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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, 2012

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, 2012, 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 $89,481,108.

As of February 28, 2013, 55,618,270 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 2013 Annual Meeting of Stockholders, to be held May 8, 2013 (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.

ENTEROMEDICS INC.

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EXHIBITS

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. In addition, some or all of the marks VBLOC, MAESTRO and ENTEROMEDICS are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, Saudi Arabia and Switzerland. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are registered in Mexico. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are the subject of pending trademark applications in 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.

Overview

We are a development stage medical device company with approvals to commercially launch our product in 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 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. Our initial product is the Maestro System, which uses VBLOC therapy to affect metabolic regulatory control, 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. Based on our understanding of vagal nerve function and nerve blocking from our preclinical studies and the results of our clinical trials, we believe the Maestro System may offer obese patients a minimally-invasive treatment that has the potential to result in significant and sustained weight loss. In addition, data from sub-group analyses demonstrate that VBLOC therapy may hold promise in improving obesity-related comorbidities such as diabetes and hypertension.

We continue to evaluate the Maestro System in human clinical trials in the United States, Australia, Mexico, Norway and Switzerland. To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in these clinical trials. 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.

In October 2010, we received an unconditional Investigational Device Exemption (IDE) Supplement approval from the U.S. Food and Drug Administration (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 (RC) 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 weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. As announced on February 7, 2013, the ReCharge trial met its primary safety endpoint, though it did not meet its predefined co-primary efficacy endpoints. The trial did however demonstrate a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% for VBLOC therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. As a result of the positive safety and efficacy profile of VBLOC therapy, we plan to use the data from the ReCharge trial to support a premarket approval (PMA) application for the Maestro Rechargeable System, which we anticipate filing during the second quarter of 2013. If the FDA grants us approval, we anticipate we will be able to commercialize the Maestro Rechargeable System in the United States in 2014.

If we obtain FDA approval of our Maestro Rechargeable System we intend to market our products in the United States through a direct sales force supported by field technical and marketing managers who provide training, technical and other support services to our customers. Outside the United States we intend to use direct, dealer and distributor sales models as the targeted geography best dictates. To date, we have relied on third-party manufacturers and suppliers for the production of our Maestro System. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of the Maestro System.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011. 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). We have been working closely with our Australian distributor, Device Technologies Australia Pty Limited, to bring the Maestro Rechargeable System to the Australian market through a controlled commercial launch and made our first commercial shipment of the Maestro ReChargeable System to Device Technologies Australia Pty Limited in March 2012. We also entered into an exclusive, multi-year agreement with Bader Sultan & Brothers Co. W.L.L. for commercialization and distribution of the Maestro ReChargeable System in the Gulf Coast Countries, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates and made our first commercial shipments to Bader Sultan & Brothers Co. W.L.L. during the second quarter of 2012. We continue to explore additional select international markets to commercialize the Maestro Rechargeable System, including Europe.

The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which is considered an Active Implantable Medical Device (AIMD) in Australia and the European Economic Area, and falls into Class III within the United States), the method involves a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. We use DEKRA Certification B.V. (formerly known as KEMA Quality) in the Netherlands as the Notified Body for our CE marking approval process.

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. Overweight and obesity are the fifth leading risk for global deaths and more than 1 in 10 of the world's adult population are obese. Currently, as many as 500 million people worldwide are estimated to be obese and more than 1.4 billion adults are estimated to be overweight, according to the World Health Organization (WHO). At least 2.8 million adults die each year as a result of being overweight or obese.

Many people with obesity also have severe and complex problems related to their disease, including Type 2 diabetes and hypertension, often referred to collectively as metabolic disease. 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. WHO predicts that approximately 2.3 billion adults will be overweight and more than 700 million people worldwide will be obese by 2015.

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 Centers for Disease Control and Prevention (CDC) estimates that 35.7% of U.S. adults are obese, having a Body Mass Index (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 by 2015, over 40% of American adults could be obese. According to data from the U.S. Department of Health and Human Services, almost 80% of adults with a BMI above 30 have an obesity-related disease or disorder, also called a co-morbidity, and almost 40% have two or more of these comorbidities. According to The Obesity Society (formerly the North American Association for the Study of Obesity) 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. In addition, a number of disorders involving the central nervous system may be complicated by obesity, such as anxiety, bipolar disorder, agoraphobia, depression and insomnia.

Currently, medical costs associated with obesity in the U.S. were estimated to be up to $210 billion annually; the medical costs paid by third-party payors for people who are obese were $1,429 higher per year than those of normal weight.

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. 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 within lower BMI ranges but carry significant safety risks and may present troublesome side effects.

Bariatric surgery. In more severe cases of obesity, patients may pursue more aggressive surgical treatment options such as 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 risks that have limited their adoption.

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 unpleasant side-effects such as persistent vomiting;
- minimizes the risks of re-operations, malnutrition and mortality; and
- reduces the natural hunger drive of patients.

EnteroMedics' Solution

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 is designed to affect metabolic regulatory control, reduce hunger feelings between meals, limit the expansion of the stomach during eating and reduce the frequency and intensity of stomach contractions. In addition, we believe VBLOC therapy also reduces the absorption of calories by decreasing the secretion of digestive enzymes. The resulting physiologic effects of VBLOC therapy are intended to 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, we have limited the body's natural tendency to circumvent the therapy, all of which we believe will result in long-term weight loss.

We have designed our Maestro System to address a significant market opportunity that 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 System is designed to offer each of the following benefits, which we believe will lead to the adoption of VBLOC 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;
- release of gastric acid to continue food processing;
- 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 is designed to affect metabolic regulatory control, control hunger sensations between meals, limit the expansion of the stomach and reduce the frequency and intensity of stomach contractions, leading to earlier fullness. In addition, we believe VBLOC therapy also reduces the absorption of calories by decreasing the secretion of digestive enzymes. The resulting physiologic effects of VBLOC therapy are intended to 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, we believe we have limited the body’s natural tendency to circumvent the therapy, which can result in long-term weight loss.

We have designed our Maestro 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 System is designed to offer each of the following benefits, which we believe could lead to the adoption of VBLOC as the surgical therapy of choice for obesity and its comorbidities:

- ***Preserves Normal Anatomy.*** The Maestro 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, we believe that patients will be 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 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 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 multiple 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 System, is intended to offer patients what we believe could be an effective, safe, outpatient solution that minimizes complications. We believe it will enable patients to lose weight and maintain long-term weight loss while enjoying a normal, healthy diet. We also believe that the Maestro System will appeal to physicians based on the inherent physiological approach of VBLOC therapy and its favorable safety profile.

Our Strategy

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

Achieve Further Regulatory Approvals for VBLOC Therapy Using Our Maestro System. We received an IDE from the FDA for use of the Maestro Rechargeable System in the United States in our ReCharge trial in October 2010 and completed enrollment and implantation in December 2011. As announced on February 7, 2013, the ReCharge trial met its primary safety endpoint, though it did not meet its predefined co-primary efficacy endpoints. The trial did however demonstrate a clinically meaningful and statistically significant EWL of 24.4% for VBLOC therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. As a result of the positive safety and efficacy profile of VBLOC therapy, we plan to use the data from the trial to pursue a PMA from the FDA to allow us to commence sales in the United States. We have received the European CE Mark for our Maestro Rechargeable System to enable the eventual commercialization of our system in the European Economic Area. In January 2012, the final Maestro Rechargeable System components were listed on

the ARTG by the Australian TGA and we have been working closely with our Australian distributor, Device Technologies Australia Pty Limited, to bring the Maestro Rechargeable System to the Australian market through a controlled commercial launch and made our first commercial shipment of the Maestro ReChargeable System to Device Technologies Australia Pty Limited in March 2012. We also entered into an exclusive, multi-year agreement with Bader Sultan & Brothers Co. W.L.L. for commercialization and distribution of the Maestro ReChargeable System in the Gulf Coast Countries, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates and made our first commercial shipments to Bader Sultan & Brothers Co. W.L.L. during the second quarter of 2012. We continue to explore additional select international markets to commercialize the Maestro Rechargeable System, including Europe.

The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which is considered an AIMD in Australia and the European Economic Area, and falls into Class III within the United States), the method involved a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. We used DEKRA Certification B.V. (formerly known as KEMA Quality) in the Netherlands as the Notified Body for our CE marking approval process.

Drive the Adoption and Endorsement of VBLOC Therapy Through Obesity Therapy Experts. 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 others involved in the obesity management process and scientific experts and we believe these individuals will be important in promoting patient awareness and gaining widespread adoption if the Maestro System is approved and commercialized.

Commercialize Our Products using a Distribution Network outside the United States. We plan to utilize specialized third-party medical device distributors in Australia, the Middle East and other non-U.S. markets to call directly on key opinion leaders and bariatric surgeons, which we believe will enable us to target them effectively. We expect that our distributor's sales force will promote the Maestro System to physicians, work with our surgeon partners, provide training and maintain regulatory required records. They may also work with patients who have concerns with current bariatric surgical procedures. We also plan to call on physicians, weight-management specialists, nurses and others involved in the obesity management process who influence patient adoption.

Commercialize Our Products using a Direct Sales and Marketing Effort within the United States. We plan to build a sales force to call directly on key opinion leaders and bariatric surgeons, primarily within bariatric Centers of Excellence. We believe this currently represents over 450 facilities within the United States, which we believe will enable us to target them effectively with a small sales force. We expect that our direct sales force will promote the Maestro System to physicians and patients who have concerns with current bariatric surgical procedures. We also plan to call on physicians, weight-management specialists, nurses and others involved in the obesity management process who influence patient adoption.

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 plan to employ a focused campaign to obtain payor support for VBLOC therapy. We plan to seek specific and appropriate coding, coverage and payment for our Maestro Recharegeable System from the Australia Medical Services Advisory Committee (MSAC) and the U.S. Centers for Medicare and Medicaid Services (CMS) and from private insurers. We have applied for unique CPT Category III codes with the American Medical Association's CPT Advisory Committee for a Vagus Nerve Blocking Therapy procedure and received approval for six of them. The approved CPT Category III codes were listed in the July 2012 edition of the CPT billing codes. We intend to use the approved codes to build evidence for a possible application for a CPT Category I Code at a later date.

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.

The Maestro System, Implantation Procedure and Usage

The Maestro System. Our Maestro 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 System has been developed in two different energy configurations, the Maestro Radio Frequency (RF) System and the Maestro ReChargeable (RC) System, delivering the same VBLOC therapy. The Maestro RF System is powered by an external controller and transmit coil worn by the patient to receive therapy. The Maestro RC System (shown below) is powered by an internal rechargeable battery.

The major components of the Maestro RC System include:

- ***Neuroregulator.*** The neuroregulator, sometimes referred to as a neuroblocking pulse generator, 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.

We developed the Maestro System in two different energy configurations, the first generation Maestro RF System, used for the early feasibility trials and the EMPOWER trial, and the second generation Maestro RC System, which is currently in use in the VBLOC-DM2 ENABLE trial and the ReCharge U.S. pivotal trial and will be our commercial device. The Maestro RF System and the Maestro RC System differ in the following ways:

- The neuroblocking pulse generator, or neuroregulator, within the Maestro RF System is powered by a battery in the externally-worn controller, which is connected to the external transmit coil. The transmit coil needs to be properly positioned over the approximately 20 cubic centimeter neuroregulator and worn daily during the patient's waking hours to deliver therapy. The controller is recharged nightly using AC wall power.
- The neuroregulator in the Maestro RC System is powered by an internal rechargeable battery. The RC neuroregulator is approximately 80 cubic centimeters in volume to accommodate its internal battery. An external mobile charger is connected to the external transmit coil to recharge the battery. The mobile charger is recharged using AC wall power.

Implantation Procedure. The Maestro 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 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: pain, 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 System. The physician activates the Maestro 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 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 heartburn, bloating, diarrhea, sweating, nausea, constipation, greasy bowel movements, tiredness and excessive feelings of fullness, especially after meals. In addition, patient noncompliance with wearing the external components of the Maestro RF System or properly charging the Maestro RC System or Maestro RF System may render VBLOC therapy less effective in achieving long-term weight loss.

Clinical Development

We are developing our Maestro System to deliver VBLOC therapy for the long-term treatment of obesity and obesity-related comorbidities. Based on our preclinical and clinical findings, we believe that our Maestro System has the potential to offer a compelling combination of efficacy and safety. We are continuing to evaluate the Maestro System in human clinical studies conducted in the United States and internationally. We announced on February 7, 2013, the ReCharge trial met its primary safety endpoint, though it did not meet its predefined co-primary efficacy endpoints. The trial did however demonstrate a clinically meaningful and statistically significant EWL of 24.4% for VBLOC therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. As a result of the positive safety and efficacy profile of VBLOC therapy, we plan to use the data from the ReCharge trial to support a PMA application for the Maestro Rechargeable System, which we anticipate filing during the second quarter of 2013.

