services. The fair value for the years ended December 31, 2015, 2014 and 2013 was calculated using the following assumptions, defined below:

	Years Ended December 31,		
	2015	2014	2013
Risk-free interest rates	0.02%–2.10%	0.08%–2.63%	0.26%–2.98%
Expected life	0.08 years–8.51 years	0.50 years–9.51 years	1.50 years–9.76 years
Expected dividends	0%	0%	0%
Expected volatility	37.36%–132.01%	56.54%–139.65%	80.00%–143.00%

Stock-based compensation expense charged to operations on options granted to nonemployees for the years ended December 31, 2015, 2014 and 2013 was $(34,712), $181,323 and $166,679, respectively.

Employee Stock-Based Awards

Compensation cost for employee stock-based awards is based on the estimated grant-date fair value and is recognized over the vesting period of the applicable award on a straight-line basis. The weighted average estimated fair value of the employee stock options granted for the years ended December 31, 2015, 2014 and 2013 was $6.09, $21.23 and $18.32 per share, respectively.

The Company uses the Black-Scholes pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant is affected by the Company’s stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the Company’s expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rates and expected dividends. The estimated grant-date fair values of the employee stock options were calculated using the Black-Scholes valuation model, based on the following assumptions for the years ended December 31, 2015, 2014 and 2013:

	Years Ended December 31,		
	2015	2014	2013
Risk-free interest rates	1.49%–1.80%	1.73%–1.96%	0.94%–1.33%
Expected life	5.50 years–6.25 years	6.00 years–6.25 years	6.00 years–6.25 years
Expected dividends	0%	0%	0%
Expected volatility	83.36%–111.77%	118.64%–120.70%	148.00%–149.00%

Expected Life. The expected life is based on the “simplified” method described in the SEC Staff Accounting Bulletin, Topic 14: *Share-Based Payment*.

Volatility. The expected volatility was based on the Company’s historical volatility.

Risk-Free Interest Rate. The risk-free rate is based on the daily yield curve rate from the U.S. Treasury with remaining terms similar to the expected term on the options.

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Notes to Consolidated Financial Statements (Continued)

Dividend Yield. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation model.

Forfeitures. The Company is required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. If the Company's actual forfeiture rate is materially different from its estimate, the stock-based compensation expense could be significantly different from what the Company has recorded in the current period.

As of December 31, 2015 there was approximately $6.1 million of total unrecognized compensation costs, net of estimated forfeitures, related to employee unvested stock option awards, which are expected to be recognized over a weighted-average period of 2.54 years.

There were no stock option exercises for the years ended December 31, 2015, 2014 and 2013.

(14) Warrants

Stock warrant activity is as follows:

	Common Shares	Price(1)
Balance, December 31, 2012	1,414,244	$ 36.83
Granted(2)	367,175	17.10
Exercised	(1,353)	20.68
Cancelled	(76,883)	137.09
Balance, December 31, 2013	1,703,183	28.07
Granted	—	—
Exercised	(88,542)	25.32
Cancelled	(1,508)	728.40
Balance, December 31, 2014	1,613,133	27.56
Granted(2)	2,250,836	1.66
Exercised	—	—
Cancelled	(22,693)	32.85
Balance, December 31, 2015	3,841,276	$ 12.36

(1) Represents weighted-average exercise price per share.
(2) See Notes 9 and 11 for discussions relating to the issuance of warrants in 2015 and 2013.

At December 31, 2015 and 2014, the weighted-average remaining contractual life of outstanding warrants was 2.18 and 1.85 years, respectively. All of the warrants outstanding are currently exercisable at the option of the holder into the equivalent number of shares of common stock.

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Notes to Consolidated Financial Statements (Continued)

(15) Related Party Transactions

Public Offerings

As discussed in Note 11, on February 27, 2013, the Company closed a public offering, selling 918,000 shares of common stock, together with warrants to purchase approximately 367,175 shares of common stock at an aggregate price of $14.25 per share and corresponding warrant. The following principal stockholder purchased shares of common stock and warrants at a price of $14.25 per share and corresponding warrant. The shares purchased, together with the proceeds, before expenses, to the Company, are shown in the table below:

Beneficial Owner	Shares Purchased	Warrants Purchased	Proceeds, before expenses, to the Company
Anthony Jansz	10,000	4,000	$ 142,500

Anthony Jansz is a director of the Company.

Consulting Agreement—Anthony Jansz

The Company entered into a consulting agreement with Anthony Jansz, who is a member of the board of directors, for the period from June 1, 2011 through April 30, 2015. In exchange for consulting services provided, Mr. Jansz was entitled to receive consulting fees and options to purchase 16,663 shares of common stock at a weighted average exercise price of $29.78. Total stock-based compensation expense recorded was approximately $600, $40,000 and $125,000 for the years ended December 31, 2015, 2014 and 2013, respectively. Due to a failure to meet certain performance conditions, 4,998 shares of the options granted to Mr. Jansz did not vest. In addition to the option grants, the Company paid Mr. Jansz approximately $75,000, $196,000 and $154,000 in fees and expenses for consulting services provided during the years ended December 31, 2015, 2014 and 2013, respectively.

Consulting Agreement—Jon Tremmel

Effective August 10, 2015, the Company entered into a one year consulting agreement with Jon Tremmel & Associates, LLC, which is wholly-owned by Jon Tremmel, a member of the board of directors. In exchange for consulting services provided, Mr. Tremmel was entitled to receive consulting fees and an option to purchase 16,666 shares of common stock at $3.45 per share. Total stock-based compensation expense recorded was approximately $13,000 for the year ended December 31, 2015. In addition to the option grant, the Company paid Mr. Tremmel approximately $50,000 in fees and expenses for consulting services provided during the year ended December 31, 2015.

Other

The Company entered into an agreement with an advisory firm to provide various consulting services. The advisory firm is partially owned by a company with whom a member of our board of directors is a partner. The Company recognized $253,000 in selling, general and administrative expense for the year ended December 31, 2014 for consulting services provided by the advisory firm.

(16) Commitments and Contingencies

Operating Lease

The Company rents its office, warehouse and laboratory facilities under an operating lease, which was originally set to expire on September 30, 2015. On August 25, 2015, the Company entered into an amendment extending the term of the operating lease for three years until September 30, 2018, with monthly base rent ranging from $18,925 to $20,345. Total rent expense recognized for the year ended December 31, 2015 was $262,059 and for each of the years ended December 31, 2014 and 2013 it was $270,872. Facility related expenses are included as general and administrative costs on the consolidated statements of operations.

The following is a schedule of total future minimum lease payments due as of December 31, 2015:

Years ending December 31:	
2016	$229,233
2017	237,749
2018	183,103
	$650,085

Product Liability Claims

The Company is exposed to product liability claims that are inherent in the testing, production, marketing and sale of medical devices. Management believes any losses that may occur from these matters are adequately covered by insurance, and the ultimate outcome of these matters will not have a material effect on the Company's financial position or results of operations. The Company is not currently a party to any litigation and is not aware of any pending or threatened litigation that could have a material adverse effect on the Company's business, operating results or financial condition.

Clinical Trials

The Company is evaluating the Maestro System in human clinical trials, including the EMPOWER trial and ReCharge trial. Both of these clinical trials require patients to be followed out to 60 months. The Company is required to pay for patient follow up visits only to the extent they occur. In the event a patient does not attend a follow up visit, the Company has no financial obligation. The Company is also required to pay for explants or revisions, including potential conversions of ReCharge control devices to active devices, should a patient request or be required to have one during the course of the clinical trials. The Company has no financial obligation unless an explant, revision or conversion is requested or required. Clinical trial costs are expensed as incurred.

Mayo Foundation for Medical Education and Research

In 2005, EnteroMedics entered into an exclusive collaborative obesity device research and development agreement with the Mayo Foundation for Medical Education and Research (Mayo Foundation), Rochester, Minnesota. Through this agreement, EnteroMedics collaborated with a group of physicians and researchers at Mayo Clinic in the field of obesity. Under the terms of this five-year agreement, EnteroMedics and this group of Mayo specialists collectively worked toward the development of new and innovative medical devices for the treatment of obesity. The agreement also includes a similar collaboration for the development of products to address a wide variety of disorders susceptible to treatment by electrically blocking neural impulses on the vagus nerve.

The Mayo Foundation received an annual $250,000 retainer fee which commenced in 2005 and continued through January 2009.

On March 11, 2010, the Company entered into Amendment No. 1 to the agreement with the Mayo Foundation extending the Company's collaboration with the Mayo Foundation for a period of two years. Pursuant to the amendment, the Mayo Foundation granted the Company certain royalty-bearing, worldwide exclusive and non-exclusive licenses and committed to the joint collaboration between the Company and a designated group of physicians and researchers at the Mayo Clinic for the development and testing of products for the treatment of obesity, including devices that use electrical signaling to block the vagal nerve, and for the treatment of other gastrointestinal diseases, solely using devices that use electrical signaling to block the vagal nerve. The Mayo Foundation received an annual retainer of $100,000 in 2010 and 2011. The agreement was further amended on January 15, 2011 with Amendment No. 2. Under the terms of Amendment No. 2, the annual retainer the Mayo Foundation received for 2011 was reduced to $75,000. The agreement was further amended on February 3, 2012 with Amendment No. 3. Under the terms of Amendment No. 3, beginning in 2012 the Mayo Foundation will be reimbursed for services provided at an hourly rate only. Amendment No. 3 does not provide for additional annual retainer payments. No other terms were changed by Amendment Nos. 2 or 3. The agreement was further amended on February 3, 2013 and on February 3, 2014 with Amendment Nos. 4 and 5, respectively, extending the joint collaboration between the company and a designated group of physicians and researchers at the Mayo Clinic. No other terms were changed by Amendment Nos. 4 or 5.

The Company may also be obligated to pay the Mayo Foundation, contingent upon the occurrence of certain future events, earned royalty payments, including a minimum annual royalty as defined by the agreement, as amended, for the commercial sale of products developed and patented by the Mayo Foundation, jointly patented by the Company and the Mayo Foundation, or a product where the Mayo Foundation provided know-how as defined by the agreement, as amended. If no products are patented, the minimum royalty is not due.

(17) Retirement Plan

The Company has a 401(k) profit-sharing plan that provides retirement benefits to employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations. The Company's matching is at the discretion of the Company's board of directors. For the years ended December 31, 2015, 2014 and 2013, the Company did not provide any matching of employees' contributions.

(18) Quarterly Data (unaudited)

The following table represents certain unaudited quarterly information for each of the eight quarters in the period ended December 31, 2015. In management's opinion, this information has been prepared on the same basis as the audited consolidated financial statements and includes all the adjustments necessary to fairly state the unaudited quarterly results of operations (in thousands, except per share data).

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2015:				
Net loss	$(7,174)	$(7,404)	$(4,151)	$(6,770)
Basic and diluted net loss per share	$ (1.48)	$ (1.49)	$ (0.60)	$ (0.95)
2014:				
Net loss	$(6,732)	$(7,501)	$(5,714)	$(6,181)
Basic and diluted net loss per share	$ (1.54)	$ (1.66)	$ (1.24)	$ (1.34)

ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE***

None.

ITEM 9A. ***CONTROLS AND PROCEDURES***

Evaluation of Disclosure Controls and Procedures

We have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)), as of the end of the period covered by this report (the Evaluation Date). Our management, including the Chief Executive Officer and the Chief Financial Officer, supervised and participated in the evaluation. Based on the evaluation, we concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's forms and rules, and the material information relating to the Company is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Control systems, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that control objectives are met. Because of inherent limitations in all control systems, no evaluation of controls can provide assurance that all control issues and instances of fraud, if any, within a company will be detected. Additionally, controls can be circumvented by individuals, by collusion of two or more people or by management override. Over time, controls can become inadequate because of changes in conditions or the degree of compliance may deteriorate. Further, the design of any system of controls is based in part upon assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Because of the inherent limitations in any cost-effective control system, misstatements due to errors or fraud may occur and not be detected.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the quarter ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company as defined in Rules 13a-15(c) and 15d-15(c) of the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has evaluated the design and operating effectiveness of our internal control over financial reporting as of December 31, 2015 utilizing the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework (2013)*. Based upon the evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2015.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to permanent exemption rules of the Dodd-Frank Wall Street Reform and Consumer Protection Act that permit the Company to provide only management's report in this annual report.

ITEM 9B. ***OTHER INFORMATION***

None.

PART III.

Certain information required by Part III is omitted from this report, and is incorporated by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A (the Proxy Statement) in connection with our 2016 Annual Meeting of Stockholders.

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*

The information required by this Item concerning our directors and executive officers is hereby incorporated by reference to the sections of our Proxy Statement under the headings “Nominees,” “Executive Officers,” “Section 16(a) Beneficial Ownership Reporting Compliance” and “Board Meetings and Committees—Audit Committee.”