Preclinical Experience

We have completed several preclinical animal studies, primarily in pigs and rats, to evaluate the safety of our Maestro System and to refine our implantation procedure. These studies have also shown that VBLOC therapy could completely block activated nerve signals, with the nerve regaining normal function within minutes after each intermittent application of therapy. Over a 12-week period of VBLOC therapy, over 91% of all nerve axons showed normal histology and the animals demonstrated unimpaired heart rate, respiration, blood pressure and glucose regulation. Additionally, we observed that VBLOC therapy resulted in a greater than 80% reduction in pancreatic exocrine secretions, which are composed of digestive enzymes, water and bicarbonate that facilitate food digestion and caloric intake.

As a result of the findings of our preclinical studies, we were able to refine the implant technique, demonstrate the biocompatibility of our Maestro System in animals and collect the data necessary to begin human clinical trials. Several publications resulting from these preclinical studies were peer-reviewed and accepted for podium presentation at the Digestive Disease Week meeting in 2006, the American Society for Bariatric Surgery meeting in 2006 and the International Federation for Surgery of Obesity meeting in 2006.

Clinical Experience

We began evaluating VBLOC therapy with our initial Maestro System, the RF1 system, in a clinical trial in February 2006. The first generation RF2 system is distinguished from the RF1 system by an improved user interface, improvements in the energy management within the neuroregulator and a more robust transmission link for delivering energy from the coil to the neuroregulator in the RF2 system. The second generation system, the RC system, has a fully implanted battery and requires the user to charge it less frequently than with the RF System. Our early clinical experience has shown that VBLOC therapy using the Maestro System offers physicians a programmable method to selectively and reversibly block the vagus nerve and results in clinically and statistically significant EWL. Excess weight represents the difference between a patient's actual weight and the patient's weight assuming a BMI of 25, which is considered healthy. EWL is reported as the percentage of excess weight that is lost by the patient.

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 feasibility trials have resulted in more than 30 publications peer-reviewed and accepted for presentation between 2006 and 2012 at the following meetings: Digestive Disease Week, American Society for Metabolic and Bariatric Surgery, International Federation for Surgery of Obesity, Obesity Surgery Society of Australia & New Zealand and The Obesity Society (formerly the North American Association for the Study of Obesity).

Below is a summary of our ongoing clinical studies.

ReCharge Trial

In October 2010, we received an unconditional 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 weight management counseling program. The primary

endpoints of efficacy and safety were evaluated at 12 months. As announced on February 7, 2013, the ReCharge trial met its primary safety endpoint, though it did not meet its predefined co-primary efficacy endpoints. The trial did however demonstrate a clinically meaningful and statistically significant EWL of 24.4% for VBLOC therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. As a result of the positive safety and efficacy profile of VBLOC therapy, we plan to use the data from the ReCharge trial to support a PMA application for the Maestro Rechargeable System, which we anticipate filing during the second quarter of 2013. If the FDA grants us approval, we anticipate we will be able to commercialize the Maestro Rechargeable System in the United States in 2014.

Further analysis of the data show that in the primary analysis (intent-to-treat) population (n=239), treatment patients achieved a 24.4% average EWL 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 treatment patients had 20% or more EWL compared to 32.5% in the control group (p=0.004), and 38.3% of treatment 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 treatment patients had an average 26.3% EWL compared to 17.3% for the sham control group (p=0.003). In total, 56.8% of 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 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).

The rate of device-related serious adverse events was 3.1% for the treatment arm, significantly lower than the threshold of 15% (p<0.0001). The safety results also confirmed VBLOC therapy had no adverse cardiovascular effect. An overall reduction in blood pressure and heart rate was also observed in the treatment arm. Approximately 93% of patients reached the 12 month assessment in the trial, consistent with a rigorously executed trial.

VBLOC-DM2 ENABLE Trial

Enrollment of the VBLOC-DM2 ENABLE trial began in the second quarter of 2008. The VBLOC-DM2 ENABLE trial is designed to evaluate the effects of VBLOC therapy on glucose regulation and blood pressure in approximately 30 patients who were hypertensive using the Maestro RC System. The trial is an international, open-label, prospective, multi-center study. We plan to evaluate the efficacy of VBLOC therapy 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. 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. As announced in June 2011 and October 2011, follow-up of patients showed the below data.

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

Visit (post-device activation)	% EWL (³ 12 hours therapy delivery per day)	N
Week 1	-9.5	25
3 Months	-20.8	26
6 Months	-25.2	24
12 Months	-27.2	24
18 Months	-24.6	22

% EWL for all patients (N=24) is -22.6 at 18 months. Two patients are not currently receiving therapy for unrelated medical reasons.

Interim analysis. N is patients who have reached those time points and were seen for the scheduled visit.

- H_bA1_c change in percentage points (Baseline HbA1c = 7.8 ± 0.2%) (Company updated interim data):

Visit (post-device activation)	% HbA1c change	N	p
Week 1	-0.3	28	0.002
6 Months	-0.9	25	0.002
12 Months	-1.0	26	0.002
18 Months	-1.1	18	0.002

- 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	P
Week 1	-20.9	28	0.01
6 Months	-28.7	25	0.01
12 Months	-27.6	25	0.01
18 Months	-32.0	17	0.01

- Change in diastolic blood pressure (DBP) in hypertensive patients (baseline 87.2 mmHg) (Company updated interim data):

Visit (post-device activation)	DBP change (mmHg)	N	p
Week 1	-10.1	12	<0.001
6 Months	-13.8	10	<0.001
12 Months	-10.2	11	0.009
18 Months	-15.9	10	<0.001

- 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	p
Week 1	-6.8	15	0.04
6 Months	-12.5	13	<0.001
12 Months	-7.8	14	0.03
18 Months	-13.0	13	0.002

As announced in April 2012, the metabolic effects at 2.5 years in diabetes, hypertension and weight loss were consistent with previous findings (above) and were all statistically significant. Change for HbA1c and fasting plasma glucose, both Type 2 diabetes indicators, were reductions of 0.8 percentage points (p=0.0492) and 29.0 mg/dl (p=0.0306) from a baseline of 7.7% and 162.8 mg/dl, respectively (n=12). Change in mean arterial pressure (n=9) and diastolic blood pressure (n=8), indicators of hypertension, showed sustained improvement, with reductions of 11.5 mmHg (p=0.0053) and 13.2 mmHg (p=0.0037) at 30 months from baselines of 99.1 mmHg and 85.9 mmHg, respectively. EWL was 22.5% (p<0.0001) for the 19 subjects who reported for their 30-month visit.

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 in 294 patients designed to evaluate the safety and efficacy of our first-generation Maestro RF System in the treatment of obesity. The purpose of the EMPOWER trial was 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. The EMPOWER trial met its safety endpoint but did not meet its comparative primary and secondary efficacy endpoints due to an unanticipated therapeutic effect seen in the control arm.

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.

The trial produced the following efficacy results:

- Both the treatment and control arm patients experienced comparable, significant, dose-dependent EWL at 12 months which resulted in the trial not meeting its efficacy endpoints; and
- The ‘dose effect’ showed a correlation between average EWL and the number of hours of device use; 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% at 12 months from implant while those in the control group who used the system for greater than or equal to 12 hours a day saw an average EWL of 22% at 12 months from implant.

As announced in June 2011, the 30 month EMPOWER EWL was approximately 20% in 107 subjects to reach that time point. In addition, it was announced in November 2012 that 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 who had greater than or equal to 9 hours of therapy delivered per day to 12 months.

- Subject demographics:

	Group A (Elevated Blood Pressure)	Group B (History of Hypertension)
# of Subjects	37	58
BMI (kg/m2)	41+/-1	41+/-1
Age (Years)	50+/-1	51+/-1
Female/Male	31/6	47/11

- 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

Research and Development

We have an experienced research and development team, including clinical, regulatory affairs and quality, 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:

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

We have spent a significant portion of our capital resources on research and development. Our research and development expenses were $10.7 million in 2012, $16.7 million in 2011 and $8.5 million in 2010. With the completion of enrollment and device implantation in our ReCharge pivotal trial for obesity in late 2011, research and development expenditures decreased in 2012 as costs were primarily associated with supporting the ReCharge trial in addition to the continued follow-up on existing trials, such as VBLOC-DM2 ENABLE and EMPOWER.

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 “Clinical Development” 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 "Clinical Development" 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 these conditions are included in our current IDE or approved for sale internationally. Additional approvals will be required to market the Maestro 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 2012. 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 to advise us as we developed our devices for vagal blocking therapy to treat obesity. 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 two 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;
- meet with governmental regulatory authorities;
- 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.

Sales and Marketing

United States

We currently do not have a sales organization and have no experience as a company in the marketing, sale or distribution of our proposed products. In the event that the Maestro System receives FDA approval, we expect to recruit and retain additional personnel responsible for commercial operations, sales and marketing, customer service, reimbursement and technical service in order to support the commercial launch of our product.

We expect that account management and patient registration processes used during the clinical trial will be transitioned to commercial registration structure. Centers responsible for implanting our product will be expanded, and trained to perform the patient selection, implant and manage appropriate follow-up procedures.

Initially, we anticipate that our sales representatives will exclusively target selected bariatric surgery Centers of Excellence and nationally recognized bariatric surgery centers. To be approved as a bariatric surgery Center of Excellence, a surgery center needs to perform a minimum of 125 bariatric surgical procedures per year. Currently there are over 450 bariatric surgery Centers of Excellence approved by the Surgical Review Corporation. In addition we expect to market our products to a small number of nationally-recognized hospitals that do not intend to pursue the Center of Excellence certification.

We plan to support our sales representatives with field clinical experts who will be responsible for training and support at various implant centers. We also expect that our sales representatives will spend time implementing joint consumer marketing programs with surgical centers and implanting surgeons. We also intend to market to potential referral source clinicians such as general practitioners, internists, endocrinologists and nurses.

To achieve commercial success for any product that receives regulatory approval, we must either develop a sales organization or enter into arrangements with others to sell our products. Developing a direct sales force can be expensive and time consuming and can delay the success of any product launch. Any sales force we develop will likely be competing against the experienced and well-funded sales and marketing operations of our competitors.

Outside of the United States

Outside of the United States, we may sell and support our products either through direct sales or medical device distributors. We plan to target countries with reasonable regulatory and reimbursement barriers and a population interested in managing their obesity. Each country we target will require specific regulatory approval from the local government or agency. In some situations, we may be able to rely on FDA approval, European CE Mark or ISO quality certificates to satisfy local regulatory requirements.

In March 2011, we entered into a multi-year distribution agreement with Device Technologies Australia Pty Limited (Device Technologies) appointing Device Technologies as our exclusive distributor of the Maestro System in Australia and New Zealand during the term of the agreement. In 2011, we received European CE Mark certification of the Maestro Rechargeable System. In January 2012, the final Maestro Rechargeable System components were listed on the ARTG by the TGA. We have been working closely with Device Technologies to bring the Maestro Rechargeable System to the Australian market through a controlled commercial launch and made our first commercial shipment of the Maestro ReChargeable System to Device Technologies in March 2012. We also entered into an exclusive, multi-year agreement with Bader Sultan & Brothers Co. W.L.L. for commercialization and distribution of the Maestro ReChargeable System in the Gulf Coast Countries, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates and made our first commercial shipments to Bader Sultan & Brothers Co. W.L.L. during the second quarter of 2012. We continue to explore additional select international markets to commercialize the Maestro Rechargeable System, including Europe.

Competition

We compete primarily in the market for obesity treatment with surgical obesity procedures and various devices used to implement neurostimulation and gastric stimulation systems. These current surgical procedures are performed in approximately less than 1% of all eligible obese patients today. We also compete with pharmaceutical therapies. The market for obesity treatments is competitive, subject to technological change and significantly affected by new product development. Although we expect to compete in the market for gastric stimulation systems and other neurotechnology devices that treat obesity, there are currently no FDA-approved neuromodulation or neuroblocking therapies for the treatment of obesity. We believe we are the first company pursuing neuroblocking therapy for the treatment of obesity.

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: Sibutramine, marketed by Abbott Labs as Meridia, which has recently been withdrawn from the market worldwide by the manufacturer based on safety concerns, Orlistat, marketed by Roche as Xenical and GlaxoSmithKline as Alli, Belviq marketed by Arena Pharmaceuticals, Inc. and Qsymia, marketed by VIVUS, Inc.

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, 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, through its acquisition of Advanced Neuromodulation Systems, is developing spinal cord stimulators. Cyberonics is developing vagus nerve stimulators to modulate epileptic seizures and other neurological disorders. Boston Scientific, through its Advanced Bionics division, is developing neurostimulation devices such as spinal cord stimulators and cochlear implants. Ethicon-Endo Surgery acquired Cyberonics' patents and patent applications pertaining to vagus nerve stimulation for the treatment of obesity and two related comorbidities, diabetes and hypertension, in overweight patients.

In addition to competition from developers of neurostimulation and gastric modulation systems, we expect our Maestro System will also compete with surgical obesity procedures, including gastric bypass, gastric banding, vertical-banded gastroplasty and biliopancreatic diversion. The leader in the field of gastric banding is Allergan, whose Lap-Band received FDA approval for marketing in 2001. In 2007, Allergan acquired EndoArt, a European band company that has developed the EasyBand, which uses RF telemetry to adjust the gastric band. Additionally, Johnson & Johnson received approval in 2007 of their gastric band product known as the Realize Adjustable Gastric Band. We are also aware that GI Dynamics has received approvals in various international countries to sell its EndoBarrier Gastrointestinal Liner and in 2011 began trading on the Australian Securities Exchange.

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.

Third-party Coverage and Reimbursement

We plan to set a market price for the Maestro 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 cochlear implant systems. We expect that the procedure will be performed in the outpatient setting.

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. Currently, there are established CPT 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 addition, we have applied for unique CPT Category III codes with the American Medical Association's CPT Advisory Committee for a Vagus Nerve Blocking Therapy procedure and received approval for six of them. The approved CPT Category III codes were listed in the July 2012 edition of the CPT billing codes. We intend to use the approved codes to build evidence for a possible application for a CPT Category I Code at a later date. With respect to possible usage of our product in the hospital inpatient setting, hospital inpatient billing is referenced by International Classifications of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure codes. There is an existing ICD-9-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-9 diagnosis code for morbid obesity. By October 2014, health plans and providers must replace the ICD-9-CM system and begin using the newer ICD-10-CM system for billing hospital inpatient procedures. The ICD-10-CM system should not impact coverage decisions, but could impact reimbursement for various procedures. 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, the federal agency that administers the Medicare program, issued a national coverage determination for several specific types of bariatric surgery in 2006, which we view as positive, potential precedent and guidance to factors that CMS might use in deciding to cover our therapy. The policy indicates 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 intend to actively work with major insurance carriers as well as CMS to obtain coverage for procedures using our product.

The Australian reimbursement landscape for medical devices is comprised of a number of different payers and schemes. There are informal funding pathways and formal reimbursement systems. There are three major payers: private health insurers; the Federal government; and State and Territory governments. Private health insurers pay for private hospital services, surgically implanted prostheses and defined health appliances. The Federal government pays for professional medical services including diagnostic investigations and the majority of the cost of services in public hospitals. State and Territory governments pay for some of the cost of services in public hospitals. In addition, various ad hoc Federal and State government grants and programs exist to provide funding for new technologies. The Medical Services Advisory Committee advises the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. This advice informs Australian Government decisions about public funding for new, and in some cases existing, medical procedures. Evaluation of evidence associated with medical services has been an integral part of the process for the listing of new medical technologies and services on the Medicare Benefits Schedule. In Australia, we plan to seek specific and appropriate coding, coverage and payment for our Maestro Rechargeable System from the MSAC.

Other manufacturers of neurostimulator 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.

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. To date, we have 24 issued U.S. patents, 22 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, most of these patents will expire in 2023. We have four granted European patents and four granted Australian patents. We also have 16 U.S. patent applications and 30 national stage patent applications, including applications in Australia, China, India, Europe 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 Mayo Foundation for Medical Education and Research for two 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. In addition, some or all of the marks VBLOC, MAESTRO and ENTEROMEDICS are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, Saudi Arabia and Switzerland. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are registered in Mexico. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are the subject of pending trademark applications in 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.

Manufacturers and Suppliers

We have designed and developed all of the elements of our Maestro 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 used in our clinical trials are procured from qualified suppliers and contract manufacturers in accordance with our proprietary specifications. We use third parties to manufacture our Maestro 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 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 commenced commercialization of the Maestro Rechargeable System in Australia and the Middle East in the first half of 2012. We expect to increase our production volume slowly as we continue to bring the Maestro Rechargeable System to the Australian and Middle East markets through a controlled commercial launch in 2013. In the event that the Maestro Rechargeable System receives FDA approval or approval from additional select international markets, we expect to increase our production volume by a significant amount. 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 requires 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. A delay in the approval process with 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 international 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 internationally or in the United Sates 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 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 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. Recent, widely-publicized events concerning the safety of certain drug, food and medical device products have raised concerns among members of Congress, medical professionals, and the public regarding the FDA's handling of these events and its perceived lack of oversight over regulated products. The increased attention to safety and oversight issues has resulted in a more cautious approach by the FDA to device clearances and approvals, as well as post-market compliance, which could prevent, delay clearance or approval of our new products or product modifications, or require us to expend additional resources on post-market studies and controls.

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 product will require prior premarket approval from the FDA. Because our Maestro System is an implanted device, it is deemed to pose a significant risk. To market the Maestro System in the United States, the FDA must approve the device after submission of a PMA. The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their approval, or subsequent to marketing. The process of obtaining premarket approval is costly, lengthy and uncertain. A PMA must be supported by extensive data including, but not limited to, technical, pre-clinical and clinical trials to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. Among other information, the PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed device labeling.

If the FDA determines that a PMA is complete, the FDA accepts the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted

PMA application, although the review and response activities generally occur over a significantly longer period of time, typically one year, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of our, and some of our contract manufacturers', facilities to evaluate compliance with the Quality System Regulation. Under the Medical Device User Fee and Modernization Act of 2002, the fee to submit a PMA can be up to $220,050 per PMA, however, we qualify for a small business exemption and, therefore, the fee for our first PMA submission will be waived. If the FDA's evaluation of the PMA is favorable, the PMA is approved, and the device may be marketed in the United States. The FDA may approve the PMA 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 a PMA, new PMAs or supplemental PMAs are 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 at 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 at 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 FDA Regulation

Both before and after FDA approval, 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; and
- notices of correction or removal and recall regulations.

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. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, 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 efficacy 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 will 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 27 countries encompassing nearly all the major countries in Europe. Other countries that are not part of the EEC, 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 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 EEC states and other countries that recognize this mark for regulatory purposes.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which is considered an AIMD in Australia and the European Economic Area, and falls into Class III within the United States), the method involved a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's 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 manufacturer's assessment included 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.

Employees

As of December 31, 2012, we had a total of 32 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 28, 2013:

Name	Age	Position
Mark B. Knudson, Ph.D.	64	President, Chief Executive Officer, Chairman and Director
Greg S. Lea	60	Senior Vice President, Chief Financial Officer and Chief Operating Officer
Adrianus (Jos) Donders	59	Senior Vice President of Research and Advanced Development
Katherine S. Tweden	52	Vice President, Clinical and Regulatory

Mark B. Knudson, Ph.D. has served as our President, Chief Executive Officer and Chairman of the Board since December 2002. Dr. Knudson also served as President and Chief Executive Officer of Venturi Group, LLC and Venturi Development, Inc., positions he held from 1999 and 2001 until their dissolutions in 2008 and 2009, respectively. Dr. Knudson served as Chairman of the Board of Restore Medical, Inc., a publicly-held medical device company focused on the treatment of sleep disordered breathing, from 1999 through July 2008 when it was acquired by Medtronic, Inc. Dr. Knudson was also a member of the audit committee of Restore Medical. Dr. Knudson received a Bachelor of Science in biology from Pacific Lutheran University and a Ph.D. in physiology from Washington State University.

Greg S. Lea has served as our Senior Vice President and Chief Financial Officer since May 21, 2007 and was appointed Chief Operating Officer on February 15, 2013. 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 the Ability Building Center, Inc. from 1981 to 1993. Mr. Lea holds a B.S. in Accounting/Business Management from Minnesota State University, Mankato.

Adrianus (Jos) Donders has served as our Senior Vice President of Research and Advanced Development since April 2005. From September 2003 to April 2005, Mr. Donders was Director Communication Systems Engineering for Medtronic USA. From June 2000 to August 2003, Mr. Donders served as Director Clinical Study Management and Research and Development Europe for Medtronic Europe. Mr. Donders received a degree equivalent to a Masters of Electrical Engineering from the Institute of Technology Eindhoven Netherlands.

Katherine S. Tweden, Ph.D. has served as our Vice President of Clinical and Regulatory since May 2011. Prior to that Dr. Tweden served as our Vice President of Research and Clinical from September 2008 to May 2011 and our Vice President of Research from January 2003 to September 2008. From November 2002 to January 2003, Dr. Tweden was a consultant to Venturi Group, a medical device incubator company. From January 2003 through August 2004, Dr. Tweden worked for Venturi Development Inc. as a consultant to us. From July 1997 to October 2002, Dr. Tweden held positions including Director of Research and Vice President of Research for HeartStent Corporation. From September 1990 to June 1997, Dr. Tweden held the positions of Senior Research Scientist and Principal Research Scientist at St. Jude Medical, Inc. Dr. Tweden received a Bachelor of Arts in chemistry from Gustavus Adolphus College and a Masters degree and Ph.D. in biomedical engineering from Iowa State University.

Our Corporate Information

We were incorporated in Minnesota in December 2002 under the name Beta Medical, Inc. In 2003, we changed our name to EnteroMedics Inc. and 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 development stage medical device company with a limited history of operations and approval to sell our product in limited countries outside the United States, and we cannot assure you that we will ever generate revenue or be profitable.

We are a development stage medical device company with a limited operating history upon which you can evaluate our business. Currently, we only have met the regulatory process required 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 completed the first commercial sale of our product outside the United States in the first quarter of 2012, but do not expect to have a commercial sale within the United States until 2014, if at all. 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 intend to commercialize initially in the form of our Maestro Rechargeable System. The success of our business will depend on our ability to obtain additional regulatory approvals to market our Maestro Rechargeable System and any products we may develop in the future and our ability to create product sales, successfully introduce new products, establish our sales force and control costs, all of which we may be unable to do. If we are unable to successfully develop, receive additional regulatory approvals for and commercialize our Maestro Rechargeable System for its indicated use, we may never generate revenue or be profitable and we may have to cease operations. 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 increasing losses for the foreseeable future.

We have incurred losses in each year since our formation in 2002. As of December 31, 2012, we had experienced net losses during the development stage of $200.0 million. Our net loss applicable to common stockholders for the fiscal years ended December 31, 2012, 2011 and 2010 was $23.5 million, $26.0 million and $17.3 million, respectively. We have funded our operations to date principally from the sale of our securities and through 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 met the regulatory process required to sell our Maestro Rechargeable System in Australia, the European Economic Area and other countries that recognize the European CE Mark, and commenced commercial sales in the first half of 2012 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 and increasing 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 research and development, including conducting current and future clinical trials for our Maestro System, and initiating the commercialization of our product. Cash used in operations was $22.5 million, $19.9 million and $13.7 million for the fiscal years ended December 31, 2012, 2011 and 2010, respectively. We expect that our cash used in operations will continue to be significant in the upcoming years, and we may need to raise additional capital to continue our research and development programs, commercialize our Maestro Rechargeable System in Australia, the Middle East, other international markets, or the United States, if approved by the FDA, explore other indications for our product, and fund our ongoing operations.

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

- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of regulatory approvals;
- 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; 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.

Additional capital 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 Patient Act) as well as other healthcare reform may have a significant impact on our business. The impact of the Patient 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. In addition, any healthcare reforms enacted in the future may, like the Patient 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 Patient Act and changes under any federal or state legislation adopted in the future.

We may be 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.

If we are successful in achieving regulatory approval to market our Maestro System, our operations will be directly, or indirectly through our 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 proposed 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 and 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, Cyberonics, 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.

Risks Associated with Development and Commercialization of Our Maestro Rechargeable System

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

We do not have the necessary regulatory approvals to market our Maestro System in the United States or 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 Community for which we received CE Mark approval for our Maestro Rechargeable System in March 2011 and other countries which accept these regulatory approvals. We commenced commercialization of our product in Australia and the Middle East in the first half of 2012.

In order to market our Maestro 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 regarding FDA approval in the United States. 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 and we commenced commercial sales in Australia and the Middle East in 2012, we cannot assure you when, or if, we will be able to commence sales in the European Economic Area or other countries outside the United States or obtain approval to market our Maestro System in other countries outside the United States.

We cannot market our product in the United States unless it has been approved by the FDA. The FDA approval process involves, among other things, successfully completing clinical trials and obtaining a premarket approval (PMA). The PMA process requires us to prove the safety and efficacy of our Maestro System to the FDA’s satisfaction. This process can be expensive and uncertain, requires detailed and comprehensive scientific

and human clinical data, generally takes one to three years after a PMA application is filed, and notwithstanding the effort and expense incurred, may never result in the FDA granting a PMA approval. 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 the FDA and other regulatory bodies will review an application for approval of our Maestro System with greater scrutiny, which could cause that process to be lengthier and more involved than that for products without such characteristics. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our inability to demonstrate safety or effectiveness to the FDA's satisfaction;
- the data from our preclinical studies and clinical trials may be insufficient to support approval;
- the facilities of our third-party manufacturers or suppliers may not meet applicable requirements;
- our failure or inability to comply with preclinical, clinical or other regulations;
- our inability to demonstrate through our ongoing clinical trials that the Maestro System causes EWL greater than the control therapy;
- our inability to meet the FDA's statistical requirements or changes in statistical tests or significance levels the FDA requires for approval of a medical device, including ours; and
- changes in the FDA 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.