We have adopted a code of business conduct and ethics, which applies to all directors and employees, including executive officers, including, without limitation, our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. A copy of this code of business conduct and ethics is available on our website at *www.enteromedics.com* (under “Investors,” “Corporate Governance”) and we intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any waivers from or amendments to any provision of the code of business conduct and ethics by disclosing such information on the same website.

In addition, we intend to promptly disclose (1) the nature of any amendment to our code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of business conduct and ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

ITEM 11. *EXECUTIVE COMPENSATION*

The information required by this Item is hereby incorporated by reference to the sections of our Proxy Statement entitled “Director Compensation,” “Executive Compensation,” “Compensation Committee Interlocks and Insider Participation” and “Compensation Committee Report.”

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

(a) Equity Compensation Plans

The following table sets forth information as of December 31, 2015 with respect to our equity compensation plans:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Second Column)
Equity compensation plans approved by security holders	1,018,752(1)	$ 32.83	296,579(2)
Equity compensation plans not approved by security holders	516,666(3)	3.75	—
Total	1,535,418	$ 23.04	296,579

(1) Consists of options awarded under the Amended and Restated 2003 Stock Incentive Plan.
(2) Represents the maximum number of shares of common stock available to be awarded as of December 31, 2015.
(3) Consists of the inducement grant awarded in 2015 to Dan W. Gladney in connection with his hiring.

(b) Security Ownership

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled “Security Ownership of Certain Beneficial Owners and Management.”

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled “Certain Relationships and Related Transactions, and Director Independence.”

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled “Principal Accountant Fees and Services” and “Administration of Engagement of Independent Auditor.”

PART IV.

ITEM 15. *EXHIBITS, FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULES*

(a) *Financial Statements and Schedules:* Consolidated Financial Statements for the three years ended December 31, 2015 are included in Part II, Item 8 of this Annual Report on Form 10-K. All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(b) *Exhibits:* The list of exhibits on the Exhibit Index on page 97 of this report is incorporated herein by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENTEROMEDICS INC.

By: /S/ DAN W. GLADNEY
Dan W. Gladney
President and Chief Executive Officer

Dated: March 28, 2016

POWERS OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dan W. Gladney and Greg S. Lea, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ DAN W. GLADNEY **Dan W. Gladney**	President, Chief Executive Officer and Director (principal executive officer)	March 28, 2016
/S/ GREG S. LEA **Greg S. Lea**	Chief Financial Officer and Chief Compliance Officer (principal financial and accounting officer)	March 28, 2016
/S/ MARK B. KNUDSON, PH.D. **Mark B. Knudson, Ph.D.**	Chairman of the Board	March 28, 2016
/S/ CATHERINE FRIEDMAN **Catherine Friedman**	Director	March 28, 2016
/S/ CARL GOLDFISCHER, M.D. **Carl Goldfischer, M.D.**	Director	March 28, 2016
/S/ BOBBY I. GRIFFIN **Bobby I. Griffin**	Director	March 28, 2016

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Signature	Title	Date
/S/ ANTHONY P. JANSZ **Anthony P. Jansz**	Director	March 28, 2016
/S/ LORI MCDOUGAL **Lori McDougal**	Director	March 28, 2016
/S/ NICHOLAS L. TETI, JR. **Nicholas L. Teti, Jr.**	Director	March 28, 2016
/S/ JON T. TREMMEL **Jon T. Tremmel**	Director	March 28, 2016

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EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-3 filed on May 9, 2014 (File No. 333-195855)).
3.2	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 8, 2016 (File No. 1-33818)).
3.3	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation. (Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on January 8, 2016 (File No. 1-33818)).
3.4	Amended and Restated Bylaws of the Company, as currently in effect. (Incorporated herein by reference to Exhibit 3.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).
10.1	Form of Warrant to purchase stock under Loan and Security Agreement, dated November 18, 2008, between the Company and Silicon Valley Bank, Compass Horizon Funding Company LLC, and Venture Lending & Leasing V, Inc. (Incorporated herein by reference to Exhibit 10.20 to the Company's Annual Report on Form 10-K filed on March 12, 2009 (File No. 1-33818)).
10.2	Loan and Security Agreement, dated April 16, 2012, between the Company and Silicon Valley Bank. (Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q/A filed on August 3, 2012 (File No. 1-33818)).
10.3	Form of Warrant to purchase stock under Loan and Security Agreement, dated April 16, 2012, between the Company and Silicon Valley Bank. (Incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 10, 2012 (File No. 1-33818)).
10.4	First Amendment to Loan and Security Agreement, dated as of May 9, 2013, by and between Silicon Valley Bank and the Company. (Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 10, 2013 (File No. 1-33818)).
10.5	Securities Purchase Agreement, dated as of October 2, 2009. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 5, 2009 (File No. 1-33818)).
10.6	Securities Purchase Agreement, dated as of January 14, 2010. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 15, 2010 (File No. 1-33818)).
10.7	Securities Purchase Agreement, dated as of September 29, 2010. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 5, 2010 (File No. 1-33818)).
10.8	Form of Up Front Warrant, dated September 29, 2010, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on October 5, 2010 (File No. 1-33818)).
10.9	Form of Conversion Warrant. (Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on October 5, 2010 (File No. 1-33818)).
10.10	Form of Common Stock Warrant, dated as of December 14, 2010, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on December 6, 2010 (File No. 333-170503)).

Exhibit Number	Description of Document
10.11	Form of Underwriter Warrant, dated as of December 14, 2010, by and between the Company and Craig-Hallum Capital Group LLC. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on December 14, 2010 (File No. 1-33818)).
10.12	Securities Purchase Agreement, dated as of September 23, 2011, by and between Craig-Hallum Capital Group LLC and the Company. (Incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on September 23, 2011 (File No. 1-33818)).
10.13	Form of Common Stock Warrant, dated as of September 23, 2011, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on September 23, 2011 (File No. 1-33818)).
10.14	Securities Purchase Agreement, dated as of February 22, 2013, by and between Craig-Hallum Capital Group LLC and the Company. (Incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on February 22, 2013 (File No. 1-33818)).
10.15	Form of Common Stock Warrant, dated as of February 22, 2013, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 22, 2013 (File No. 1-33818)).
10.16	Sales Agreement, dated as of June 13, 2014, by and between Cowen and Company, LLC and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 13, 2014 (File No. 1-33818)).
10.17	Amendment No. 1 to the Sales Agreement, dated as of August 25, 2015, by and between Cowen and Company, LLC and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 1, 2015 (File No. 1-33818)).
10.18	Underwriting Agreement, dated as of July 7, 2015, by and between Canaccord Genuity Inc. and the Company. (Incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on July 7, 2015 (File No. 1-33818)).
10.19	Form of Series A Warrant, dated as of July 8, 2015, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 7, 2015 (File No. 1-33818)).
10.20	Form of Series C Warrant, dated as of July 8, 2015, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 7, 2015 (File No. 1-33818)).
10.21	Form of Securities Purchase Agreement. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
10.22	Form of Senior Convertible Note. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
10.23	Form of Warrant. (Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
10.24†	Amended and Restated 2003 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 filed on June 10, 2014 (File No. 333-196646)).
10.25†	Standard form of Incentive Stock Option Agreement pursuant to the Amended and Restated 2003 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).

Exhibit Number	Description of Document
10.26†	Standard form of Non-Incentive Stock Option Agreement pursuant to the Amended and Restated 2003 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.27†	Form of Non-Incentive Stock Option Agreement for the new options granted October 29, 2010 pursuant to the option exchange program. (Incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on November 8, 2010 (File No. 1-33818)).
10.28†	Form of 2012 Senior Management Non-Incentive Stock Option Agreement pursuant to the Amended and Restated 2003 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 13, 2012 (File No. 1-33818)).
10.29†	Standard form of Restricted Stock Agreement. (Incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.30†	Form of Indemnification Agreement entered into by and between the Company and each of its executive officers and directors. (Incorporated herein by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).
10.31†	Form of Tandem Stock Purchase Right and Bonus Share Agreement. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 13, 2015 (File No. 1-33818)).
10.32†	Inducement Option Plan. (Incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.33†*	Form of Non-Incentive Stock Option Agreement pursuant to the Inducement Option Plan.
10.34†	Consulting Agreement, effective June 1, 2011, by and between Anthony Jansz and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 8, 2011 (File No. 1-33818)).
10.35†	Amendment to Consulting Agreement, effective October 1, 2012, by and between Anthony Jansz and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 24, 2013 (File No. 1-33818)).
10.36†	Amendment No. 2 to Consulting Agreement, effective September 1, 2014, by and between Anthony Jansz and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 1, 2014 (File No. 1-33818)).
10.37†	Consulting Agreement, dated as of August 21, 2015, by and between Jon Tremmel & Associates, LLC and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 25, 2015 (File No. 1-33818)).
10.38†	Amended and Restated Executive Employment Agreement, dated May 4, 2009, by and between the Company and Mark B. Knudson. (Incorporated herein by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 7, 2009 (File No. 1-33818)).
10.39†	Executive Employment Agreement, dated May 21, 2007, by and between the Company and Greg S. Lea. (Incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.40†	Amendment No. 1 to Executive Employment Agreement, dated May 21, 2007, by and between the Company and Greg S. Lea. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 19, 2010 (File No. 1-33818)).

Exhibit Number	Description of Document
10.41†	Amendment No. 2 to Executive Employment Agreement, dated May 21, 2007, by and between the Company and Greg S. Lea, dated January 27, 2016. (Incorporated herein by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on February 3, 2016 (File No. 1-33818)).
10.42†	Executive Employment Agreement, dated February 9, 2007, by and between the Company and Adrianus Donders. (Incorporated herein by reference to Exhibit 10.10 to the Company’s Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.43†	Executive Employment Agreement, dated August 5, 2008, by and between the Company and Katherine S. Tweden. (Incorporated herein by reference to Exhibit 10.4 to the Company’s Quarterly Report on Form 10-Q filed on May 7, 2009 (File No. 1-33818)).
10.44†	Executive Employment Agreement, by and between the Company and Brad Hancock, dated November 17, 2014. (Incorporated herein by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed on May 12, 2015 (File No. 1-33818)).
10.45†*	Separation Agreement, by and between the Company and Brad Hancock, dated February 24, 2016.
10.46†	Executive Employment Agreement, dated October 28, 2015, by and between the Company and Dan W. Gladney. (Incorporated herein by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on November 2, 2015 (File No. 1-33818)).
10.47†*	Form of Non-Incentive Stock Option Agreement for non-plan executive inducement option grants.
10.48†	Executive Employment Agreement, dated January 19, 2016, by and between the Company and Naqeeb “Nick” Ansari. (Incorporated herein by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.49†	Executive Employment Agreement, dated January 18, 2016, by and between the Company and Peter DeLange. (Incorporated herein by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.50†	Executive Employment Agreement, dated January 22, 2016, by and between the Company and Paul Hickey. (Incorporated herein by reference to Exhibit 10.3 to the Company’s Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.51†	Management Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on February 12, 2008 (File No. 1-33818)).
10.52†	Amendments to the Management Incentive Plan described in Item 5.02(e). (Incorporated herein by reference to Item 5.02(e) of the Company’s Current Report on Form 8-K filed on March 13, 2015 (File No. 1-33818)).
10.53†	Amendments to the Management Incentive Plan described in Item 5.02(e). (Incorporated herein by reference to Item 5.02(e) of the Company’s Current Report on Form 8-K filed on September 15, 2015 (File No. 1-33818)).
10.54	Licensing Agreement, by and between Mayo Foundation for Medical Education and Research and the Company, dated February 3, 2005. (Incorporated herein by reference to Exhibit 10.1 to Amendment No. 2 to the Company’s Registration Statement on Form S-1 filed on August 14, 2007 (File No. 333-143265)).
10.55	Amendment No. 1, effective as of February 3, 2010, to License Agreement between Mayo Foundation for Medical Education and Research and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on March 17, 2010 (File No. 1-33818)).
10.56	Amendment No. 2, effective as of January 4, 2011, to License Agreement between Mayo Foundation for Medical Education and Research and the Company. (Incorporated herein by reference to Exhibit 10.34 to the Company’s Annual Report on Form 10-K filed on March 7, 2011 (File No. 1-33818)).

Exhibit Number	Description of Document
10.57	Amendment No. 3, effective as of February 3, 2012, to License Agreement between Mayo Foundation for Medical Education and Research and the Company. (Incorporated herein by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on August 8, 2012 (File No. 1-33818)).
10.58	Amendment No. 4, effective as of February 3, 2013, to License Agreement between Mayo Foundation for Medical Education and Research and the Company. (Incorporated herein by reference to Exhibit 10.44 to the Company's Annual Report on Form 10-K filed on March 27, 2014 (File No. 1-33818)).
10.59	Amendment No. 5, effective as of February 3, 2014, to License Agreement between Mayo Foundation for Medical Education and Research and the Company. (Incorporated herein by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed on March 27, 2014 (File No. 1-33818)).
10.60	Lease Agreement, effective October 1, 2008, by and between the Company and Roseville Properties Management Company. (Incorporated herein by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on March 12, 2009 (File No. 1-33818)).
10.61	First Amendment to Lease Agreement, entered into August 25, 2015, by and between the Company and Roseville Properties Management Company. (Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 1, 2015 (File No. 1-33818)).
10.62	Distribution Agreement, dated as of March 28, 2011, by and between Device Technologies Australia Pty Limited and the Company. (Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 6, 2011 (File No. 1-33818)).
10.63	Amendment No. 1, effective as of July 10, 2012, to Distribution Agreement by and between Device Technologies Australia Pty Limited and the Company. (Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 8, 2012 (File No. 1-33818)).
10.64	Distribution Agreement, dated as of February 21, 2012, by and between Bader Sultan & Brothers Co. W.L.L. and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 10, 2012 (File No. 1-33818)).
14.1	Code of Conduct and Ethics of the Company. (Incorporated herein by reference to Exhibit 14.1 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on signature page to this Form 10-K).
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Annual Report on Form 10-K of the Company for the year ended December 31, 2015, formatted in Extensible Business Reporting Language: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Stockholders' Equity; (v) the Consolidated Statements of Cash Flows and (vi) the Notes to Consolidated Financial Statements.

* Filed herewith.

† Indicates management contract or compensation plan or agreement.

ENTEROMEDICS INC.

NON-INCENTIVE STOCK OPTION AGREEMENT

GRANTED TO	GRANT DATE	NUMBER OF SHARES SUBJECT TO OPTION	EXERCISE PRICE PER SHARE	EXPIRATION DATE

1. **This Agreement**. This agreement, together with Exhibit A (collectively, the "*Agreement*"), sets forth the terms and conditions of a non-incentive stock option award representing the right to purchase shares of common stock ("*Common Stock*") of EnteroMedics Inc., a Delaware corporation (the "*Company*").

2. **The Grant**. Pursuant to the Inducement Option Plan adopted December 22, 2015 (the "*Plan*"), the Company hereby grants to the individual named above (the "*Optionee*"), as of the above grant date (the "*Grant Date*"), an option (the "*Option*") to purchase the number of shares of Common Stock of the Company set forth above (the "*Shares*") at the price per share set forth above (the "*Exercise Price*") with the expiration date set forth above (the "*Expiration Date*"). The Option constitutes an employment inducement grant under NASDAQ Rule 5635(c)(4) and is being granted pursuant to the terms of the Employment Agreement, entered into as of , between the Company and the Optionee (the "*Employment Agreement*"). The Option is not intended to qualify as an incentive stock option within the meaning of Section 422A of the Internal Revenue Code of 1986, as amended (the "*Code*").

3. **Exercise of Option**. The exercise of the Option is subject to the following terms and conditions:

   (a) During the lifetime of Optionee, the Option shall be exercisable only by Optionee. The Option shall not be assignable or transferable by Optionee, other than by will or the laws of descent and distribution. The Option may be exercised only by the Optionee (or by the Optionee's appropriate legal representatives or guardian in the event of the Optionee's death or if the Optionee becomes Disabled, as defined in the Employment Agreement), in whole or in part from time to time as provided in paragraph 3(b) below, during the period commencing on the date set forth in paragraph 3(b) below and ending on the earlier of (i) the Expiration Date or (ii) the expiration of the applicable period following the date of the Optionee's termination of employment with the Company, as provided in paragraph 5 below. In no event, however, may the Option be exercised to any extent after the Expiration Date.

   (b) The Option shall become exercisable in accordance with the schedule set forth below. Once the Option has become exercisable, the Optionee may exercise it to the extent set forth in the schedule at any time thereafter, subject to the provisions of this Agreement and the Employment Agreement.

On or after each of the following dates	Shares as to which the Option is vested
Each subsequent monthly anniversary for ____ months	

   (c) In the event the Optionee's employment is terminated (i) without Cause (as defined in the Employment Agreement), (ii) by the Optionee for Good Reason (as defined in the Employment Agreement), or (iii) as a result of the Company giving notice to Employee of Company's desire to terminate the Employment Agreement (pursuant to Section of the Employment Agreement), then provided that Optionee has executed, delivered and not rescinded a written release as described in Section of the Employment Agreement, the remaining unvested shares of the Option shall vest in accordance with the terms of the Employment Agreement).

   (d) Upon the occurrence of a Change in Control, the Option shall become fully exercisable on the date the Change of Control is completed. In addition, upon a Change in Control, the Committee may, in its sole discretion, provide that upon the consummation of such Change in Control, the Option shall be cancelled (after its full acceleration) in exchange for a cash payment equal to the difference between (a) the per share amount paid to holders of the Common Stock in such transaction and (b) the Exercise Price.

4. **Manner of Exercise**. The Option shall be exercised by the delivery of written notice of exercise (the "*Notice*") to the Company at its principal executive office. The Notice shall be in such form as the Committee may prescribe (including electronic form) and shall specify the number of Shares as to which the Optionee is exercising the Option, and shall be accompanied by payment of the Exercise Price of the Shares either in cash (bank check, certified check or personal check payable to the Company or by wire transfer to the Company) or by the delivery of Shares owned by the Optionee with a Fair Market Value (as defined in the attached Exhibit A) equal to the amount of the Exercise Price, or a combination of both. The Notice shall also be accompanied by such other information and documents as the Committee, in its discretion, may request.

5. **Effect of Termination of Relationship with the Company**.

   (a) In the event that Optionee's relationship with the Company or its Affiliates shall terminate, for any reason other than for Cause or Optionee's death or Disability, Optionee shall have the right to exercise the Option at any time within five years after such termination to the extent of the full number of Shares Optionee was entitled to purchase under the Option on the Separation Date, subject to the condition that the Option shall not be exercisable after the expiration of its term.

   (b) In the event that Optionee's relationship with the Company or its Affiliates shall terminate for Cause, the Option shall terminate as of the Separation Date and shall not be exercisable thereafter.

   (c) If Optionee shall die during its relationship with the Company or its Affiliates, or within three months after termination of such relationship with the Company for any reason other than for Cause, or if Optionee's relationship with the Company or its Affiliates is terminated because the Optionee has become Disabled (as defined in Section   of the Employment Agreement), and Optionee shall not have fully exercised the Option, the Option may be exercised at any time within twelve months after the date of Optionee's death or termination of Optionee's relationship because of Disability by the legal representative or, if applicable, guardian of Optionee or by any person to whom the Option is transferred by will or the applicable laws of descent and distribution to the extent of the full number of Shares Optionee was entitled to purchase under the Option on the date of death (or Separation Date, if earlier) or termination of Optionee's relationship because of Disability, and subject to the condition that the Option shall not be exercisable after the Expiration Date.

6. **Income Taxes**. The Optionee is liable for any federal, state and local income or other taxes applicable upon the grant or exercise of the Option or the disposition of the Shares, and the Optionee acknowledges that he should consult with his own tax advisor regarding the applicable tax consequences. Upon exercise of the Option, the Optionee shall promptly pay to the Company the minimum statutory withholding taxes required to be withheld or collected by the Company in connection with the exercise of the Option. The Optionee may pay all or a portion of the minimum statutory withholding taxes by (a) having the Company withhold Shares otherwise to be delivered upon the exercise of the Option with a Fair Market Value equal to the amount of such taxes, (b) delivering to the Company shares of Common Stock other than Shares issuable upon the exercise of the Option with a Fair Market Value equal to the amount of such taxes or (c) paying cash. For federal income tax purposes, the Option shall not be eligible for treatment as a qualified or incentive stock option.

7. **No Right to Employment**. The grant of the Option shall not be construed as giving the Optionee the right to be retained as an employee of the Company or any Affiliate, nor will it affect in any way the right of the Company or an Affiliate to terminate the Optionee's employment at any time, with or without Cause.

8. **Plan**. The Option is issued pursuant to the Plan and is subject to its terms. In the event that any of the terms of this Option conflict or are inconsistent in any respect with the terms of the Plan, the Plan terms shall control. Optionee hereby acknowledges receipt of a copy of the Plan. The Plan is also available for inspection during business hours at the principal office of the Company.

9. **Adjustments**. In the event that there is any change in the Common Stock or corporate structure of the Company as a result of any dividend or other distribution (whether in the form of cash, Common Stock, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase Common Stock or other securities of the Company or other similar corporate transaction or event, then the Committee shall, in such manner as it deems equitable, adjust the number and type of Shares and the Exercise Price; provided, however, that the number of Shares covered by the Option shall always be a whole number.

10. **Governing Law**. The validity, construction and effect of the Agreement, and any rules and regulations relating to the Agreement, shall be determined in accordance with the laws of the State of Minnesota.

11. **Acknowledgment**. This Option shall not be effective until the Optionee dates and signs the form of Acknowledgment below and returns a signed copy of this Agreement to the Company. By signing the Acknowledgment, the Optionee agrees to the terms and conditions of this Agreement.

ACKNOWLEDGMENT:

ENTEROMEDICS INC.

____
OPTIONEE'S SIGNATURE

____
DATE

By:____________________________________
[Name]
[Title]

EXHIBIT A

DEFINED TERMS USED IN THE
STOCK OPTION AGREEMENT

The following terms used in this Agreement have the following meanings:

"*Affiliate*" shall have the meaning ascribed to such term in Rule 12b-2 promulgated under the Exchange Act.

"*Associate*" shall have the meaning ascribed to such term in Rule 12b-2 promulgated under the Exchange Act.

"Change in Control" shall mean:

(i) any "person" (as such term is used in Sections 13(d) and 14(d)(2) of the Exchange Act who did not own shares of the capital stock of the Company on the date of grant of the Option shall, together with his, her or its Affiliates and Associates (as such terms are defined in Rule 12b-2 promulgated under the Exchange Act), become the "Beneficial Owner" (as such term is defined in Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities (any such person being hereinafter referred to as an "Acquiring Person");

(ii) the Continuing Directors cease to constitute a majority of the Company's Board;

(iii) There should occur (A) any consolidation or merger involving the Company and the Company shall not be the continuing or surviving corporation or the shares of the Company's capital stock shall be converted into cash, securities or other property; provided, however, that this subclause (A) shall not apply to a merger or consolidation in which (i) the Company is the surviving corporation and (ii) the stockholders of the Company immediately prior to the transaction have the same proportionate ownership of the capital stock of the surviving corporation immediately after the transaction; (B) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of the Company; or (C) any liquidation or dissolution of the Company; or

(iv) The majority of the Continuing Directors determine, in their sole and absolute discretion, that there has been a Change in Control.

"*Committee*" shall mean the Compensation Committee of the Company's Board of Directors.

"*Continuing Director*" shall mean any person who is a member of the Board of Directors of the Company, while such person is a member of the Board of Directors, who is not an Acquiring Person, an Affiliate or Associate of an Acquiring Person or a representative of an Acquiring Person or of any such Affiliate or Associate and who (i) was a member of the Company's Board of Directors on the date of grant of the Option or (ii) subsequently became a member of the Board of Directors, upon the nomination or recommendation, or with the approval of, a majority of the Continuing Directors.

"*Exchange Act*" shall mean the Securities and Exchange Act of 1934, as amended.

"*Fair Market Value*" shall mean the closing sale price of the Common Stock as reported on the NASDAQ Capital Market on such date or, if such market is not open for trading on such date, on the most recent preceding date when such market is open for trading.

Exhibit 10.45

CONFIDENTIAL SEPARATION AGREEMENT AND GENERAL RELEASE

This Confidential Separation Agreement and General Release (hereinafter "Agreement") is entered into by and between Bradford Hancock (hereinafter "you") and EnteroMedics Inc. (hereinafter "EnteroMedics").

WHEREAS, you and EnteroMedics entered into an Executive Employment Agreement dated November 17, 2014 ("Employment Agreement") which terminates effective January 6, 2016, except as to certain provisions outlined below;

WHEREAS, EnteroMedics wishes to provide you with the separation benefits described in Section 2 below; and

WHEREAS, you and EnteroMedics want to fully and finally settle all issues, differences, and claims, whether potential or actual, between you and EnteroMedics, including, but not limited to, any claim that might arise out of your employment with EnteroMedics or the termination of your employment with EnteroMedics;

NOW, THEREFORE, in consideration of the provisions and of the mutual covenants contained herein, you and EnteroMedics agree as follows:

1. <u>Separation from Employment</u>. Effective January 6, 2016 (your "date of separation"), your employment with EnteroMedics terminates. Except as provided in this Agreement, all benefits and privileges of employment end as of your date of separation.