In addition, recent, widely-publicized events concerning the safety of certain drug, food and medical device products have raised concerns among members of Congress, medical professionals, and the public regarding the FDA's handling of these events and its perceived lack of oversight over regulated products. The increased attention to safety and oversight issues has resulted in a more cautious approach by the FDA to clearances and approvals for devices such as ours.

We plan to submit a PMA application for our Maestro Rechargeable System in the second quarter of 2013. We may never be able to produce sufficient data to support a successful PMA application with the FDA or commercialize a product in the United States. We may not obtain the necessary regulatory approvals to market our Maestro System in the United States or additional geographies. Even if we obtain approval, the FDA or other regulatory authorities may require expensive or burdensome post-market testing or controls. Any delay in, failure to receive or maintain, or significant limitation on approval for our Maestro System could prevent us from generating revenue or achieving profitability and we may be forced to cease operations.

The preliminary results of the blinded segment of our EMPOWER trial and the blinded segment of our ReCharge trial have created uncertainty regarding our ability to obtain regulatory approval of our Maestro System in the United States and have complicated our future financing plans.

Our inability to achieve the efficacy endpoints in our EMPOWER trial and our ReCharge trial have delayed our timeline for pursuing regulatory approval in the United States, have caused us to need additional capital and have resulted in uncertainty and complication regarding our future financing plans and the regulatory approval of our Maestro System in the United States.

- EMPOWER: In September 2009, we completed the blinded segment of our EMPOWER pivotal trial, a randomized, prospective, placebo-controlled multi-center trial of our Maestro System in the United States. Based on our initial analysis, the EMPOWER trial did not meet its primary and secondary efficacy endpoints in that the weight loss for the treatment arm was not statistically different from the control arm in which therapy was turned off. The study did meet its safety endpoint. The preliminary results of the EMPOWER trial were not sufficient to support approval of a PMA application. The inability to achieve our primary and secondary efficacy endpoints in the EMPOWER trial delayed our timeline for achieving regulatory approval of the Maestro System in the United States and caused us to need additional capital to fund a new pivotal trial.

- ReCharge: In October 2010, we received an unconditional 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 weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. In February 2013, we announced the preliminary results of the ReCharge trial. Based on our initial analysis, the ReCharge trial did not meet its co-primary efficacy endpoints in that the pre-specified super-superiority margin for the difference in weight loss between the treatment arm and the control arm was not met and the pre-specified percent excess weight loss thresholds were not met. The ReCharge trial did meet its safety endpoint. We plan to use the data from the ReCharge trial to support a PMA application for the Maestro Rechargeable System, which we anticipate filing during the second quarter of 2013. Although we believe we have sufficient data to support a PMA application, the inability to achieve our co-primary efficacy endpoints in our ReCharge trial has created uncertainty regarding our ability to achieve regulatory approval of our Maestro Rechargeable System in the United States, has caused us to need additional capital to fund the regulatory process, and has created complications and uncertainty regarding our future financing options.

We may be unable to complete our clinical trials, or we may experience significant delays in completing our clinical trials, which could prevent or delay regulatory approval of our Maestro System and impair our financial position.

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 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 outside the United States 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 in the United States 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.

Even if we obtain the necessary regulatory approvals, our efforts to commercialize our Maestro System may not succeed or may encounter delays which could significantly harm our ability to generate revenue.

Even if we obtain additional regulatory approval to market our Maestro Rechargeable System, as we recently have in Australia, the European Economic Area and other countries that recognize the European CE Mark, our ability to generate revenue will depend upon the successful commercialization of this product. Our efforts to commercialize our Maestro Rechargeable System may not succeed for a number of reasons, including:

- our Maestro System may not be accepted in the marketplace by physicians, patients and third-party payors;
- the price of our Maestro System, associated costs of the surgical procedure and treatment and the availability of sufficient third-party reimbursement for the procedure and therapy 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 System at a price that allows us to meet the revenue targets necessary to generate 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 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 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 System or to develop sales and marketing capabilities for our Maestro 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 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. We commenced commercial sales of our Maestro Rechargeable System in Australia and the Middle East in the first half of 2012. The earliest we expect to be able to commercialize our Maestro Rechargeable System in the United States is 2014, if at all. If we are not successful in the commercialization of our Maestro Rechargeable System for the treatment of obesity we may never generate any revenue and may be forced to cease operations.

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, to 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 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, and we may be unable to obtain regulatory approval for, or successfully commercialize, our product.

Assuming we receive regulatory approval for the Maestro System, modifications to the Maestro 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 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 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 System and VBLOC therapy. We believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our Maestro 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 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 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 System will be impaired and our future revenue, if any, would be adversely affected. As such, even if we obtain regulatory clearance or approval for our Maestro System and begin to market it, the availability and level of third-party coverage and reimbursement could substantially affect our ability to commercialize our Maestro System and other products we may develop.

The efficacy, safety, ease of use and cost-effectiveness of our Maestro 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 System will be more difficult if our clinical trials do not demonstrate a percentage of EWL from a pre-implementation baseline that healthcare providers and obese individuals consider 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 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 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.

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

Completion of our clinical trials and commercialization of our Maestro 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 System, and do not currently plan to manufacture or assemble our Maestro 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. We and our third-party manufacturers and suppliers have not yet been inspected by the FDA but 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 the United States and will have to successfully complete such inspections before we receive regulatory approvals for our Maestro System in 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.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed. 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 will be 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 System. The loss of any of these manufacturer or supplier relationships could delay our clinical trials or prevent or delay commercialization of our Maestro System.

We rely entirely on third parties to manufacture our Maestro System and to supply us with all of the critical components of our Maestro 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, 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 System could be interrupted for an extended period of time, which could delay completion of our clinical trials or commercialization of our Maestro System. In addition, we may be required to use different suppliers or components to obtain regulatory approval from the FDA.

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

In order to produce our Maestro 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 the requirements for the initial commercial launch of the product or 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 System. If we develop and obtain regulatory approval for our product and 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 System, our business may be harmed.

We do not have a sales organization and have no experience as a company in sales, marketing and distribution of our product. We have entered into an agreement with Device Technologies, a third-party distributor in Australia, to commence the commercial sale of our product in Australia and we have entered into an agreement with Bader Sultan & Brothers, a third-party distributor in Kuwait, to commence the commercial sale of our product in the Middle East. To generate sales in Australia 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 third party will be successful in selling our product. We will also need to develop a sales and marketing infrastructure or contract with third parties to perform that function before launching the commercialization of our product in markets outside of Australia and the Middle East. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. Even if we obtain approval from the FDA to market our Maestro System, we may be unable to develop an effective sales and marketing organization on a timely basis, if at all. 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.

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

We have commenced commercialization of our product internationally, in Australia and the Middle East, and intend to commercialize our product in 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 research and development 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 System. Upon receiving regulatory approval for our product in the United States, we expect to expand our operations and grow our research and development, product development and administrative operations. Our 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 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 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 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 System and to perform the related VBLOC therapy. If these medical personnel are not properly trained or are negligent, the therapeutic effect of our Maestro System and 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 System and VBLOC therapy by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. To date, we have 24 issued U.S. patents, 22 of which pertain to treating gastrointestinal disorders, and 16 U.S. patent applications. We have four granted European patents and four granted Australian patents. We also have 30 national stage patent applications, including applications in Australia, China, India, Europe and Japan. In addition, we are the exclusive licensee to two U.S. patents owned by 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 or re-examinations. 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) 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 may change, 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. Since patent applications are confidential until patents are issued in the United States, or in most cases, until after 18 months from filing of 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 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 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 28, 2013 our stock price has fluctuated from a low of $0.81 to a high of $64.62, as adjusted for the 1-for-6 reverse split of our common stock that was effected on July 9, 2010. 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, if it receives regulatory approval, 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;
- 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 Capital 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 Capital Market. If we do not maintain compliance with the continued listing requirements for the NASDAQ Capital 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.

The low trading volume of our common stock may adversely affect the price of our shares.

Although our common stock is listed on the NASDAQ Capital Market, our common stock has experienced low trading volume. Reported average daily trading volume in our common stock for the three month period ended December 31, 2012, was approximately 170,486 shares. Although we believe that recent offerings will improve the liquidity for our common stock, there is no assurance that the recent offerings will increase the volume of trading in our common stock. Limited trading volume subjects our common stock to greater price volatility and may make it difficult for you to sell your shares at a price that is attractive to you.

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 of 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, 2012), approximately 29.3% 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 of 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 or in connection with acquisitions or corporate alliances and we 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 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.

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 credit agreement also restricts 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.

ITEM1B. ***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 lease agreement began October 1, 2008 and ends September 30, 2015.

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.

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 28, 2013, there were approximately 75 holders of record of our common stock and 55,618,270 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.

Price Range of Common Stock

	Price Range	
	High	Low
Fiscal 2011		
First Quarter	$3.32	$2.39
Second Quarter	$2.84	$2.31
Third Quarter	$2.81	$1.58
Fourth Quarter	$2.10	$1.52
Fiscal 2012		
First Quarter	$2.40	$1.73
Second Quarter	$3.77	$2.15
Third Quarter	$4.40	$2.86
Fourth Quarter	$3.93	$2.25

The closing price for our common stock as reported by the NASDAQ Capital Market on February 28, 2013 was $0.84 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

As previously described in our Current Report on Form 8-K filed April 17, 2012, on April 16, 2012, we entered into a new Loan and Security Agreement with Silicon Valley Bank. As required by the new Loan and Security Agreement, on April 16, 2012, we issued a warrant to Silicon Valley Bank to purchase 106,746 shares of our common stock with an exercise price of $2.34 per share and a ten year exercise period. See Note 7 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K for more detail about the Loan and Security Agreement. The sale and issuance of this warrant was deemed to be exempt from registration under the Securities Act of 1933 (the Securities Act) by virtue of Section 4(2) of the Securities Act, as a transaction by an issuer not involving any public offering.

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

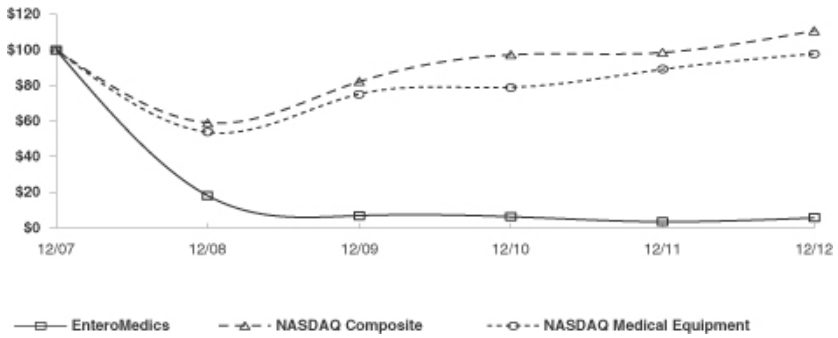
The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except 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, 2007.

Data for the NASDAQ Composite Index and the NASDAQ Medical Equipment Index assume reinvestment of dividends. The Company has never paid dividends on its common stock and has 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 Inc., the NASDAQ Composite Index
and the NASDAQ Medical Equipment Index



* $100 invested on 12/31/07 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, 2007	December 31, 2008	December 31, 2009	December 31, 2010	December 31, 2011	December 31, 2012
EnteroMedics Inc.	$ 100.00	$ 18.14	$ 6.96	$ 6.38	$ 3.52	$ 5.80
NASDAQ Composite	100.00	59.03	82.25	97.32	98.63	110.78
NASDAQ Medical Equipment	100.00	53.91	75.19	78.88	89.14	97.76

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.

	Fiscal Years				
	2012	2011	2010(1)	2009	2008
	(In thousands, except per share data)				
Sales	$ 311	$ —	$ —	$ —	$ —
Operations:					
Loss from operations	(22,549)	(25,257)	(16,177)	(24,212)	(36,270)
Net loss	(23,460)	(25,997)	(17,347)	(31,929)	(37,874)
Basic and diluted net loss per share	(0.59)	(0.86)	(2.06)	(6.42)	(13.50)
Shares used to compute basic and diluted net loss per share	39,537	30,205	8,420	4,974	2,806
Financial Position:					
Cash, cash equivalents, restricted cash and short-term investments	22,509	29,693	37,368	14,618	26,295
Working capital (current assets less current liabilities)	16,866	22,003	33,807	8,821	20,916
Total assets	26,096	32,486	38,687	16,214	28,279
Long-term debt, net of current portion and discounts	6,684	2,881	4,983	3,881	10,996
Deficit accumulated during development stage	(200,172)	(176,712)	(150,715)	(133,368)	(101,307)
Total stockholders' equity	11,875	20,041	29,707	5,581	11,405

(1) Basic and diluted net loss per share and shares used to compute basic and diluted net loss per share include the impact of converting 3,394,309 shares of convertible preferred stock into common stock immediately following the closing of our public offering on December 14, 2010.

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 development stage medical device company with approvals to commercially launch our product in 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 currently, we only 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. Our initial product is the Maestro System, which uses VBLOC therapy to affect metabolic regulatory control, 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 were formerly known as Beta Medical, Inc. and were incorporated in Minnesota on December 19, 2002. We later reincorporated in Delaware on July 22, 2004. Since inception, we have devoted substantially all of our resources to the development and commercialization of our Maestro System.

Based on our understanding of vagal nerve function and nerve blocking from our preclinical studies and the results of our clinical trials, we believe the Maestro System may offer obese patients a minimally-invasive treatment that has the potential to result in significant and sustained weight loss. We believe that our Maestro System will allow bariatric surgeons to help obese patients who are concerned about the risks and complications associated with currently available restrictive and malabsorptive surgical procedures. 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 continue to evaluate the Maestro System in human clinical trials in the United States, Australia, Mexico, Norway and Switzerland. To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in these clinical trials. 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.

In October 2010, we received an unconditional Investigational Device Exemption (IDE) Supplement approval from the U.S. Food and Drug Administration (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 (RC) 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 weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. As announced on February 7, 2013, the ReCharge trial met its primary safety endpoint, though it did not meet its predefined co-primary efficacy endpoints. The trial did however demonstrate a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% for VBLOC therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. As a result of the positive

safety and efficacy profile of VBLOC therapy, we plan to use the data from the ReCharge trial to support a premarket approval (PMA) application for the Maestro Rechargeable System, which we anticipate filing during the second quarter of 2013. If the FDA grants us approval, we anticipate we will be able to commercialize the Maestro Rechargeable System in the United States in 2014.

If we obtain FDA approval of our Maestro Rechargeable System we intend to market our products in the United States through a direct sales force supported by field technical and marketing managers who provide training, technical and other support services to our customers. Outside the United States we intend to use direct, dealer and distributor sales models as the targeted geography best dictates. To date, we have relied on third-party manufacturers and suppliers for the production of our Maestro System. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of the Maestro System.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011. 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). We have been working closely with our Australian distributor, Device Technologies Australia Pty Limited, to bring the Maestro Rechargeable System to the Australian market through a controlled commercial launch and made our first commercial shipment of the Maestro ReChargeable System to Device Technologies Australia Pty Limited in March 2012. We also entered into an exclusive, multi-year agreement with Bader Sultan & Brothers Co. W.L.L. for commercialization and distribution of the Maestro ReChargeable System in the Gulf Coast Countries, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates and made our first commercial shipments to Bader Sultan & Brothers Co. W.L.L. during the second quarter of 2012. We continue to explore additional select international markets to commercialize the Maestro Rechargeable System, including Europe.

The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which is considered an Active Implantable Medical Device (AIMD) in Australia and the European Economic Area, and falls into Class III within the United States), the method involves a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer’s quality system. We use DEKRA Certification B.V. (formerly known as KEMA Quality) in the Netherlands as the Notified Body for our CE marking approval process.

We have only recently begun to generate revenue from the sale of products, and we have incurred net losses in each year since our inception. As of December 31, 2012, we had experienced net losses during the development stage of $200.0 million. Although we recently received ARTG listings to sell our Maestro Rechargeable System in Australia and European CE Mark to sell our Maestro Rechargeable System in the European Economic Area and other countries that recognize the European CE Mark, resulting in our first commercial sales in 2012, 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 and increasing operating losses for the next several years. We have financed our operations to date principally through the sale of capital stock, debt financing and interest earned on investments.

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 internationally through distributors and revenue is recognized upon sale to the distributor as these sales are considered to be final and 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. We do not provide for rights of return to customers on product sales and therefore do not record a provision for returns.

Inventory

Since inception, inventory related purchases primarily have been used for research and development related activities and have 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 approximately $1.3 million and $1.1 million as of December 31, 2012 and 2011, 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 approximately $862,000 and $228,000 of long-term inventory as of December 31, 2012 and 2011, respectively.

Stock-Based Compensation

Prior to January 1, 2006, we accounted for stock-based employee compensation arrangements using the intrinsic value method and recognizing the expense over the option vesting period. The intrinsic value method is calculated as the difference, if any, between the fair value of our common stock and the exercise price on the date of the grant. We also followed the minimum value disclosure provisions. Using the intrinsic value method, we were not required to recognize stock-based compensation expense for employee stock options granted from inception through 2005 as the exercise prices, for financial reporting purposes, were determined to be at or above the deemed fair value of the underlying common stock on the date of grant. The fair value of our common stock was assessed and approved by our board of directors, the members of which have extensive experience in the life sciences industry and all but one of whom are nonemployee directors. In determining the appropriateness of the fair value of our common stock, the board of directors considered several factors, such as our life cycle, results of research and development, recent financings and financial projections.

Effective January 1, 2006, we adopted the fair value method of accounting for share-based payments, which superseded the previous accounting method, and 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. We adopted the new provisions using the prospective transition method. Under this method, compensation cost is recognized for all share-based payments granted or modified subsequent to December 31, 2005. All option grants valued after January 1, 2006 are expensed on a straight-line basis over the vesting period.

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.

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.

Common Stock Warrant Liability

Effective January 1, 2009, we adopted new authoritative accounting guidance regarding the financial reporting for outstanding equity-linked financial instruments. This adoption required certain warrants issued by us to be recorded as a liability and recorded at fair value. Calculating the fair value of the warrant liability requires the input of highly subjective assumptions, which requires our best estimates, and involves inherent uncertainties and the application of management's judgment. The common stock warrant liability and related changes in fair value are significant to our consolidated financial statements and is based on a weighted-average Black-Scholes valuation model, however the warrant liability will never result in the payment of cash by us.

Net Operating Losses and Tax Credit Carryforwards

At December 31, 2012, we had federal net operating loss carryforwards of approximately $70.6 million. Of this amount, approximately $22.5 million is available after the application of Internal Revenue Code (IRC) Section 382 limitations, discussed below. These net operating loss carryforwards will expire in varying amounts from 2022 through 2032, if not utilized. The 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 the Company's 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. The Company's 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. The Section 382 limitation and accompanying recognized built-in loss limitation is currently estimated to result in the expiration of $48.1 million of our gross federal net operating loss carryforward, as well as a write-off of $5.9 million of capitalized start-up costs, $14.2 million of capitalized research and development costs, $1.5 million of property and equipment and $2.4 million of research and development credits. An IRC Section 382 review has not been completed since 2011. 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 have received the European CE Mark for our Maestro Rechargeable System, which enables commercialization in the European Economic Area and other countries that recognize the European CE Mark. In January 2012, the final Maestro Rechargeable System components were listed on the ARTG by the Australian TGA and we have been working closely with Device Technologies Australia Pty Limited to bring the Maestro Rechargeable System to the Australian market through a controlled commercial launch and made our first commercial shipment of the Maestro ReChargeable System to Device Technologies Australia Pty Limited in March 2012. We also entered into an exclusive, multi-year agreement with Bader Sultan & Brothers Co. W.L.L. for commercialization and distribution of the Maestro ReChargeable System in the Gulf Coast Countries, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates and made our first commercial shipments to Bader Sultan & Brothers Co. W.L.L. during the second quarter of 2012. For the year ended December 31, 2012, we recognized $311,000 in revenue.

In the United States, we completed enrollment and device implantation in our ReCharge pivotal trial for obesity in December 2011. The primary endpoints of efficacy and safety were evaluated at 12 months. As announced on February 7, 2013, the ReCharge trial met its primary safety endpoint, though it did not meet its predefined co-primary efficacy endpoints. The trial did however demonstrate a clinically meaningful and statistically significant EWL of 24.4% for VBLOC therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. As a result of the positive safety and efficacy profile of VBLOC therapy, we plan to use the data from the ReCharge trial to support a premarket approval (PMA) application for the Maestro Rechargeable System, which we anticipate filing during the second quarter of 2013. If the FDA grants us approval, we anticipate we will be able to commercialize the Maestro Rechargeable System in the United States in 2014. 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.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development and clinical and regulatory expenses, incurred in the development of our Maestro 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. From inception through December 31, 2012, we have incurred a total of $127.4 million in research and development expenses. With the completion of enrollment and device implantation in our ReCharge pivotal trial for obesity in late 2011, research and development expenditures decreased in 2012 as costs were primarily associated with supporting the ReCharge trial in addition to the continued follow-up on existing trials, such as VBLOC-DM2 ENABLE and EMPOWER.

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, 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. From inception through December 31, 2012, we have incurred $60.1 million in selling, general and administrative expenses.

Results of Operations

Comparison of the Years Ended December 31, 2012 and 2011

Sales. Sales were $311,000 for the year ended December 31, 2012, compared to no sales for the year ended December 31, 2011. The $311,000 of sales for the year ended December 31, 2012 were the result of beginning a controlled commercial launch of the Maestro ReChargeable System in Australia and the Gulf Coast Countries of the Middle East with our first commercial shipments occurring in the first quarter of 2012.

Cost of Goods Sold. Cost of goods sold were $232,000 for the year ended December 31, 2012, compared to no cost of goods sold for the year ended December 31, 2011. Gross margin was 25.7% for the year ended December 31, 2012.

Research and Development Expenses. Research and development expenses were $10.7 million for the year ended December 31, 2012, compared to $16.7 million for the year ended December 31, 2011. The decrease of $6.0 million, or 36.0%, is primarily due to decreases of $4.8 million and $984,000 in professional services and device costs, respectively. The decreases in professional services and device costs are primarily the result of the completion of enrollments and device implantation in our ReCharge pivotal trial for obesity in late 2011. Ongoing costs in 2012 were for follow-up visits, which are significantly less than the implantation costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $12.0 million for the year ended December 31, 2012, compared to $8.6 million for the year ended December 31, 2011. The increase of $3.4 million, or 39.4%, is primarily due to an increase of $2.1 million in compensation and benefits, including $1.3 million in stock-based compensation, and an increase of $1.1 million in professional services. The increase in compensation and benefits, including stock-based compensation, is the result of increased staff to support international commercialization efforts as well as stock option grants made to management on July 10, 2012. The increase in professional services is also the result of international commercialization efforts.

Interest Expense. Interest expense was $902,000 for the year ended December 31, 2012, compared to $723,000 for the year ended December 31, 2011, an increase of $179,000, or 24.8%. Modifications to the loan agreement with Silicon Valley Bank (SVB) occurred in March 2011 and April 2012. The March 2011 loan modification reduced the interest rate from 11.00% to 6.25% with interest only payments through September 30, 2011. The principal balance was approximately $6.0 million at the time of the modification. The April 2012 loan modification increased the interest rate from 6.25% to 8.00% effective April 23, 2012 with interest only payments through March 31, 2013. The April 2012 loan modification resulted in the principal balance increasing from $4.7 million to $10.0 million.

Comparison of the Years Ended December 31, 2011 and 2010

Research and Development Expenses. Research and development expenses were $16.7 million for the year ended December 31, 2011, compared to $8.5 million for the year ended December 31, 2010. The increase of $8.2 million, or 96.2%, is primarily due to increases of $6.8 million, $964,000 and $225,000 in professional services, device costs and travel, respectively. The increases are primarily due to efforts in support of the ReCharge trial, including patient recruiting and the completion of enrollment and implantation in 233 patients during 2011.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $8.6 million for the year ended December 31, 2011, compared to $7.7 million for the year ended December 31, 2010. The increase of $905,000, or 11.8%, is primarily due to increases of $275,000, $271,000 and $255,000 in employee stock-based compensation, professional services and compensation and benefits expense, respectively. The increase in employee stock-based compensation is primarily the result of granting 2.0 million stock options during 2011 with a weighted average fair value of $2.13 per share. The increase in professional services and compensation and benefits was due to commercialization efforts in Australia and additional select international markets.

Interest Expense. Interest expense was $723,000 for the year ended December 31, 2011, compared to $1.3 million for the year ended December 31, 2010. The decrease of $536,000, or 42.6%, was the result of a decrease in the gross principal balance outstanding from approximately $6.3 million on December 31, 2010 to approximately $5.4 million on December 31, 2011 and a modification to the loan agreement with SVB that reduced our annual interest rate from 11.0% to 6.25% effective March 1, 2011.