2. <u>Separation Benefits</u>. As consideration for your promises and obligations under this Agreement, and subject to the terms and conditions of this Agreement, including the release of claims set forth below, EnteroMedics agrees to pay you, as separation pay, the gross amount of three hundred thirty thousand dollars ($330,000.00), less applicable deductions and withholdings for state and federal taxes, which amount represents 12 months of your base salary as of your date of separation. The separation pay will be divided and paid to you in substantially equal periodic payments at the usual and customary pay intervals of EnteroMedics, less deductions and withholdings. The payments will begin within 30 business days of the date on which EnteroMedics receives this Agreement signed by you, *provided that* you do not revoke or rescind this Agreement as set forth below. You agree that you are not entitled to the separation benefits provided to you in this Agreement if you do not sign this Agreement.

3. <u>2015 Incentive Compensation</u>. EnteroMedics will notify you in writing no later than February 12, 2016, of the amount of incentive compensation, if any, to be paid to you related to the objectives set for you for calendar year 2015.

4. <u>Medical, Dental, and Life Insurance</u>. If you elect to extend EnteroMedics-provided medical, dental, and/or life insurance coverage under COBRA after your date of separation, then EnteroMedics will pay the same share of any COBRA premiums as it paid of the premiums while you were employed for the shorter of (a) twelve (12) months beginning February 1, 2016, and continuing through January 31, 2017, or (b) until you obtain comparable benefits through another employer or entity. You agree that any COBRA premium paid on your behalf and/or any reimbursement made to you for COBRA premiums paid by you will be treated as taxable by EnteroMedics.

5. Stock Options. All options to purchase shares of common stock of EnteroMedics held by you (the "Options") are subject to the terms of one or more Stock Option Agreements between you and the Company (each, an "Option Agreement") and were granted pursuant to the EnteroMedics Inc. Amended and Restated 2003 Stock Incentive Plan, as amended (the "Plan"). Pursuant to the terms and conditions set forth in the Option Agreements, EnteroMedics agrees that, notwithstanding anything to the contrary set forth in such Option Agreements or the Plan, during the two-year period following your date of separation, you shall be permitted to exercise any Option immediately to the extent that such Option was vested as of your date of separation or would have vested within one year of your date of separation had your employment with Company not terminated. Notwithstanding anything to the contrary set forth in such Option Agreements or the Plan, EnteroMedics shall have a right, following your date of separation, to buy back all such Options based on the per share exercise price under the applicable Option Agreement. The parties agree and acknowledge that, with respect to any Options that were intended by the parties to be treated as "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, such Options, to the extent they may be exercised by you more than 90 days following your date of separation, shall be treated as non-qualified options, notwithstanding any provision in the Option Agreements to the contrary.

6. Confidential Information; Noncompetition and Nonsolicitation. You executed an Employment Agreement with EnteroMedics, a copy of which is attached hereto as Exhibit A. All provisions of the Employment Agreement that, by their terms, survive the termination of your employment will continue in full force and effect and are not negated or otherwise affected by this Agreement, including but not limited to Article IV: Confidential Information and Article VI: Noncompetition and Nonsolicitation; and Section 7.1: Company Remedies.

7. Return of EnteroMedics Property. You acknowledge that, on or before the date you sign this Agreement, you have returned all EnteroMedics property in your possession, including, but not limited to, all files, memoranda, documents, records, copies of the foregoing, any EnteroMedics credit card, computer, fax machine, printer, copier, keys, access cards, and any other property of EnteroMedics in your possession. You also acknowledge that, on or before the date you sign this Agreement, you have provided EnteroMedics with any and all pass codes and/or personal identification numbers used by you to access the EnteroMedics computer system, e-mail system, and/or the Internet, and/or documents or files contained on and saved in the EnteroMedics computer system.

8. Duty to Cooperate. You agree that, beginning on the date you are presented with this Agreement, you will cooperate with EnteroMedics with respect to the transition of your duties, the preservation of effective operations and customer service, and EnteroMedics' strategic and commercial initiatives. As part of your agreement to cooperate, you will provide a list identifying the status of major projects under way, pending customer interactions, the status of sale cycles with customers, the names and contact information of key contacts at customers, and any other information reasonably requested by EnteroMedics regarding your duties and responsibilities. You further agree that, in the 30 day period following your acceptance of this Agreement you will periodically make yourself accessible and available during normal business hours for consultation with EnteroMedics representatives in connection with the transition of your duties and responsibilities. You agree that such consultation may include appearing from time to time at the office of EnteroMedics for conferences.

9. Confidentiality. You agree that the existence and terms and conditions of this Agreement (other than Exhibit A) shall remain confidential and that you will not disclose any information concerning the provisions of this Agreement to any person or entity, including, but not limited to, any present or former employee of EnteroMedics. These confidentiality provisions are subject to the following exceptions: you may disclose the provisions of this Agreement to your attorneys, accountants, tax and financial advisors, and immediate family, or in the course of legal proceedings involving EnteroMedics, or in response to a subpoena, court order, or inquiry by a government agency. You further agree that, if any information concerning the provisions of this Agreement is revealed as permitted by this section, you shall inform the recipient of the information that it is confidential, and the recipient shall agree to keep the information confidential.

10. Release. By this Agreement, you intend to settle any and all claims that you have or may have against EnteroMedics as a result of EnteroMedics hiring you, your employment with EnteroMedics, and the decision to terminate your employment with EnteroMedics. You agree that, in exchange for EnteroMedics' promises in this Agreement, and in exchange for the consideration provided to you by EnteroMedics, described above in Section 2, you, on behalf of your heirs, successors and assigns, hereby release and discharge EnteroMedics, its predecessors, successors, assigns, parents, affiliates, subsidiaries, and related companies, and their officers, directors, shareholders, agents, servants, employees, and insurers (collectively "the Released Parties") from all liability for damages and from all claims that you may have against the Released Parties occurring up through the date you sign this Agreement. You understand and agree that your release of claims in this Agreement includes, but is not limited to, any claims you may have under: Title VII of the Federal Civil Rights Act of 1964, as amended; the Americans with Disabilities Act; the Equal Pay Act; the Employee Retirement Income Security Act; the Age Discrimination in Employment Act of 1967, as amended; the Older Workers Benefit Protection Act; the Family and Medical Leave Act; the Worker Adjustment and Retraining Notification Act of 1988; the False Claims Act; the Minnesota Human Rights Act; Minnesota Equal Pay for Equal Work Law, Minn. Stat. §§ 181.66–181.71; Minn. § 181.81 (age discrimination); Minn. Stat. § 176.82 (retaliatory discharge); Minn. Stat. §§ 181.931, 181.932, 181.935 (whistleblower protection); Minn. Stat. §§ 181.940–181.944 (family leave); or any other federal, state, or local statute, ordinance, or law.

You also agree and understand that you are giving up all other claims, whether grounded in contract or tort theories, including but not limited to: wrongful discharge; breach of contract; any claim for unpaid compensation (including, but not limited to, any claims for PTO or severance except as set forth in this Agreement, or for incentive compensation from calendar year 2016); tortious interference with contractual relations; promissory estoppel; detrimental reliance; breach of the implied covenant of good faith and fair dealing; breach of express or implied promise; breach of manuals or other policies; breach of fiduciary duty; assault; battery; fraud; false imprisonment; invasion of privacy; intentional or negligent misrepresentation; defamation, including libel, slander, discharge defamation and self-publication defamation; discharge in violation of public policy; whistleblower; qui tam actions; intentional or negligent infliction of emotional distress; or any other theory, whether legal or equitable.

You understand that nothing contained in this Agreement, including but not limited to this Section 10, will be interpreted to prevent you from filing a charge with the Equal Employment Opportunity Commission ("EEOC"), or any other governmental agency, or from participating in or cooperating with an EEOC or other governmental agency investigation or proceeding. However, you agree that you are waiving the right to monetary damages or other individual legal or equitable relief awarded as a result of any such proceeding.

11. Time to Accept. You are hereby informed that the terms of this Agreement shall be open for acceptance and execution by you through and including February 12, 2016, during which time you may consult with an attorney and consider whether to accept this Agreement. You may not sign this Agreement until February 12, 2016. Changes to this Agreement, whether material or immaterial, will not restart the running of this acceptance period. You hereby are advised to consult with an attorney prior to signing this Agreement.

12. Right to Revoke and Rescind. You are hereby informed of your right to revoke your release of claims, insofar as it extends to potential claims under the Age Discrimination in Employment Act, by informing EnteroMedics of your intent to revoke your release of claims within 7 calendar days following your signing of this Agreement. You are also informed of your right to rescind your release of claims, insofar as it extends to potential claims under the Minnesota Human Rights Act, by delivering a written rescission to EnteroMedics within 15 calendar days after your signing of this Agreement. You understand that any such revocation or rescission must be made in writing and delivered by hand or by certified mail, return receipt requested, postmarked on or before the last day within the applicable revocation period to: Greg Lea, Senior Vice President, CFO and COO, EnteroMedics, Inc., 2800 Patton Road, St. Paul, MN 55113.

If you exercise your right to revoke or rescind this Agreement, EnteroMedics may, at its option, either nullify this Agreement in its entirety, or keep it in effect in all respects other than as to that portion of your release of claims that you have revoked or rescinded. You agree and understand that if EnteroMedics chooses to nullify the Agreement in its entirety, EnteroMedics will have no obligations under this Agreement to you or to others whose rights derive from you.

13. Entire Agreement. This Agreement, as well as the exhibits hereto and any agreements referenced herein, is the final, complete and exclusive agreement of the parties and sets forth the entire agreement between EnteroMedics and you with respect to your employment by EnteroMedics, and there are no undertakings, covenants or commitments other than as set forth herein. The Agreement may not be altered or amended, except by a writing executed by you and a member of the Board. Except as otherwise indicated, this Agreement supersedes, terminates, replaces and supplants any and all prior understandings or agreements between the parties relating in any way to you hiring or employment by EnteroMedics.

14. Governing Law. The laws of the State of Minnesota will govern the validity, construction and performance of this Agreement, without regard to the conflict of law provisions of any other jurisdictions. If any part of this Agreement is construed to be in violation of any

law, such part shall be modified to achieve the objective of the parties to the fullest extent permitted and the balance of this Agreement shall remain in full force and effect. If such modification is not possible, said provision will be deemed severable from the remaining provisions of this Agreement and the balance of this Agreement shall remain in full force and effect.

15. Remedies. To the extent that the EnteroMedics wishes to pursue remedies against you under Section 7.1 of the Employment Agreement, you and EnteroMedics agree that such action shall be venued in Minnesota District Court, Hennepin County, or United States District Court, District of Minnesota. For any other dispute, you and EnteroMedics irrevocably consent that any litigation commenced or arising in connection with the interpretation or enforcement of this Agreement that has not been settled through negotiation within a period of thirty (30) days after the date on which either party shall first have notified the other party in writing of the existence of a dispute shall be settled by final and binding arbitration under the then-applicable Commercial Arbitration Rules of the American Arbitration Association ("AAA"). Any such arbitration shall be conducted by one (1) neutral arbitrator appointed by mutual agreement of the parties or, failing such agreement, in accordance with the AAA Rules. The arbitrator shall be an experienced attorney with a background in employment law. Any arbitration shall be conducted in Minneapolis, Minnesota. An arbitration award may be enforced in any court of competent jurisdiction. Notwithstanding any contrary provision in the AAA Rules, the following additional procedures and rules shall apply to any such arbitration:

(A) Each party shall have the right to request from the arbitrator, and the arbitrator shall order upon good cause shown, reasonable and limited pre-hearing discovery, including (1) exchange of witness lists, (2) depositions under oath of named witnesses at a mutually convenient location, (3) written interrogatories, and (4) document requests;

(B) Upon conclusion of the pre-hearing discovery, the arbitrator shall promptly hold a hearing upon the evidence to be adduced by the parties and shall promptly render a written opinion and award;

(C) The arbitrator may award damages or injunctive relief consistent with the terms of this Agreement but may not award or assess punitive damages against either party; and

(D) Each party shall bear his or its own costs and expenses of the arbitration and one-half (1/2) of the fees and costs of the arbitrator, subject to the power of the arbitrator, in his or her sole discretion, to award all such reasonable costs, expenses and attorneys' fees to the prevailing party.

16. No Admission. Nothing in this Agreement is intended to be, and nothing will be deemed to be, an admission of liability by EnteroMedics or you that either party has violated any state or federal statute, local ordinance or principle of common law, or that either party has engaged in any wrongdoing.

17. Waiver. No waiver of any provision of this Agreement shall be binding unless executed in writing by the party making the waiver. The waiver by either party of a breach by the other party of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach.