Change in Value of Warrant Liability. There was no warrant liability during the year ended December 31, 2011. The value of the warrant liability decreased $159,000 for the year ended December 31, 2010. In 2010 the warrant liability consisted of warrants issued to Compass Horizon Funding Company LLC (Horizon). The fair market value of the remaining 141,025 warrants, with a weighted-average exercise price of $3.90, was $313,000 as of May 18, 2010, the date on which the warrants' down round protection expired. The fair market value for these remaining warrants was calculated using the Black-Scholes valuation model, which resulted in a decrease of $159,000 for the year ended December 31, 2010 as our stock price decreased from $3.36 on December 31, 2009 to $2.46 on May 18, 2010.

Liquidity and Capital Resources

We have incurred losses since our inception in December 2002 and, as of December 31, 2012 we had experienced net losses during the development stage of $200.0 million. We have financed our operations to date principally through the sale of capital stock, debt financing and interest earned on investments. Through December 31, 2011, we had received net proceeds of $173.8 million from the sale of common stock and preferred stock, including $39.1 million from our initial public offering in November 2007 and $71.5 million from public offerings, private placements and registered direct offerings in 2011, 2010 and 2009. In addition, through December 31, 2011, we had received $35.8 million in debt financing, $746,000 to finance equipment purchases and $35.0 million to finance working capital. On April 20, 2012, we completed the sale of 2,271,705 shares of common stock in a registered direct offering at a purchase price of $2.223 per share. We received gross proceeds of $5.0 million before deducting estimated offering expenses. We have also received approximately $6.1 million from the exercise of common stock warrants during the year ended December 31, 2012. On February 27, 2013, we closed a public offering, selling 13,770,000 shares of common stock, together with warrants to purchase approximately 5,508,000 shares of common stock at an aggregate price of $0.95 per share and corresponding warrant, for gross proceeds of $13.1 million before deducting offering expenses. See Note 17 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K for a more detailed description of the public offering.

As of December 31, 2012 we had $22.5 million in cash, cash equivalents and restricted cash. Of this amount $20.5 million was invested in 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 and $200,000 was invested in restricted cash collateral money market accounts as required by the terms of our lease agreement. 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 believe that the cash, cash equivalents and restricted cash balance as of December 31, 2012, together with $13.1 million in gross proceeds from the public offering completed February 27, 2013 and any interest income we earn on these balances, will be sufficient to meet our anticipated cash requirements (including scheduled or potentially accelerated debt obligations) into 2014, assuming we do not receive any other additional funds.

On November 18, 2008 we entered into a Loan and Security Agreement with SVB, Venture Lending & Leasing V, Inc. (a private equity fund under the management of Western Technology Investment (WTI)) and Horizon, in an aggregate principal amount of up to $20.0 million. On December 1, 2009, we repaid the outstanding principal amount due to WTI and Horizon. During 2010 and 2011, we entered into four amendments to the Loan and Security Agreement with SVB, which modified the payment terms, annual interest rate and

financial covenants. See Note 7 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K for a more detailed description of the Loan and Security Agreement and amendments thereto.

On April 16, 2012, we entered into a new Loan and Security Agreement with SVB pursuant to which SVB agreed to make term loans to us in an aggregate principal amount of up to $20.0 million. Pursuant to the Loan and Security 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 the outstanding debt of approximately $4.7 million. The remaining $10.0 million of capacity under the Loan and Security Agreement is not available as we did not meet the predefined primary efficacy measures of the ReCharge trial as well as certain financial objectives for 2012. The term loan requires 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 and Security Agreement bear interest at a fixed annual rate equal to 8.0%. Pursuant to the Loan and Security Agreement, SVB has the right to require us to maintain a restricted cash balance of $7.5 million in an SVB account as a result of our not meeting the predefined primary efficacy measures of the ReCharge trial. To date, SVB has not exercised this right. We may voluntarily prepay the term loan in full, but not in part, and any voluntary or mandatory prepayment is subject to applicable prepayment premiums and will also include the final payment fee. We are required to comply with certain financial covenants that require us to generate certain minimum amounts of revenue from the sale of our Maestro System and to implant certain minimum numbers of Maestro Systems during cumulative quarterly measurement periods beginning with the period ending March 31, 2013 and ending with the period ending June 30, 2015. If we fail to meet the financial covenants, the term loan will be in default. We do not anticipate that we will be able to meet the financial covenants for the period ending March 31, 2013, and that we will attempt to renegotiate the terms of the Loan and Security Agreement with SVB. If we are not able to renegotiate these terms we may be required to repay the $10.0 million term loan and any associated fees. See Note 7 to our consolidated financial statements included Item 8 of this Annual Report on Form 10-K for a more detailed description of the new Loan and Security Agreement.

On October 4, 2012, we entered into a Common Stock Purchase Agreement (the Purchase Agreement) with Terrapin Opportunity, L.P. (Terrapin) under which we may sell up to the lesser of $45.0 million of common stock or 8,312,122 shares of our common stock over an approximately 24-month period pursuant to the terms of the Purchase Agreement. We are not obligated to utilize any portion of the facility and we generally remain free to enter into and consummate other equity and debt financing transactions. We will determine, at our sole discretion, the timing, the dollar amount and the price per share of each draw under this facility, subject to certain conditions. When and if we elect to use the facility, we will issue shares to Terrapin at a discount ranging from 4.00% to 6.80% to the volume weighted average price of our common stock over a preceding period of trading days. Terrapin is not required to purchase any shares at a pre-discounted purchase price below $1.25 per share, or any shares that would cause it to hold over 9.9% of our common stock. Any shares sold under this facility will be sold pursuant to a shelf registration statement declared effective by the U.S Securities and Exchange Commission (SEC) on August 29, 2012. Subject to earlier termination under certain conditions, the Purchase Agreement will terminate on November 1, 2014.

Net Cash Used in Operating Activities

Net cash used in operating activities was $22.5 million, $19.9 million and $13.7 million for the years ended December 31, 2012, 2011 and 2010, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, which was partially offset by stock-based compensation, depreciation and amortization, change in the carrying value of warrant liability, loss on sale of equipment and changes in operating assets and liabilities, including inventory which was recorded as an asset beginning in 2011 as we began receiving ARTG listings for components of the Maestro Rechargeable System from the Australian TGA in December 2011.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $1.0 million and $5.1 million for the years ended December 31, 2012 and 2011, respectively, compared to net cash used in investing activities of $6.5 million for

the year ended December 31, 2010. Net cash provided by investing activities for the year ended December 31, 2012 is primarily related to a $1.0 million in maturities of short-term investments available for sale offset by the purchase of $76,000 in property and equipment. Net cash provided by investing activities for the year ended December 31, 2011 is primarily related to a $6.3 million decrease in the restricted cash balance as a result of an amendment to a the loan agreement with SVB and $4.0 million in maturities of short-term investments available for sale offset by the purchase of $5.0 million in short-term investments available for sale and $252,000 in property and equipment. Net cash used in investing activities for the year ended December 31, 2010 is primarily related to an increase in restricted cash of $6.5 million per the terms of our debt and lease agreements.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $15.4 million, $12.5 million and $36.4 million for the years ended December 31, 2012, 2011 and 2010, respectively. For the year ended December 31, 2012, net cash provided by financing activities was primarily the result of $5.3 million in net proceeds from the initial term loan funded pursuant to the new loan agreement entered into on April 16, 2012 with SVB, net proceeds of $4.7 million from the April 16, 2012 registered direct offering and $6.1 million from the exercise of common stock warrants. These increases were partially offset by principal repayments of $753,000 on our long-term debt.

For the year ended December 31, 2011, net cash provided by financing activities was primarily attributable to the completion of a public offering that resulted in gross proceeds of $14.5 million for the issuance of common stock and common stock warrants, offset by $1.2 million in financing costs and the repayment of $922,000 on our long-term debt.

For the year ended December 31, 2010, net cash provided by financing activities was primarily attributable to the completion of a public offering that resulted in gross proceeds of $29.8 million for the issuance of common stock and common stock warrants, offset by $2.2 million in financing costs, a private placement transaction that resulted in gross proceeds of $6.3 million for the issuance of preferred stock and common stock warrants, offset by $61,000 in financing costs and a registered direct offering that resulted in gross proceeds of $4.8 million for the issuance of common stock, offset by $340,000 in financing costs, partially offset by repayments on our long-term debt.

On February 27, 2013, we closed a public offering, selling 13,770,000 shares of common stock, together with warrants to purchase approximately 5,508,000 shares of common stock at an aggregate price of $0.95 per share and corresponding warrant, for gross proceeds of $13.1 million before deducting offering expenses. See Note 17 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K for a more detailed description of the public offering.

Operating Capital and Capital Expenditure Requirements

We have only recently begun to generate revenue from the sale of products. We obtained European CE Mark approval for our Maestro Rechargeable System in 2011. In January 2012, the final Maestro Rechargeable System components were listed on the ARTG by the TGA. We have been working closely with our Australian distributor, Device Technologies Australia Pty Limited, to bring the Maestro Rechargeable System to the Australian market through a controlled commercial launch and made our first commercial shipment of the Maestro ReChargeable System to Device Technologies Australia Pty Limited in March 2012. We also entered into an exclusive, multi-year agreement with Bader Sultan & Brothers Co. W.L.L. for commercialization and distribution of the Maestro ReChargeable System in the Gulf Coast Countries, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates and began commercial shipments to Bader Sultan & Brothers Co. W.L.L. during the second quarter of 2012. We continue to explore additional select international markets to commercialize the Maestro Rechargeable System, including Europe. In the United States, we completed enrollment and device implantation in our ReCharge pivotal trial for obesity in December 2011. The primary endpoints of efficacy and safety were evaluated at 12 months. As announced on February 7, 2013, the ReCharge trial met its primary safety endpoint, though it did not meet its predefined co-primary efficacy endpoints. The

trial did however demonstrate a clinically meaningful and statistically significant EWL of 24.4% for VBLOC therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. As a result of the positive safety and efficacy profile of VBLOC therapy, we plan to use the data from the ReCharge trial to support a premarket approval (PMA) application for the Maestro Rechargeable System, which we anticipate filing during the second quarter of 2013. If the FDA grants us approval, we anticipate we will be able to commercialize the Maestro Rechargeable System in the United States in 2014. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our products, prepare for the potential commercial launch of 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 believe that the cash, cash equivalents and restricted cash balance as of December 31, 2012, together with $13.1 million in gross proceeds from the public offering completed February 27, 2013 and any interest income we earn on these balances, will be sufficient to meet our anticipated cash requirements (including scheduled or potentially accelerated debt obligations) into 2014, assuming we do not receive any other additional funds. If our available cash, cash equivalents and restricted cash balances are insufficient to satisfy our liquidity requirements, we may seek additional funding through our existing issuer managed equity financing facility with Terrapin, sell additional equity or debt securities or enter into a credit facility. Obtaining funds through our existing issuer managed equity financing facility or 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. 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.

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 this 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 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 scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- 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;
- the cost of establishing clinical and commercial supplies of our Maestro System and any products that we may develop;
- the rate of market acceptance of our Maestro 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 System or our future 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

The following table summarizes our contractual obligations as of December 31, 2012 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	$ 798,814	$ 285,656	$ 513,158	$ —	$ —
Long-term debt, including interest	11,749,852	3,729,778	8,020,074	—	—
Total contractual cash obligations	$12,548,666	$4,015,434	$8,533,232	$ —	$ —

The table above reflects only payment obligations that are fixed and determinable based on our current agreements and does not reflect the potential accelerated debt payments in the event of a default. Our operating lease commitments relate to our corporate headquarters in St. Paul, Minnesota.

On April 16, 2012, we entered into a new Loan and Security Agreement with SVB pursuant to which SVB agreed to make term loans to us in an aggregate principal amount of up to $20.0 million. Pursuant to the Loan and Security 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 the outstanding debt of approximately $4.7 million. The remaining $10.0 million of capacity under the Loan and Security Agreement is not available as we did not meet the predefined primary efficacy measures of the ReCharge trial as well as certain financial objectives for 2012. The term loan requires 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 and Security Agreement bear interest at a fixed annual rate equal to 8.0%. Pursuant to the Loan and Security Agreement, SVB has the right to require us to maintain a restricted cash balance of $7.5 million in an SVB account as a result of our not meeting the predefined primary efficacy measures of the ReCharge trial. To date, SVB has not exercised this right. We may voluntarily prepay the term loan in full, but not in part, and any voluntary or mandatory prepayment is subject to applicable prepayment premiums and will also include the final payment fee. We are required to comply with certain financial covenants that require us to generate certain minimum amounts of revenue from the sale of our Maestro System and to implant certain minimum numbers of Maestro Systems during cumulative quarterly measurement periods beginning with the period ending March 31, 2013 and ending with the period ending June 30, 2015. If we fail to meet the financial covenants, the term loan will be in default. We do not anticipate that we will be able to meet the financial covenants for the period ending March 31, 2013, and that we will attempt to renegotiate the terms of the Loan and Security Agreement with SVB. If we are not able to renegotiate these terms we may be required to repay the $10.0 million term loan and any associated fees. See Note 7 to our consolidated financial statements included Item 8 of this Annual Report on Form 10-K for a more detailed description of the new Loan and Security Agreement.

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 Financial Accounting Standards Board (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 June 2011, the Financial Accounting Standards Board issued guidance on the presentation of comprehensive income in financial statements. Entities are required to present total comprehensive income either in a single, continuous statement of comprehensive income or in two separate, but consecutive, statements. We adopted this standard during the first quarter of 2012 and present net loss and other comprehensive loss in two separate, but consecutive, statements. The adoption of this standard did not have a material effect on our financial statement disclosures.

There have been no other significant changes in recent accounting pronouncements during the year ended December 31, 2012.

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

Our exposure to market risk is confined to our cash, cash equivalents and restricted cash. As of December 31, 2012, we had approximately $22.5 million in cash, cash equivalents and restricted cash. 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.

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

Index to Financial Statements

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 (a development stage company) (the "Company") as of December 31, 2012 and 2011 and the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012 and for the period from December 19, 2002 (date of inception) to December 31, 2012. These consolidated 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 and its subsidiary as of December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, and for the period from December 19, 2002 (date of inception) to December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on the criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 7, 2013, expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, MN
March 7, 2013

ENTEROMEDICS INC.
(A development stage company)

Consolidated Balance Sheets

	December 31, 2012	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,308,781	$ 28,487,688
Restricted cash	200,000	200,000
Short-term investments available for sale	—	1,005,411
Accounts receivable	52,406	—
Inventory	1,271,207	1,068,623
Prepaid expenses and other current assets	571,654	804,799
Total current assets	24,404,048	31,566,521
Property and equipment, net	609,672	630,354
Other assets	1,082,765	288,980
Total assets	$ 26,096,485	$ 32,485,855
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable	$ 3,000,000	$ 2,307,162
Accounts payable	340,555	434,436
Accrued expenses	3,673,609	6,373,370
Accrued interest payable	523,678	448,821
Total current liabilities	7,537,842	9,563,789
Notes payable, less current portion (net discounts of $316,028 and $216,711 at December 31, 2012 and 2011, respectively)	6,683,972	2,881,161
Total liabilities	14,221,814	12,444,950
Commitments and contingencies (note 14)		
Stockholders' equity:		
Common stock, $0.01 par value; 125,000,000 and 85,000,000 shares authorized at December 31, 2012 and 2011, respectively; 41,843,270 and 36,752,746 shares issued and outstanding at December 31, 2012 and 2011, respectively	418,433	367,527
Additional paid-in capital	211,628,650	196,384,995
Accumulated other comprehensive income	—	692
Deficit accumulated during development stage	(200,172,412)	(176,712,309)
Total stockholders' equity	11,874,671	20,040,905
Total liabilities and stockholders' equity	$ 26,096,485	$ 32,485,855

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Consolidated Statements of Operations

	Years ended December 31,			Period from December 19, 2002 (inception) to December 31, 2012
	2012	2011	2010	
Sales	$ 311,493	$ —	$ —	$ 311,493
Cost of goods sold	231,520	—	—	231,520
Gross profit	79,973	—	—	79,973
Operating expenses:				
Research and development	10,668,044	16,673,238	8,498,857	127,449,618
Selling, general and administrative	11,960,893	8,583,347	7,678,259	60,129,863
Total operating expenses	22,628,937	25,256,585	16,177,116	187,579,481
Operating loss	(22,548,964)	(25,256,585)	(16,177,116)	(187,499,508)
Other income (expense):				
Interest income	9,877	12,241	5,597	4,046,140
Interest expense	(901,835)	(722,859)	(1,258,406)	(12,464,605)
Change in value of warrant liability	—	—	158,834	(3,840,622)
Other, net	(19,181)	(30,119)	(76,296)	(282,849)
Net loss	$ (23,460,103)	$ (25,997,322)	$ (17,347,387)	$ (200,041,444)
Net loss per share—basic and diluted	$ (0.59)	$ (0.86)	$ (2.06)	
Shares used to compute basic and diluted net loss per share	39,536,500	30,205,447	8,419,575	

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Consolidated Statements of Comprehensive Loss

	Years ended December 31,			Period from December 19, 2002 (inception) to December 31, 2012
	2012	2011	2010	
Net loss	$ (23,460,103)	$ (25,997,322)	$ (17,347,387)	$ (200,041,444)
Change in unrealized gain (loss) on available for sale investments	(692)	692	—	—
Comprehensive loss	$ (23,460,795)	$ (25,996,630)	$ (17,347,387)	$ (200,041,444)

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Consolidated Statements of Stockholders' Equity (Deficit)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Common stock issued at inception of Alpha Medical, Inc. on December 19, 2002 at $0.54 per share for cash	—	$ —	—	$ —	—	$ —	18,315	$ 183	$ 9,817	$ —	$ —	$ —	$ 10,000
Common stock issued at inception of Beta Medical, Inc. on December 19, 2002 at $0.54 per share for cash	—	—	—	—	—	—	18,315	183	9,817	—	—	—	10,000
Alpha Medical, Inc. Series A convertible preferred stock issued on December 31, 2002 at $54.60 per share for cash	—	—	—	—	5,525	55	—	—	301,619	—	—	—	301,674
Beta Medical, Inc. Series A convertible preferred stock issued on December 31, 2002 at $54.60 per share for cash	—	—	—	—	5,525	55	—	—	301,619	—	—	—	301,674
Net loss	—	—	—	—	—	—	—	—	—	—	—	(603,348)	(603,348)
Balance, December 31, 2002	—	$ —	—	$ —	11,050	$ 110	36,630	$ 366	$ 622,872	$ —	$ —	$ (603,348)	$ 20,000
Alpha Medical, Inc. Series A convertible preferred stock issued on October 1, 2003 at $54.60 per share for cash	—	$ —	—	$ —	6,410	$ 64	—	$ —	$ 349,936	$ —	$ —	$ —	$ 350,000
Beta Medical, Inc. Series A convertible preferred stock issued on October 1, 2003 at $54.60 per share for cash	—	—	—	—	15,568	156	—	—	849,844	—	—	—	850,000
Cancellation of Alpha Medical, Inc. Series A convertible preferred stock and common stock upon merger with Beta Medical, Inc. effective October 1, 2003	—	—	—	—	(11,936)	(119)	(18,315)	(183)	(661,372)	—	—	—	(661,674)
Issuance of Series A convertible preferred stock upon merger of Alpha Medical, Inc. and Beta Medical, Inc. effective October 1, 2003	—	—	—	—	10,989	110	—	—	661,564	—	—	—	661,674
Common stock issued in October 2003 at $0.54 per share for cash	—	—	—	—	—	—	19,229	192	10,308	—	—	—	10,500
Warrants issued for the purchase of 3,919 shares of Series B convertible preferred stock for cash at $0.03 per share in connection with the November 13, 2003 convertible bridge notes	—	—	—	—	—	—	—	—	107	—	—	—	107
Net loss	—	—	—	—	—	—	—	—	—	—	—	(1,900,288)	(1,900,288)
Balance, December 31, 2003	—	$ —	—	$ —	32,081	$ 321	37,544	$ 375	$ 1,833,259	$ —	$ —	$ (2,503,636)	$ (669,681)

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2003	—	$ —	—	$ —	32,081	$ 321	37,544	$ 375	$ 1,833,259	$ —	$ —	$ (2,503,636)	$ (669,681)
Warrants issued for the purchase of 1,081 shares of Series B convertible preferred stock for cash at $0.03 per share in connection with the April 23, 2004 convertible bridge notes	—	—	—	—	—	—	—	—	30	—	—	—	30
Exercise of 20,963 Series A convertible preferred stock warrants on April 23, 2004 for cash at $8.95 per share	—	—	—	—	20,963	209	—	—	187,443	—	—	—	187,652
Warrants issued for the purchase of 733 shares of Series B convertible preferred stock for cash at $0.03 per share in connection with the June 30, 2004 convertible bridge notes	—	—	—	—	—	—	—	—	20	—	—	—	20
Fair value of warrants related to convertible bridge notes	—	—	—	—	—	—	—	—	153,722	—	—	—	153,722
Series B convertible preferred stock issued upon conversion of $1,564,843 of convertible bridge notes and $34,809 of accrued interest payable on July 30, 2004 at $23.66 per share	—	—	67,615	676	—	—	—	—	1,598,976	—	—	—	1,599,652
Series B convertible preferred stock issued on July 30, 2004 for cash at $23.66 per share, net of financing costs of $94,776	—	—	319,128	3,191	—	—	—	—	7,452,034	—	—	—	7,455,225
Warrants issued for the purchase of 7,556 shares of Series B convertible preferred stock on December 1, 2004 valued at $6.45 per warrant for debt commitment	—	—	—	—	—	—	—	—	48,720	—	—	—	48,720
Issuance of 3,819 common stock options to nonemployees in 2004 valued at $0.94 per option	—	—	—	—	—	—	—	—	3,610	(3,610)	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—	—	—	—	830	—	—	830
Net loss	—	—	—	—	—	—	—	—	—	—	—	(3,448,752)	(3,448,752)
Balance, December 31, 2004	—	$ —	386,743	$ 3,867	53,044	$ 530	37,544	$ 375	$11,277,814	$ (2,780)	$ —	$ (5,952,388)	$ 5,327,418

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2004	—	$ —	386,743	$ 3,867	53,044	$ 530	37,544	$ 375	$11,277,814	$ (2,780)	$ —	$ (5,952,388)	$ 5,327,418
Series B convertible preferred stock issued on June 17, 2005 for cash at $23.66 per share, net of financing costs of $5,218	—	—	126,806	1,268	—	—	—	—	2,993,514	—	—	—	2,994,782
Warrants issued for the purchase of 11,624 shares of Series B convertible preferred stock in September 2005 valued at $6.42 per warrant for debt commitment and funding	—	—	—	—	—	—	—	—	74,636	—	—	—	74,636
Warrants issued for the purchase of 28,389 shares of common stock on December 12, 2005 for cash at $0.54 per warrant	—	—	—	—	—	—	—	—	15,500	—	—	—	15,500
Series B convertible preferred stock issued on December 12, 2005 at $23.66 per share, net of financing costs of $11,085	—	—	200,776	2,008	—	—	—	—	4,736,908	—	—	—	4,738,916
Common stock issued to nonemployees in 2005 valued at $2.76 per share	—	—	—	—	—	—	37,546	376	102,124	(102,500)	—	—	—
Issuance of 7,757 common stock options to nonemployees in 2005 valued at $0.94 per option	—	—	—	—	—	—	—	—	7,288	(7,288)	—	—	—
Exercise of 4,927 common stock options in 2005 for cash at $2.76 per share	—	—	—	—	—	—	4,927	49	13,401	—	—	—	13,450
Amortization of deferred compensation	—	—	—	—	—	—	—	—	—	25,041	—	—	25,041
Net loss	—	—	—	—	—	—	—	—	—	—	—	(11,215,191)	(11,215,191)
Balance, December 31, 2005	—	$ —	714,325	$ 7,143	53,044	$ 530	80,017	$ 800	$19,221,185	$ (87,527)	$ —	$ (17,167,579)	$ 1,974,552

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2005	—	$ —	714,325	$ 7,143	53,044	$ 530	80,017	$ 800	$19,221,185	$ (87,527)	$ —	$ (17,167,579)	$ 1,974,552
Warrants issued for the purchase of 5,812 shares of Series B convertible preferred stock in March 2006 valued at $17.55 per warrant for debt funding	—	—	—	—	—	—	—	—	102,022	—	—	—	102,022
Series C convertible preferred stock issued upon conversion of $5,250,003 of convertible bridge notes and $131,013 of accrued interest payable on July 6, 2006 at $48.56 per share	110,820	1,108	—	—	—	—	—	—	5,379,908	—	—	—	5,381,016
Series C convertible preferred stock issued on July 6, 2006 for cash at $48.56 per share, net of financing costs of $2,222,342	820,190	8,202	—	—	—	—	—	—	37,594,459	—	—	—	37,602,661
Warrants issued for the purchase of 24,606 shares of Series C convertible preferred stock on July 6, 2006 valued at $29.89 per warrant for equity financing	—	—	—	—	—	—	—	—	735,438	—	—	—	735,438
Series C convertible preferred stock issued on December 11, 2006 for cash at $48.56 per share	20,595	206	—	—	—	—	—	—	999,794	—	—	—	1,000,000
Series C convertible preferred stock warrants reclassified to convertible preferred stock warrant liability on December 11, 2006	—	—	—	—	—	—	—	—	(735,438)	—	—	—	(735,438)
Common stock issued to nonemployees in 2006 valued at $2.76 per share	—	—	—	—	—	—	1,648	16	4,484	(4,500)	—	—	—
Common stock issued to nonemployees in 2006 valued at $11.46 per share	—	—	—	—	—	—	458	5	5,245	(5,250)	—	—	—
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	47,479	—	—	—	47,479
Nonemployee stock-based compensation expense	—	—	—	—	—	—	—	—	86,125	—	—	—	86,125
Exercise of 14,504 common stock options in 2006 for cash at $2.76 per share	—	—	—	—	—	—	14,504	145	39,451	—	—	—	39,596
Amortization of deferred compensation	—	—	—	—	—	—	—	—	—	30,798	—	—	30,798
Net loss	—	—	—	—	—	—	—	—	—	—	—	(17,690,477)	(17,690,477)
Balance, December 31, 2006	951,605	$ 9,516	714,325	$ 7,143	53,044	$ 530	96,627	$ 966	$63,480,152	$ (66,479)	$ —	$ (34,858,056)	$ 28,573,772