IN WITNESS WHEREOF, the parties have duly executed this Agreement on the dates set forth below to be effective as of the date shown below.

I acknowledge and agree that I have read this Agreement in its entirety and that I agree to the conditions and obligations set forth herein. Further, I agree that I have had adequate time to consider the terms of this Agreement and that I am voluntarily entering into this Agreement with a full understanding of its meaning. I understand that I am hereby advised to consult with an attorney before signing this Agreement.

DO NOT SIGN BEFORE FEBRUARY 12, 2016

Dated: February 12, 2016	/s/ Bradford Hancock Bradford Hancock
	ENTEROMEDICS INC.
Dated: February 24, 2016	By /s/ Greg S. Lea
	Its CFO

Exhibit A

ENTEROMEDICS INC.
EXECUTIVE EMPLOYMENT AGREEMENT

This Employment Agreement (“Agreement”) is made and entered on November 17, 2014 (“Agreement Date”) between EnteroMedics Inc. (“Company”), a Delaware corporation with its principal place of business at 2800 Patton Road, St. Paul, Minnesota 55113, and Bradford Hancock (“Employee”), a Minnesota resident, whose address is 8680 Great Waters Alcove, Eden Prairie, MN 55347, for the purpose of setting forth the terms and conditions of Employee’s employment by the Company.

RECITALS

WHEREAS, Employee possesses certain skills, talents, contacts, judgment and knowledge of the business of Company;

WHEREAS, Employee is currently employed by the Company as Chief Commercial Officer, the Company desires to have the continued benefit of Employee’s employment in such capacities, and Employee desires to continue to serve in such capacities, pursuant to the terms and conditions set forth in this Agreement;

WHEREAS, Employee will continue to be a key employee of the Company with significant access to confidential and proprietary information concerning the Company and its business, and Employee understands and agrees that the disclosure of such information or the engaging in competitive activities would cause substantial harm to the Company; and

WHEREAS, Employee understands that such continued employment is expressly conditioned on execution of this Agreement.

AGREEMENT

NOW, **THEREFORE**, in consideration of Employee’s continued employment with Company and the foregoing premises, the mutual covenants set forth below and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Company and Employee agree as follows:

ARTICLE I: EMPLOYMENT, TERM, AND DUTIES

1.1 **Employment**. Company hereby employs Employee as Chief Commercial Officer and Employee accepts such employment and agrees to perform services for Company pursuant to the terms and conditions set forth in this Agreement.

1.2 **Term**. The term (“Term”) of this Agreement shall commence on the Agreement Date and, unless earlier terminated in accordance with Article III of this Agreement, shall terminate one year from the Agreement Date; provided, however, the term of this Agreement shall automatically renew for successive one year terms thereafter unless prior to ninety (90) days of the expiration of the initial Term or any additional Terms, either party provides written notice to the other of its or his desire to terminate this Agreement.

1.3 **Position and Duties**.

1.3.1 **Service with Company**. During the Term, Employee agrees to perform such duties and responsibilities as are assigned to him from time to time by the CEO and Company's Board of Directors ("Board") which currently encompasses financial and administrative services.

1.3.2 **Performance of Duties**. During the Term, Employee agrees to serve Company in an Executive capacity as Chief Commercial Officer and shall perform such duties as are required by the CEO and the Board. Employee hereby warrants and represents that Employee has no contractual commitments or other obligations to third parties inconsistent with Employee's acceptance of this employment and performance of the obligations set forth in this Agreement. Employee shall perform such duties and carry out Employee's responsibilities hereunder faithfully and to the best of Employee's ability, and shall devote Employee's full business time and best efforts to the business and affairs of the Company (exclusive of periods of vacation, sickness, disability, or other leaves to which Employee is entitled). Employee will perform all of Employee's responsibilities in compliance with all applicable laws and in a professional manner consistent with generally accepted industry practices and procedures and any specific Company policies or guidelines, and Employee will ensure that the operations Employee manages are in compliance with all applicable laws

ARTICLE II: COMPENSATION, BENEFITS AND EXPENSES

2.1 **Base Salary**. Subject to the provisions of Article III of this Agreement, during the Term, Company shall pay Employee a Base Salary not less than $330,000 per year or such higher annual rate as may from time to time be approved by the Board. Such Base Salary shall be paid in substantially equal regular periodic payments, less deductions and withholdings, in accordance with Company's regular payroll procedures, policies and practices as such may be modified from time to time. The Base Salary shall be reviewed by the compensation committee of the Board annually for potential adjustment on the basis of performance and Employee shall be eligible, at Company's sole discretion, for annual salary increases consistent with Company's procedures, policies and practices. If Employee's Base Salary is increased from time to time during the Term, the increased amount shall become the Base Salary for the remainder of the Term and any extensions of the Term and for as long thereafter as required pursuant to Article III as applicable, subject to any subsequent increases.

2.2 I**ncentive Compensation**. In addition to Base Salary, Company shall make Employee eligible for such cash and equity pursuant to Company's Incentive Compensation Plan, if any, as may be applicable and adopted by Company. Payment of incentive compensation will be subject to Employee achieving certain objectives set annually by Employee and the Compensation Committee of the Board, with the target amount of any cash incentive compensation for any calendar year to be approved by the Compensation Committee of the Board, which in no event shall exceed 40% of Employee's base salary in effect from time to time. Employee and the CEO will meet and review the objectives set by the CEO for the upcoming calendar year prior to March 31 of each year.

2.3 **Participation in Benefits**. During the Term of Employee's employment by Company, Employee shall be entitled to participate in the employee benefits offered generally by Company to its employees in accordance with the Company's existing policies and benefits plans, to the extent that Employee's position, tenure, salary, health and other qualifications make Employee eligible to participate. Without limiting the foregoing, Employee shall be eligible to participate in any pension plan, or group life, health or accident insurance or any such other plan or policy that may presently be in effect or that may hereafter be adopted by the Company for the benefit of its employees and corporate officers generally. Employee is eligible to receive Paid Time Off ("PTO") on an annual basis subject to Company's PTO policy. PTO includes all forms of personal leave including vacation and sick leave. Employee's participation in such benefits shall be subject to the terms of the applicable plans, as the same may be amended from time to time. Company does not guarantee the adoption or continuance of any particular employee benefit during Employee's employment, and nothing in this Agreement is intended to, or shall in any way restrict the right of Company, to amend, modify or terminate any of its benefits during the Term of this Agreement. As with all benefits, the Company reserves the right to alter related policies and plans, or to cancel such policies or plans altogether, at any time and at its sole discretion.

ARTICLE III: TERMINATION AND COMPENSATION FOLLOWING TERMINATION

3.1 **Termination**. Subject to the respective continuing obligations of the parties under this Agreement, this Agreement and Employee's employment hereunder may be terminated prior to the end of the Term (the "Separation Date") under the following circumstances; in no event, however, shall the Separation Date be deemed to occur until Employee experiences a "separation from service" within the meaning of Section 409A of the Internal Revenue Code:

3.1.1 **Termination By Mutual Agreement**. By mutual written agreement of the parties at any time.

3.1.2 **Termination By Employee's Death**. In the event of Employee's death.

3.1.3 **Termination By Employee's Disability**. In the event Employee becomes Disabled. For purposes of this Agreement, "Disabled" or "Disability" means the incapacity or inability of Employee, whether due to accident, sickness or otherwise (with the exception of the illegal use of drugs), as determined by a medical doctor acceptable to Company and confirmed in writing by such doctor, to perform the essential functions of Employee's position under this Agreement, with or without reasonable accommodation (provided that no accommodation that imposes undue hardship on Company will be required) for an aggregate of ninety (90) days during any period of one hundred eighty (180) consecutive days, or such longer period as may be required under applicable law, including any entitlement to any applicable disability-related leave of absence if Employee requests to take such leave and satisfies all eligibility requirements for such leave and provided such leave does not impose an undue hardship on the Company.

3.1.4 **Termination By Company For Cause**. Company may terminate this Agreement and Employee's employment for Cause at any time after providing written notice to Employee. For purposes of this Agreement, "Cause" means: (a) willful breach of Employee's duties to Company or willful breach of this Agreement; (b) conviction of any felony or any crime involving fraud, dishonesty, or moral turpitude; (c) participation in any fraud against or affecting

Company or any subsidiary, affiliate, customer, supplier, client, agent, or employee thereof; or (d) any other act Company determines constitutes gross or willful misconduct detrimental to Company including, but not limited to, unethical practices, dishonesty, disloyalty, or any other acts harmful to Company; provided, however that a for Cause termination pursuant to clause (a), if susceptible of cure, shall not become effective unless Employee fails to cure such failure to perform or breach within thirty (30) days after his receipt of written notice from Company, such notice to describe such failure to perform or breach and identify what reasonable actions shall be required to cure such failure to perform or breach.

3.1.5 **Termination By Employee Without Good Reason**. The Employee may terminate Employee's employment under this Agreement at any time for any reason or no reason with thirty (30) days written notice. Upon receiving Employee's notice, Company has the option, at its discretion (a) to continue to engage Employee's services through the 30-day notice period until the Separation Date, or (b) terminate the use of Employee's services during the 30-day notice period, but for salary purposes, treat the Employee as if employment continued through the 30-day notice period through the Separation Date. In the event that Employee fails to provide thirty (30) days' prior written notice, Employee shall not be entitled to any payment of incentive compensation, in accordance with Section 3.2.2 below.

3.1.6 **Termination By Company Without Cause**. Company may terminate Employee's employment under this Agreement at any time for any reason or no reason with 30 days written notice including following a Change in Control as defined in Employee's applicable Company Incentive Stock Option Agreement(s) or Non-Incentive Stock Option Agreement(s) ("Employee's Stock Option Agreements") as the case may be, except that no notice shall be required for a termination without Cause following a Change in Control. In the event the Company should give Employee notice of termination without Cause, the Company has the option, at its discretion (a) to continue to engage Employee's services through the 30-day notice period until the Separation Date, or (b) terminate the use of Employee's services during the 30-day notice period, but for salary purposes, treat the Employee as if employment continued through the 30-day notice period through the Separation Date.

3.1.7 **Termination By Employee For Good Reason**. Employee may terminate Employee's employment pursuant to this Agreement for Good Reason. For purposes of this Agreement, "Good Reason" means: (a) at any time, the assignment by Company to Employee of employment duties, functions or responsibilities that are significantly different from, and result in a substantial diminution of, Employee's compensation, duties, functions or responsibilities without Employee's consent; or (b) at any time, a requirement that Employee be based at any office or location more than 75 miles from Employee's primary work location prior to the date of this Agreement without Employee's consent, provided that the Employee shall have Good Reason to terminate Employee's employment if (i) within 30 days following Employee's actual knowledge of the event which Employee determines constitutes Good Reason, Employee notifies the Company in writing that Employee has determined a Good Reason exists and specifies the event creating Good Reason, and (ii) following receipt of such notice, the Company fails to remedy such event within 30 days. If either condition is not met, Employee shall not have a Good Reason to terminate employment.

3.2 **Compensation Following Termination Prior to End of the Term**. In the event that Employee's employment pursuant to this Agreement is terminated prior to the end of the Term, Employee shall be entitled to the following compensation and benefits upon such termination:

3.2.1 **Payment of Base of Salary**. In the event that Employee's employment is terminated pursuant to any subsection of Section 3.1 of this Agreement, Company shall pay to Employee, Employee's spouse or Employee's estate, as the case may be, any amounts due to Employee for Base Salary through the Separation Date in accordance with applicable law.

3.2.2 **Payment of Incentive Compensation**. In the event that Employee's employment is terminated prior to the expiration of the Term pursuant to subsections 3.1.1; 3.1.2; 3.1.3; 3.15 (with proper notice); 3.1.6; or 3.1.7 of Section 3.1 of this Agreement, Company shall, within 14 calendar days following the Separation Date or following the expiration of any revocation and/or rescission period in any applicable release of claims, whichever is later, also pay to Employee, Employee's spouse or Employee's estate, as the case may be, an amount equivalent to a pro rata portion of any payment under the Company's Incentive Compensation Plan to which Employee would have been entitled pursuant to Section 2.2 of this Agreement and the Company's policies had Employee remained employed through the end of the year in question, to be determined at the sole discretion of the Compensation Committee of the Board.

3.2.3 **Payment of Severance for Termination By Company Without Cause or By Employee for Good Reason**. In the event that Employee's employment is terminated by the Company at the end of the term in accordance with Section 1.2 (Term), or prior to the expiration of the Term pursuant to subsection 3.1.6 (By Company Without Cause) or 3.1.7 (By Employee for Good Reason), and provided Employee has executed a written release to Company in substantially the same form attached hereto as **Exhibit A** and the revocation and/or rescission period specified therein has expired, Company shall also continue to pay, as severance pay, Employee's Base Salary at the rate in effect on the Separation Date, for a period of 6 months following the Separation Date if employment is terminated by either party within the first 6 months of Employee's employment with the Company, and for a period of 12 months following the Separation Date if employment is terminated at or after 6 months of Employee's employment with the Company. Such payments will be at usual and customary pay intervals of Employer and will be subject to all appropriate deductions and withholdings. In the event that a Change in Control occurs, to the extent Employee receives related severance benefits, Employee shall be entitled to receive either of the following options at the Employee's discretion: (a) severance pay to be capped at an amount $1.00 below the allowable amount under Internal Revenue Code Sections 280G and 4999, or (b) unreduced severance pay, with Employee assuming all responsibility for any excise tax liability.

Additionally, pursuant to the terms and conditions set forth in Employee's applicable Stock Option Agreements with Company, Company agrees that, notwithstanding anything to the contrary set forth in such Stock Option Agreements or Company's Stock Incentive Plan, as may be amended from time to time, during the two-year period following the Separation Date, Employee shall be permitted to exercise immediately all Options granted to Employee that have vested as of the Separation Date and those Options that would have vested within one year of the Separation Date had Employee's employment with Company not terminated. Notwithstanding anything to the contrary set forth in such Stock Option Agreements or Company's Stock

Incentive Plan, the Company shall have a right, following the Separation Date, to buy back all such Options granted to Employee based on the per share exercise price under the applicable option agreement. The parties hereto agree and acknowledge that, with respect to any Options previously granted to Employee that were intended by the parties to be treated as "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, such Options, to the extent they may be exercised by Employee more than 90 days following the Separation Date shall be treated as non-qualified Options, notwithstanding any provision in Employee's Stock Option Agreements to the contrary.

In the event that a Change in Control occurs, and Employee is not terminated, the vesting schedule of Options held by Employee shall accelerate such that on the date the Change of Control is completed 50% of any unvested shares of Employee shall immediately vest and shall anything to the contrary set forth in Employee's applicable Stock Option Agreements with the Company or Company's Stock Incentive Plan; provided, however, that if, in connection with the consummation of the transaction resulting in the Change in Control, Employee receives a cash payment with respect to each Option equal to the difference or "spread" between (i) the per share amount paid to holders of Common Stock in such transaction and (ii) the per share exercise price under the applicable option agreement, his Options shall be cancelled upon the consummation of the Change in Control in exchange for such cash payment.

In the event that a Change in Control occurs, and Employee is terminated, the vesting schedule of Options held by Employee shall accelerate such that on the date the Change of Control is completed 100% of any unvested shares of Employee shall immediately vest and shall be exercisable during the five-year period following the Separation Date notwithstanding anything to the contrary set forth in Employee's applicable Stock Option Agreements with the Company or Company's Stock Incentive Plan; provided, however, that if, in connection with the consummation of the transaction resulting in the Change in Control, Employee receives a cash payment with respect to each Option equal to the difference or "spread" between (i) the per share amount paid to holders of Common Stock in such transaction and (ii) the per share exercise price under the applicable option agreement, his Options shall be cancelled upon the consummation of the Change in Control in exchange for such cash payment.

3.2.4 **General Provision Regarding Treatment of Options**. Except as otherwise specified in Sections 3.2.3 of this Agreement, the terms of the Stock Incentive Plan and Employee's Stock Option Agreements, as applicable, shall govern the treatment of Employee's Options following the Separation Date.

3.3 **Benefits Following Termination Prior to the End of the Term**. In the event that Employee's employment is terminated pursuant to subsections 3.1.2; 3.1.3; 3.1.6; or 3.1.7 of Section 3.1 of this Agreement, Employee shall, at no cost to Employee, be entitled to continue to participate in Company-provided medical, dental, and life insurance programs for a period of 6 months following the Separation Date if employment is terminated by either party within the first 6 months of Employee's employment with the Company, and for a period of 12 months following the Separation Date if employment is terminated at or after 6 months of Employee's employment with the Company – or until Employee obtains comparable benefits through another entity – irrespective of any then pre-existing health conditions of Employee or Employee's spouse. To avoid adverse tax consequences to Employee under rules that prohibit discrimination in favor of highly compensated individuals with respect to health plan eligibility or benefits, the Company must collect the full fair market value of the cost of Employee's medical, dental, and life insurance coverage (using applicable COBRA rates to determine the cost of such coverage) from Employee's salary on an after-tax basis or by personal check from Employee. Because Employee is only obligated to pay the employee share of the cost of coverage during this period, the Company will reimburse Employee on a taxable basis for the difference between the full fair market value of the cost of the coverage and the employee rate. The Company will provide a gross up so the net result is Employee's payment of the employee rate for coverage.

If this Agreement is terminated as a result of Employee's death, Employee's then current spouse shall be entitled to continue to participate in Company-provided medical and dental insurance programs for one year after Employee's death irrespective of any then pre-existing health conditions, unless, in each case, such continued participation is prohibited by any applicable laws or benefits plans or would otherwise jeopardize the tax qualified status of any such programs. If Company is prohibited by applicable law or benefits plans or would otherwise jeopardize the tax qualified status of any medical, dental, or life insurance plan and as a result Company terminates coverage, it shall promptly reimburse Employee (or Employee's spouse as the case may be) for the cost of obtaining comparable third party coverage irrespective of any then preexisting health conditions of Employee and/or his spouse.

Except as otherwise provided in this Section 3.3, the benefits to which Employee (or, as applicable, Employee's spouse or estate) may be entitled upon termination pursuant to the plans and policies of Company specified Article II of this Agreement shall be determined and paid in accordance with such plans and policies.

3.4 **Surrender of Records and Property**. Upon termination of Employee's employment with Company, Employee shall deliver promptly to Company all Confidential Information as defined in Section 4.1 and all Company property including, but not necessarily limited to records, manuals, books, blank forms, documents, letters, memoranda, business plans, minutes, notes, notebooks, reports, computer disks, computer software, computer programs (including source code, object code, on-line files, documentation, testing materials and plans and reports), computer print-outs, member or customer lists, credit cards, keys, identification, products, access cards, designs, drawings, sketches, devices, specifications, formulae, data, tables or calculations or copies thereof, and all other tangible or intangible property relating in any way to the business of Company that are the property of Company or any subsidiary or affiliate, if any, or which relate in any way to the business, products, practices or techniques of Company or any subsidiary or affiliate. After returning any such documents, data, and other property Employee will permanently delete from any electronic media in Employee's possession, custody, or control (such as computers, cell phones, hand-held devices, back-up devices, zip drives, PDAs, etc.), or to which Employee has access (such as remote e-mail exchange servers, back-up servers, off-site storage, etc.), all documents or electronically stored images of the Company, including writings, drawings, graphs, charts, sound recordings, images, and other data or data compilations stored in any medium from which such information can be obtained.

Furthermore, Employee agrees that, on or before the Separation Date, Employee will provide the Company with a list of any documents that Employee created as, or is otherwise aware to be, password protected and the password(s) necessary to access such password-protected documents.

ARTICLE IV: CONFIDENTIAL INFORMATION

4.1 **Definition**. For purposes of this Agreement, “Confidential Information” means any information that is not generally known to the public or to other persons who can obtain economic value from its disclosure or use; information which derives independent economic benefit from not being known to such persons; and/or information about the activities or business of Company that is not generally known to others engaged in similar business or activities, its products, services, finances, trade secrets, contracts, patents filed or pending, the techniques used in completing customer projects, research and development, data and information, processes, designs, engineering, marketing plans or techniques, organization or operation. The foregoing list is intended to be illustrative rather than comprehensive. Additionally, the term “Confidential Information” shall mean any confidential information as that term is defined in any other agreements Employee has entered with the Company, in any Company policies, as well as in any agreement the Company may have with its customers or other third parties from time to time.

4.2 **Nondisclosure**. During the term of this Agreement or at any time thereafter, Employee agrees not to disclose Confidential information to any other third party or company, other than in connection with Employee’s employment with Company, or use such information, directly or indirectly, for any purpose whatsoever, without the prior written consent of Company.

4.3 **Confidential Information of Others**.

4.3.1 **No Conflicts**. Employee represents that Employee’s performance of all the terms of this Agreement does not and will not breach any agreement to keep in confidence proprietary information acquired by me in confidence or in trust prior to the execution of this Agreement. Employee has not entered into, and shall not enter into, any agreement, either written or oral, in conflict with this Agreement.

4.3.2 **No Unauthorized Use of Others’ Secrets**. Employee represents that Employee has not brought and will not bring with Employee to the Company, or use in the performance of my responsibilities at the Company, any materials or documents of a present or former employer or client that are not generally available to the public, unless Employee has obtained the express written authorization from the present or former employer or client for their possession and use and provided a copy of such authorization to the Company.

4.4 **The terms of this Article 4 are in addition to, and not in lieu of, the covenants set forth in the Non-Disclosure Noncompetition Agreement dated October 26, 2014 as well as any statutory or other contractual or legal obligation to which Employee may be subject relating to the protection of Confidential Information.**

ARTICLE V: INVENTIONS

5.1 **Disclosure and Assignment of Inventions and Other Works**. During the term of this Agreement and for one year following the Separation Date, Employee shall promptly disclose to Company in writing all ideas, improvements and discoveries, whether or not such are patentable or copyrightable, and whether or not in writing or reduced to practice (“Inventions”) and any writings, drawings, diagrams, charts, tables, databases, software (in object or source code and recorded on any medium), and any other works of authorship, whether or not such are copyrightable (“Works of Authorship”) that are conceived, made, discovered, written or created by Employee alone or jointly with any person, group or entity, whether during the normal hours of his employment at Company or on Employee’s own time. Employee hereby assigns all rights to all such Inventions and Works of Authorship to Company. Employee shall give Company all the assistance it reasonably requires for Company to perfect, protect, and use its rights to such Inventions and Works of Authorship. Employee shall sign all such documents, take all such actions and supply all such information that Company considers necessary or desirable to transfer or record the transfer of Company’s entire right, title and interest in such Inventions and Works of Authorship and to enable Company to obtain exclusive patent, copyright, or other legal protection for Inventions and Works of Authorship anywhere in the world, provided Company shall bear all reasonable expenses of Employee in rendering such cooperation.

5.2 **Notice and Acknowledgement**. In accordance with Minnesota Statute § 181.78, the foregoing Section 5.1 does not require Employee to assign or offer to assign to Company any of Employee’s rights in an Invention that Employee developed entirely on Employee’s own time without using Company’s equipment, supplies, facilities or trade secret information, and (1) that does not relate directly to Company’s business or to Company’s actual or demonstrably anticipated research or development, or (2) that does not result from any work performed by Employee for Company. For the purpose of this Section, “Company’s business” shall be defined as development pertaining to implantable medical devices to treat obesity or devices to apply signals to a vagus nerve to treat a gastrointestinal disorder (e.g., obesity, pancreatitis or irritable bowel syndrome).

To the extent a provision in this Agreement purports to require Employee to assign Inventions otherwise excluded by this paragraph, the provision is against the public policy of the State of Minnesota and is unenforceable. By signing this Agreement, Employee acknowledges receipt of the notification required by Minnesota Statute § 181.78.

5.3 **Previous Works or Inventions**. As a matter of record Employee has identified in **Exhibit B** attached hereto all Works of Authorship or Inventions that have been generated or conceived or first reduced to practice, written, composed, created or learned by Employee, alone or jointly with others, prior to Employee’s employment by the Company, which Employee desires to remove from the operation of this Agreement. Employee represents and warrants that such list is complete and accurate. If there is no such list Exhibit B, Employee represents that Employee has no such Inventions or Works of Authorship at the time of signing this Agreement.

ARTICLE VI: NONCOMPETITION AND NONSOLICITATION

6.1 **Agreement Not to Compete**. During the Term of Employee’s employment by Company, and for a period of 1 (one) year from the Separation Date (whether termination of employment is occasioned by Employee or Company), Employee shall not, directly or indirectly, in any place in the world, render services to any conflicting organization, or engage in competition with Company, in any manner or capacity, nor direct any other individual or business enterprise to engage in competition with Company in any manner or capacity, (e.g., as an advisor, principal, agent, partner, officer, director, stockholder of more than 1% of the outstanding shares of the capital stock of a publicly traded company, employee, member of any association or limited liability company or otherwise) on any products competitive with

Company’s existing products, any products competitive with Company’s announced products or any products competitive with Company’s pending products that have not yet been announced but which Employee has, or should have, actual or constructive knowledge. For the purposes of this Section, “conflicting organization” shall be defined as any person, corporation or entity that competes with any product, process or service, in existence or under development, of Company pertaining to implantable medical devices to treat obesity or devices to apply signals to a vagus nerve to treat a gastrointestinal disorder (e.g., obesity, pancreatitis or irritable bowel syndrome).

6.2 **Agreement Not to Solicit**. Employee hereby acknowledges that the Company’s customers constitute vital and valuable aspects of its business on a worldwide basis. In recognition of that fact, for a period of one (1) year following the Separation Date (whether termination of employment is occasioned by Employee or Company), Employee shall not solicit, or assist anyone else in the solicitation of, any of the Company’s then-current customers to terminate their respective relationships with the Company and to become customers of any enterprise with which Employee may then be associated, affiliated or connected.

6.3 **Agreement Not to Recruit**.

Employee hereby acknowledges that the Company’s employees, consultants and other contractors constitute vital and valuable aspects of its business and missions on a worldwide basis. In recognition of that fact, for a period of one (1) year following the Separation Date (whether termination of employment is occasioned by Employee or Company), Employee shall not solicit, or assist anyone else in the solicitation of, any of the Company’s then-current employees, consultants and other contractors to terminate their respective relationships with the Company and to become employees, consultants and other contractors of any enterprise with which Employee may then be associated, affiliated or connected.

6.4 **Judicial Enforcement**.

6.4.1 Employee and the Company agree that, if the period of time or the scope of any of the provisions set forth in this Article 6 shall be adjudged unreasonably overbroad in any court or other proceeding, then the period of time and/or scope shall be modified accordingly so that the covenants contained herein may be enforced to the fullest extent permissible by law.

6.4.2 In the event of a breach or violation of any provision of this Article 6 by Employee, the parties agree that, in addition to any other remedies it may have, the Company shall be entitled to equitable relief for specific performance, and Employee hereby agrees and acknowledges that the Company has no adequate remedy at law for the breach of the employment covenants contained herein.

6.5 **The terms of this Article 6 are in addition to, and not in lieu of, the covenants set forth in the Nondisclosure and Noncompetition Agreement, as well as any statutory or other contractual or legal obligation to which Employee may be subject relating to non-competition and non-solicitation.**

ARTICLE VII: MISCELLANEOUS PROVISIONS

7.1 **Company Remedies**. Employee acknowledges and agrees that the restrictions and agreements contained in this Agreement are reasonable and necessary to protect the legitimate interests of Company, that the services to be rendered by Employee are of a special, unique and extraordinary character, that it would be difficult to replace such services and that any violation of Articles IV, V or VI of this Agreement would be highly injurious to Company, that Employee's violation of any of Articles IV, V or VI of this Agreement would cause Employer irreparable harm that would not be adequately compensated by monetary damages and that the remedy at law for any breach of any of the provisions of Articles IV, V and VI will be inadequate. Accordingly, Employee specifically agrees that Company shall be entitled, in addition to any remedy at law, to preliminary and permanent injunctive relief and specific performance for any actual or threatened violation of this Agreement and to enforce the provisions of Articles IV, V and VI of this Agreement.

7.2 **Assignment**. This Agreement shall not be assignable, in whole or in part, by Employee without the written consent of Company and any purported or attempted assignment or transfer of this Agreement or any of Employee's duties, responsibilities or obligations hereunder shall be void. This Agreement is binding upon Employee, Employee's heirs and personal representatives. This Agreement shall inure to the benefit of and be binding upon Company and its successors and assigns. Notwithstanding the foregoing, Company may, without the consent of Employee, assign its rights and obligations under this Agreement to any business entity that has become the successor to Company in the event of a sale, merger, liquidation or similar transaction. After any such assignment by Company, Company shall be discharged from all further liability hereunder and such successor assignee shall thereafter be deemed to be Company for the purposes of all provisions of this Agreement.

7.3 **Notices**. All notices, requests, demands and other communications under this Agreement shall be in writing, shall be deemed to have been duly given on the date of service if personally served on the parties to whom notice is to be given, or on the third day after mailing if mailed to the parties to whom notice is given, whether by first class, registered, or certified mail, and properly addressed as follows:

If to the Company, at:	EnteroMedics Inc. 2800 Patton Road St. Paul, MN 55113
If to Employee, at:	26321 607th Street Mantorville, MN 55955

Any party may change the address for the purpose of this Section by giving the other written notice of the new address in the manner set forth above.

7.1 **Governing Law /Venue**. The validity, interpretation, performance and enforcement of this Agreement shall be governed by the laws of the State of Minnesota, without regard to conflicts of laws principles thereof. The parties agree that any disputes arising out of this Agreement shall be venued in Minnesota District Court, Hennepin County, or United States

District Court, District of Minnesota. The parties consent to the exclusive jurisdiction of the Minnesota District Court, Hennepin County, or the United States District Court for the District of Minnesota, for this purpose.

7.2 **Arbitration**. The parties irrevocably consent that any litigation commenced or arising in connection with the interpretation or enforcement of this Agreement that has not been settled through negotiation within a period of thirty (30) days after the date on which either party shall first have notified the other party in writing of the existence of a dispute shall be settled by final and binding arbitration under the then-applicable Commercial Arbitration Rules of the American Arbitration Association (“AAA”). Any such arbitration shall be conducted by one (1) neutral arbitrator appointed by mutual agreement of the parties or, failing such agreement, in accordance with the AAA Rules. The arbitrator shall be an experienced attorney with a background in employment law. Any arbitration shall be conducted in Minneapolis, Minnesota. An arbitration award may be enforced in any court of competent jurisdiction. Notwithstanding any contrary provision in the AAA Rules, the following additional procedures and rules shall apply to any such arbitration:

(A) Each party shall have the right to request from the arbitrator, and the arbitrator shall order upon good cause shown, reasonable and limited pre-hearing discovery, including (1) exchange of witness lists, (2) depositions under oath of named witnesses at a mutually convenient location, (3) written interrogatories, and (4) document requests;

(B) Upon conclusion of the pre-hearing discovery, the arbitrator shall promptly hold a hearing upon the evidence to be adduced by the parties and shall promptly render a written opinion and award;

(C) The arbitrator may award damages or injunctive relief consistent with the terms of this Agreement but may not award or assess punitive damages against either party; and

(D) Each party shall bear his or its own costs and expenses of the arbitration and one-half (1/2) of the fees and costs of the arbitrator, subject to the power of the arbitrator, in his or her sole discretion, to award all such reasonable costs, expenses and attorneys’ fees to the prevailing party.

7.3 **Construction**. Notwithstanding the general rules of construction, both Company and Employee acknowledge that both parties were given an equal opportunity to negotiate the terms and conditions contained in this Agreement, and agree that the identity of the drafter of this Agreement is not relevant to any interpretation of the terms and conditions of this Agreement.

7.4 **Severability**. hi the event any provision of this Agreement (or portion thereof) shall be held illegal or invalid for any reason, said illegality or invalidity shall not in any way affect the legality or validity of any other provision of this Agreement. To the extent any provision (or portion thereof) of this Agreement shall be determined to be invalid or unenforceable in any jurisdiction, such provision (or portion thereof) shall be deemed to be deleted from this Agreement as to such jurisdiction only, and the validity and enforceability of the remainder of such provision and of this Agreement shall be unaffected.

7.5 **Entire Agreement**. This Agreement, as well as the exhibits hereto and any agreements referenced herein, is the final, complete and exclusive agreement of the parties and sets forth the entire agreement between Company and Employee with respect to Employee's employment by Company, and there are no undertakings, covenants or commitments other than as set forth herein. The Agreement may not be altered or amended, except by a writing executed by Employee and a member of the Board. Except as otherwise indicated, this Agreement supersedes, terminates, replaces and supplants any and all prior understandings or agreements between the parties relating in any way to the hiring or employment of Employee by Company.

7.6 **Survival**. The parties expressly acknowledge and agree that the provisions of this Agreement that by their express or implied terms extend beyond the expiration of this Agreement or the termination of Employee's employment under this Agreement, shall continue in full force and effect, notwithstanding Employee's termination of employment under this Agreement or the expiration of this Agreement.

7.7 **Waivers**. No failure on the part of either party to exercise, and no delay in exercising, any right or remedy under this Agreement shall operate as a waiver thereof; nor shall any single or partial exercise of any right or remedy under this Agreement preclude any other or further exercise thereof or the exercise of any other right or remedy granted hereby or by any related document or by law.

7.8 **Attorneys' Fees**. Upon receipt by Company of a statement for legal services from the attorneys representing Employee, Company shall reimburse Employee or pay on behalf of Employee the reasonable and necessary attorneys' fees and associated expenses incurred by Employee in connection with the negotiation of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

ENTEROMEDICS INC.

By: /s/ Mark B. Knudson
Mark B. Knudson
Its: President and CEO

Date: February 2, 2015

EMPLOYEE

By: /s/ Bradford Hancock
Bradford Hancock

Date: January 9, 2015

<u>EXHIBIT A</u>
GENERAL RELEASE

This General Release is made and entered into as of the ______ day of ______, by Employee (“Employee”).

WHEREAS, EnteroMedics Inc. (“Company”) and Employee are parties to an Employment Agreement dated __________;

WHEREAS, Employee intends to settle any and all claims that Employee has or may have against Company as a result of Employee’s employment with Company and the cessation of Employee’s employment with Company; and

WHEREAS, Under the terms of the Employment Agreement, which Employee agrees are fair and reasonable, Employee agreed to enter into this General Release as a condition precedent to the severance arrangements described in Article III of the Employment Agreement.

NOW, **THEREFORE**, in consideration of the provisions and the mutual covenants herein contained, the parties agree as follows:

1. **Release**. For the consideration expressed in the Employment Agreement, Employee does hereby fully and completely release and waive any and all claims, complaints, causes of action, demands, suits and damages, of any kind or character, which Employee has or may have against the Released Parties, as hereinafter defined, arising out of any acts, omissions, conduct, decisions, behavior or events occurring up through the date of Employee’s signature on this General Release, including Employee’s employment with Company and the cessation of that employment. For purposes of this General Release, “Released Parties” means collectively Company, its predecessors, successors, assigns, parents, affiliates, subsidiaries, related companies, officers, directors, shareholders, agents, servants, employees and insurers, and each and all thereof.

Employee understands and accepts that Employee’s release of claims includes any and all possible discrimination claims, including, but not limited to, claims based upon: Title VII of the Federal Civil Rights Act of 1964, as amended; the Age Discrimination in Employment Act; the Americans with Disabilities Act; the Equal Pay Act; the Fair Labor Standards Act; the Employee Retirement Income Security Act; the Minnesota Human Rights Act; Minn. Stat. §181.81; or any other federal, state or local statute, ordinance or law, <u>except</u> for any claims raised with the Equal Employment Opportunity Commission (“EEOC”), or other local civil rights enforcement agency. Employee also understands that Employee is giving up all other claims, including those grounded in contract or tort theories, including, but not limited to: wrongful discharge; violation of Minn. Stat. §176.82; breach of contract; tortious interference with contractual relations; promissory estoppel; breach of the implied covenant of good faith and fair dealing; breach of express or implied promise; breach of manuals or other policies; assault; battery; fraud; false imprisonment; invasion of privacy; intentional or negligent misrepresentation; defamation, including libel, slander, discharge defamation and self-publication defamation; discharge in violation of public policy; whistleblower; intentional or negligent infliction of emotional distress; or any other theory, whether legal or equitable.

Employee further understands that Employee is releasing, and does hereby release, any claims for damages, by charge or otherwise, whether brought by Employee or on Employee's behalf by any other party, governmental or otherwise, and agrees not to institute any claims for damages via administrative or legal proceedings against any of the Released Parties. Employee also waives and releases any and all rights to money damages or other legal relief awarded by any governmental agency related to any charge or other claim against any of the Released Parties.

This General Release does not apply to any post-termination claim that Employee may have for benefits under the provisions of any employee benefit plan maintained by Company.

Employee's release of claims shall not apply to any claims Employee might have to indemnification under Minnesota Statute §302A.521, any other applicable statute or regulation or Company's by-laws.

2. **Right to Revoke or Rescind**. Employee is hereby informed of Employee's right to revoke the release of claims, insofar as it extends to potential claims under the Age Discrimination in Employment Act, by informing the Company of Employee's intent to do so within 7 calendar days following the signing of this Agreement. Employee is also informed of Employee's right to rescind Employee's release of claims, insofar as it extends to potential claims under the Minnesota Human Rights Act, by delivering a written rescission to the Company within 15 calendar days after the signing of this Agreement. Employee understands that any such revocation or rescission must be made in writing and delivered by hand or by certified mail, return receipt requested, postmarked on or before the last day within the applicable revocation period to: EnteroMedics, 2800 Patton Road, St. Paul, MN 55113.

If Employee exercises the right to revoke or rescind any portion of the release of claims, the Company may, at its option, either nullify this Agreement in its entirety, or keep it in effect in all respects other than as to that portion of the release of claims that Employee has revoked or rescinded. Employee agrees and understands that if the Company chooses to nullify the Agreement in its entirety, the Company will have no obligations under this Agreement.

3. **Acceptance Period; Advice of Counsel**. The terms of this General Release will be open for acceptance by Employee for a period of 21 days during which time Employee may consider whether or not to accept this General Release. Employee agrees that changes to this General Release, whether material or immaterial, will not restart this acceptance period. Employee is hereby advised to seek the advice of an attorney regarding this General Release.

4. **Binding Agreement**. This General Release shall be binding upon, and inure to the benefit of, Employee and Company and their respective successors and permitted assigns.

5. **Representation**. Employee hereby acknowledges and states that Employee has read this General Release. Employee further represents that this General Release is written in language that is understandable to Employee, that Employee fully appreciates the meaning of its terms, and that Employee enters into this General Release freely and voluntarily.

IN WITNESS WHEREOF, Employee, after due consideration, has authorized, executed and delivered this General Release all as of the date first written.

____
Employee

<u>EXHIBIT B</u>
LIST OF ALL WORKS OF AUTHORSHIP AND INVENTIONS

TO ENTEROMEDICS, INC.:

The following is a complete list of all works of authorship or inventions that may be relevant to the subject matter of my service as an employee of EnteroMedics, Inc. (the "Company") and that have been written, composed, created, generated, conceived or first reduced to practice or learned by me, alone or jointly with others, prior to my employment by the Company:

☐ There are no such works of authorship or inventions.

☐ See below:

☐ Additional Sheets are Attached.

____
(Employee's signature)

____
(Employee's name — please print)

Date: ________________________

Exhibit 10.47

ENTEROMEDICS INC.

NON-INCENTIVE STOCK OPTION AGREEMENT

GRANTED TO	GRANT DATE	NUMBER OF SHARES SUBJECT TO OPTION	EXERCISE PRICE PER SHARE	EXPIRATION DATE

1. **This Agreement**. This agreement, together with Exhibit A (collectively, the "*Agreement*"), sets forth the terms and conditions of a non-incentive stock option award representing the right to purchase shares of common stock ("*Common Stock*") of EnteroMedics Inc., a Delaware corporation (the "*Company*").

2. **The Grant**. The Company hereby grants to the individual named above (the "*Optionee*"), as of the above grant date (the "*Grant Date*"), an option (the "*Option*") to purchase the number of shares of Common Stock of the Company set forth above (the "*Shares*") at the price per share set forth above (the "*Exercise Price*") with the expiration date set forth above (the "*Expiration Date*"). The Option constitutes an employment inducement grant under NASDAQ Rule 5635(c)(4) and is being granted pursuant to the terms of the Employment Agreement, entered into as of , between the Company and the Optionee (the "*Employment Agreement*"). The Option is not intended to qualify as an incentive stock option within the meaning of Section 422A of the Internal Revenue Code of 1986, as amended (the "*Code*").

3. **Exercise of Option**. The exercise of the Option is subject to the following terms and conditions:

    (a) During the lifetime of Optionee, the Option shall be exercisable only by Optionee. The Option shall not be assignable or transferable by Optionee, other than by will or the laws of descent and distribution. The Option may be exercised only by the Optionee (or by the Optionee's appropriate legal representatives or guardian in the event of the Optionee's death or if the Optionee becomes Disabled, as defined in the Employment Agreement), in whole or in part from time to time as provided in paragraph 3(b) below, during the period commencing on the date set forth in paragraph 3(b) below and ending on the earlier of (i) the Expiration Date or (ii) the expiration of the applicable period following the date of the Optionee's termination of employment with the Company, as provided in paragraph 5 below. In no event, however, may the Option be exercised to any extent after the Expiration Date.

    (b) The Option shall become exercisable in accordance with the schedule set forth below. Once the Option has become exercisable, the Optionee may exercise it to the extent set forth in the schedule at any time thereafter, subject to the provisions of this Agreement and the Employment Agreement.

On or after each of the following dates	Shares as to which the Option is vested
Each subsequent monthly anniversary for ____months	

    (c) In the event the Optionee's employment is terminated (i) without Cause (as defined in the Employment Agreement), (ii) by the Optionee for Good Reason (as defined in the Employment Agreement), or (iii) as a result of the Company giving notice to Employee of Company's desire to terminate the Employment Agreement (pursuant to Section of the Employment Agreement), then provided that Optionee has executed, delivered and not rescinded a written release as described in Section of the Employment Agreement, the Option shall become fully exercisable on the Separation Date (as defined in the Employment Agreement).

    (d) Upon the occurrence of a Change in Control, the Option shall become fully exercisable on the date the Change of Control is completed. In addition, upon a Change in Control, the Committee may, in its sole discretion, provide that upon the consummation of such Change in Control, the Option shall be cancelled (after its full acceleration) in exchange for a cash payment equal to the difference between (a) the per share amount paid to holders of the Common Stock in such transaction and (b) the Exercise Price.

4. **Manner of Exercise**. The Option shall be exercised by the delivery of written notice of exercise (the "*Notice*") to the Company at its principal executive office. The Notice shall be in such form as the Committee may prescribe (including electronic form) and shall specify the number of Shares as to which the Optionee is exercising the Option, and shall be accompanied by payment of the Exercise Price of the Shares either in cash (bank check, certified check or personal check payable to the Company or by wire transfer to the Company) or by the delivery of Shares owned by the Optionee with a Fair Market Value (as defined in the attached Exhibit A) equal to the amount of the Exercise Price, or a combination of both. The Notice shall also be accompanied by such other information and documents as the Committee, in its discretion, may request.

5. **Effect of Termination of Relationship with the Company**.

   (a) In the event that Optionee's relationship with the Company or its Affiliates shall terminate, for any reason other than for Cause or Optionee's death or Disability, Optionee shall have the right to exercise the Option at any time within five years after such termination to the extent of the full number of Shares Optionee was entitled to purchase under the Option on the Separation Date, subject to the condition that the Option shall not be exercisable after the expiration of its term.

   (b) In the event that Optionee's relationship with the Company or its Affiliates shall terminate for Cause, the Option shall terminate as of the Separation Date and shall not be exercisable thereafter.

   (c) If Optionee shall die during its relationship with the Company or its Affiliates, or within three months after termination of such relationship with the Company for any reason other than for Cause, or if Optionee's relationship with the Company or its Affiliates is terminated because the Optionee has become Disabled (as defined in Section   of the Employment Agreement), and Optionee shall not have fully exercised the Option, the Option may be exercised at any time within twelve months after the date of Optionee's death or termination of Optionee's relationship because of Disability by the legal representative or, if applicable, guardian of Optionee or by any person to whom the Option is transferred by will or the applicable laws of descent and distribution to the extent of the full number of Shares Optionee was entitled to purchase under the Option on the date of death (or Separation Date, if earlier) or termination of Optionee's relationship because of Disability, and subject to the condition that the Option shall not be exercisable after the Expiration Date.

6. **Income Taxes**. The Optionee is liable for any federal, state and local income or other taxes applicable upon the grant or exercise of the Option or the disposition of the Shares, and the Optionee acknowledges that he should consult with his own tax advisor regarding the applicable tax consequences. Upon exercise of the Option, the Optionee shall promptly pay to the Company the minimum statutory withholding taxes required to be withheld or collected by the Company in connection with the exercise of the Option. The Optionee may pay all or a portion of the minimum statutory withholding taxes by (a) having the Company withhold Shares otherwise to be delivered upon the exercise of the Option with a Fair Market Value equal to the amount of such taxes, (b) delivering to the Company shares of Common Stock other than Shares issuable upon the exercise of the Option with a Fair Market Value equal to the amount of such taxes or (c) paying cash. For federal income tax purposes, the Option shall not be eligible for treatment as a qualified or incentive stock option.

7. **No Right to Employment**. The grant of the Option shall not be construed as giving the Optionee the right to be retained as an employee of the Company or any Affiliate, nor will it affect in any way the right of the Company or an Affiliate to terminate the Optionee's employment at any time, with or without Cause.

8. **Adjustments**. In the event that there is any change in the Common Stock or corporate structure of the Company as a result of any dividend or other distribution (whether in the form of cash, Common Stock, other securities or other property), recapitalization, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase or exchange of Common Stock or other securities of the Company, issuance of warrants or other rights to purchase Common Stock or other securities of the Company or other similar corporate transaction or event, then the Committee shall, in such manner as it deems equitable, adjust the number and type of Shares and the Exercise Price; provided, however, that the number of Shares covered by the Option shall always be a whole number.

9. **Governing Law**. The validity, construction and effect of the Agreement, and any rules and regulations relating to the Agreement, shall be determined in accordance with the laws of the State of Minnesota.

10. **Acknowledgment**. This Option shall not be effective until the Optionee dates and signs the form of Acknowledgment below and returns a signed copy of this Agreement to the Company. By signing the Acknowledgment, the Optionee agrees to the terms and conditions of this Agreement.

ACKNOWLEDGMENT:

____
OPTIONEE'S SIGNATURE

____
DATE

ENTEROMEDICS INC.

By: ______________________________________
[Name]
[Title]

EXHIBIT A

DEFINED TERMS USED IN THE STOCK OPTION AGREEMENT

The following terms used in this Agreement have the following meanings:

"*Affiliate*" shall have the meaning ascribed to such term in Rule 12b-2 promulgated under the Exchange Act.

"*Associate*" shall have the meaning ascribed to such term in Rule 12b-2 promulgated under the Exchange Act.

"Change in Control" shall mean:

(i) any "person" (as such term is used in Sections 13(d) and 14(d)(2) of the Exchange Act who did not own shares of the capital stock of the Company on the date of grant of the Option shall, together with his, her or its Affiliates and Associates (as such terms are defined in Rule 12b-2 promulgated under the Exchange Act), become the "Beneficial Owner" (as such term is defined in Rule 13d-3 promulgated under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities (any such person being hereinafter referred to as an "Acquiring Person");

(ii) the Continuing Directors cease to constitute a majority of the Company's Board;

(iii) There should occur (A) any consolidation or merger involving the Company and the Company shall not be the continuing or surviving corporation or the shares of the Company's capital stock shall be converted into cash, securities or other property; provided, however, that this subclause (A) shall not apply to a merger or consolidation in which (i) the Company is the surviving corporation and (ii) the stockholders of the Company immediately prior to the transaction have the same proportionate ownership of the capital stock of the surviving corporation immediately after the transaction; (B) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of the Company; or (C) any liquidation or dissolution of the Company; or

(iv) The majority of the Continuing Directors determine, in their sole and absolute discretion, that there has been a Change in Control.

"*Committee*" shall mean the Compensation Committee of the Company's Board of Directors.

"*Continuing Director*" shall mean any person who is a member of the Board of Directors of the Company, while such person is a member of the Board of Directors, who is not an Acquiring Person, an Affiliate or Associate of an Acquiring Person or a representative of an Acquiring Person or of any such Affiliate or Associate and who (i) was a member of the Company's Board of Directors on the date of grant of the Option or (ii) subsequently became a member of the Board of Directors, upon the nomination or recommendation, or with the approval of, a majority of the Continuing Directors.

"*Exchange Act*" shall mean the Securities and Exchange Act of 1934, as amended.

"*Fair Market Value*" shall mean the closing sale price of the Common Stock as reported on the NASDAQ Capital Market on such date or, if such market is not open for trading on such date, on the most recent preceding date when such market is open for trading.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-196646, 333-184181, 333-176174, 333-171244, 333-159592, and 333-149662 on Form S-8 and Registration Statement Nos.333-205353, 333-195855, 333-171944, 333-170503, 333-171052, 333-166011, and 333-158516 on Form S-3 of our report dated March 28, 2016, relating to the consolidated financial statements of EnteroMedics Inc. and subsidiary, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2015.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, MN
March 28, 2016

EXHIBIT 31.1

CERTIFICATIONS

I, Dan W. Gladney, certify that:

1. I have reviewed this Annual Report on Form 10-K of EnteroMedics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

/S/ DAN W. GLADNEY

Dan W. Gladney
President and Chief Executive Officer

Date: March 28, 2016

EXHIBIT 31.2

CERTIFICATIONS

I, Greg S. Lea, certify that:

1. I have reviewed this Annual Report on Form 10-K of EnteroMedics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

/S/ GREG S. LEA

Greg S. Lea
Chief Financial Officer
and Chief Compliance Officer

Date: March 28, 2016

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of EnteroMedics Inc. (the Company) on Form 10-K for the period ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Dan W. Gladney, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ DAN W. GLADNEY

Dan W. Gladney
President and Chief Executive Officer

March 28, 2016

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of EnteroMedics Inc. (the Company) on Form 10-K for the period ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Greg S. Lea, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ GREG S. LEA

Greg S. Lea
Chief Financial Officer
and Chief Compliance Officer

March 28, 2016