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2006	951,605	$ 9,516	714,325	$ 7,143	53,044	$ 530	96,627	$ 966	$ 63,480,152	$ (66,479)	$ —	$ (34,858,056)	$ 28,573,772
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	883,310	—	—	—	883,310
Nonemployee stock-based compensation expense	—	—	—	—	—	—	—	—	1,289,349	—	—	—	1,289,349
Warrants issued for the purchase of 11,327 shares of Series C convertible preferred stock in May 2007 valued at $48.56 per warrant for debt facility commitment	—	—	—	—	—	—	—	—	550,212	—	—	—	550,212
Warrants issued for the purchase of 5,664 shares of Series C convertible preferred stock in May 2007 valued at $49.67 per warrant for debt funding	—	—	—	—	—	—	—	—	281,321	—	—	—	281,321
Warrants issued for the purchase of 2,832 shares of Series C convertible preferred stock in August 2007 valued at $69.83 per warrant for debt funding	—	—	—	—	—	—	—	—	197,731	—	—	—	197,731
Warrants issued for the purchase of 2,832 shares of Series C convertible preferred stock in October 2007 valued at $68.76 per warrant for debt funding	—	—	—	—	—	—	—	—	194,716	—	—	—	194,716
Series C convertible preferred stock warrants reclassified from convertible preferred stock warrant liability	—	—	—	—	—	—	—	—	1,090,345	—	—	—	1,090,345
Issuance of common stock in initial public offering (IPO) in November 2007 for cash at $48.00 per share, net of financing costs of $4,552,663	—	—	—	—	—	—	833,333	8,333	35,439,004	—	—	—	35,447,337
Conversion of preferred stock to common stock in November 2007 in connection with the IPO	(951,605)	(9,516)	(714,325)	(7,143)	(53,044)	(530)	1,748,030	17,480	(291)	—	—	—	—
Reclassification of amounts due to shareholders for fractional shares upon reverse stock split	—	—	—	—	—	—	—	—	(355)	—	—	—	(355)
Common stock issued to Mayo Foundation upon closing the IPO in November 2007 with a fair value of $48.30 per share	—	—	—	—	—	—	34,341	343	1,658,311	—	—	—	1,658,654
Exercise of over-allotment option by underwriters in December 2007 in connection with the IPO for cash at $48.00 per share, net of financing costs of $274,315	—	—	—	—	—	—	81,642	817	3,643,660	—	—	—	3,644,477
Exercise of 5,854 common stock options in 2007 for cash at $3.60 per share	—	—	—	—	—	—	5,854	59	21,128	—	—	—	21,187
Amortization of deferred compensation	—	—	—	—	—	—	—	—	—	24,812	—	—	24,812
Net loss	—	—	—	—	—	—	—	—	—	—	—	(28,575,348)	(28,575,348)
Balance, December 31, 2007	—	$ —	—	$ —	—	$ —	2,799,827	$ 27,998	$108,728,593	$ (41,667)	$ —	$ (63,433,404)	$ 45,281,520

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2007	—	$ —	—	$ —	—	$ —	2,799,827	$ 27,998	$108,728,593	$ (41,667)	$ —	$ (63,433,404)	$ 45,281,520
Net loss	—	—	—	—	—	—	—	—	—	—	—	(37,874,028)	(37,874,028)
Change in unrealized gain (loss) on available for sale investments	—	—	—	—	—	—	—	—	—	—	12,988	—	12,988
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	2,648,410	—	—	—	2,648,410
Nonemployee stock-based compensation expense	—	—	—	—	—	—	—	—	(147,855)	—	—	—	(147,855)
Warrants issued for the purchase of 233,117 shares of common stock in November 2008 valued at $7.80 per warrant for debt funding	—	—	—	—	—	—	—	—	1,398,702	—	—	—	1,398,702
Exercise of 16,829 common stock options in 2008 for cash from $2.76 to $11.46 per share	—	—	—	—	—	—	16,829	169	65,238	—	—	—	65,407
Amortization of deferred compensation	—	—	—	—	—	—	—	—	—	20,000	—	—	20,000
Balance, December 31, 2008	—	$ —	—	$ —	—	$ —	2,816,656	$ 28,167	$112,693,088	$ (21,667)	$ 12,988	$(101,307,432)	$ 11,405,144

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2008	—	$ —	—	$ —	—	$ —	2,816,656	$ 28,167	$112,693,088	$ (21,667)	$ 12,988	$(101,307,432)	$ 11,405,144
Net loss	—	—	—	—	—	—	—	—	—	—	—	(31,929,200)	(31,929,200)
Change in unrealized gain (loss) on available for sale investments	—	—	—	—	—	—	—	—	—	—	(12,988)	—	(12,988)
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	2,209,216	—	—	—	2,209,216
Nonemployee stock-based compensation expense	—	—	—	—	—	—	—	—	210,075	—	—	—	210,075
Issuance of common stock and warrants to purchase approximately 1,092,533 shares or common stock in private investment public equity offering in February 2009 for cash at an aggregate price of $7.28 per share and corresponding warrant, net of financing costs of $806,499	—	—	—	—	—	—	2,185,066	21,851	15,068,002	—	—	—	15,089,853
Issuance of common stock in registered direct offering in October 2009 for cash at $4.80 per share, net of financing costs of $92,470	—	—	—	—	—	—	1,026,845	10,268	4,826,117	—	—	—	4,836,385
Common stock warrants reclassified to common stock warrant liability on January 1, 2009	—	—	—	—	—	—	—	—	(1,398,702)	—	—	(130,968)	(1,529,670)
Cashless exercise of 159,420 warrants with an exercise price of $6.90 per share in exchange for 125,470 shares of common stock in September 2009	—	—	—	—	—	—	125,470	1,255	4,748,871	—	—	—	4,750,126
Cashless exercise of 104,700 warrants with exercise prices ranging from $6.90 to $23.64 per share in exchange for 62,244 shares of common stock in October 2009	—	—	—	—	—	—	62,244	622	494,030	—	—	—	494,652
Exercise of 13,450 common stock options in 2009 for cash from $2.76 to $22.20 per share	—	—	—	—	—	—	13,450	134	37,383	—	—	—	37,517
Amortization of deferred compensation	—	—	—	—	—	—	—	—	—	20,000	—	—	20,000
Balance, December 31, 2009	—	$ —	—	$ —	—	$ —	6,229,731	$ 62,297	$138,888,080	$ (1,667)	$ —	$(133,367,600)	$ 5,581,110

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2009	—	$ —	—	$ —	—	$ —	6,229,731	$ 62,297	$138,888,080	$ (1,667)	$ —	$(133,367,600)	$ 5,581,110
Net loss	—	—	—	—	—	—	—	—	—	—	—	(17,347,387)	(17,347,387)
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	2,529,355	—	—	—	2,529,355
Nonemployee stock-based compensation expense	—	—	—	—	—	—	—	—	33,204	—	—	—	33,204
Issuance of common stock in registered direct offering in January 2010 for cash at $3.90 per share, net of financing costs of $339,547	—	—	—	—	—	—	1,239,717	12,398	4,482,949	—	—	—	4,495,347
Common stock warrants reclassified to equity from common stock warrant liability on May 18, 2010	—	—	—	—	—	—	—	—	312,751	—	—	—	312,751
Warrants issued for the purchase of 150,642 shares of common stock in July 2010 valued at $1.92 per share for debt modification	—	—	—	—	—	—	—	—	289,257	—	—	—	289,257
Adjustment for fractional shares upon reverse stock split	—	—	—	—	—	—	45	—	—	—	—	—	—
Issuance of Series A convertible preferred stock in September 2010 at $1.72 per share for cash, net of financing costs of $60,679	—	—	—	—	3,394,309	33,943	—	—	5,743,589	—	—	—	5,777,532
Warrants issued for the purchase of 3,394,309 shares of common stock in September 2010 for cash at $0.125 per warrant	—	—	—	—	—	—	—	—	424,289	—	—	—	424,289
Issuance of common stock and warrants to purchase approximately 17,020,000 shares of common stock in public offering in December 2010 for cash at an aggregate price of $1.75 per share and corresponding warrant, net of financing costs of $2,198,865	—	—	—	—	—	—	17,020,000	170,200	27,415,935	—	—	—	27,586,135
Warrants issued for the purchase of 340,400 shares of common stock in December 2010 for $100 cash	—	—	—	—	—	—	—	—	100	—	—	—	100
Conversion of Series A convertible preferred stock to common stock upon closing of the public offering in December 2010	—	—	—	—	(3,394,309)	(33,943)	3,394,309	33,943	—	—	—	—	—
Exercise of 8,586 common stock options in 2010 for cash at $2.76 per share	—	—	—	—	—	—	8,586	86	23,611	—	—	—	23,697
Amortization of deferred compensation	—	—	—	—	—	—	—	—	—	1,667	—	—	1,667
Balance, December 31, 2010	—	$ —	—	$ —	—	$ —	27,892,388	$278,924	$180,143,120	$ —	$ —	$(150,714,987)	$ 29,707,057

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2010	—	$ —	—	$ —	—	$ —	27,892,388	$278,924	$180,143,120	$ —	$ —	$(150,714,987)	$ 29,707,057
Net loss	—	—	—	—	—	—	—	—	—	—	—	(25,997,322)	(25,997,322)
Change in unrealized gain (loss) on available for sale investments	—	—	—	—	—	—	—	—	—	—	692	—	692
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	2,817,082	—	—	—	2,817,082
Nonemployee stock-based compensation expense	—	—	—	—	—	—	—	—	75,614	—	—	—	75,614
Additional financing costs related to December 2010 public offering	—	—	—	—	—	—	—	—	(45,745)	—	—	—	(45,745)
Exercise of 1,139 common stock options in 2011 for cash at $1.90 per share	—	—	—	—	—	—	1,139	11	2,153	—	—	—	2,164
Exercise of 59,219 warrants in 2011 for cash at $2.19 per share	—	—	—	—	—	—	59,219	592	129,097	—	—	—	129,689
Issuance of common stock and warrants to purchase approximately 1,760,000 shares of common stock in registered public offering in September 2011 for cash at an aggregate price of $1.65 per share and corresponding warrant, net of financing costs of $1,168,326	—	—	—	—	—	—	8,800,000	88,000	13,263,674	—	—	—	13,351,674
Balance, December 31, 2011	—	$ —	—	$ —	—	$ —	36,752,746	$367,527	$196,384,995	$ —	$ 692	$(176,712,309)	$ 20,040,905

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

(A development stage company)
Consolidated Statements of Stockholders' Equity (Deficit) (Continued)
Period from December 19, 2002 (inception) to December 31, 2012

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Deferred Compensation	Accumulated Other Comprehensive Income	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount					
Balance, December 31, 2011	—	$ —	—	$ —	—	$ —	36,752,746	$367,527	$196,384,995	$ —	$ 692	$(176,712,309)	$ 20,040,905
Net loss	—	—	—	—	—	—	—	—	—		—	(23,460,103)	(23,460,103)
Change in unrealized gain (loss) on available for sale investments	—	—	—	—	—	—	—	—	—	—	(692)	—	(692)
Employee stock-based compensation expense	—	—	—	—	—	—	—	—	4,173,132	—	—	—	4,173,132
Nonemployee stock-based compensation expense	—	—	—	—	—	—	—	—	52,190	—	—	—	52,190
Issuance of common stock in registered direct offering in April 2012 for cash at $2.22 per share, net of financing costs of $367,871	—	—	—	—	—	—	2,271,705	22,717	4,659,412	—	—	—	4,682,129
Warrants issued for the purchase of 106,746 shares of common stock in April 2012 valued at $2.22 per warrant for debt funding	—	—	—	—	—	—	—	—	237,349	—	—	—	237,349
Exercise of 5,219 common stock options in 2012 for cash from $1.90 to $2.58 per share	—	—	—	—	—	—	5,219	53	12,613	—	—	—	12,666
Exercise of 2,813,600 warrants in 2012 for cash from $1.90 to $2.19 per share	—	—	—	—	—	—	2,813,600	28,136	6,108,959	—	—	—	6,137,095
Balance, December 31, 2012	—	$ —	—	$ —	—	$ —	41,843,270	$418,433	$211,628,650	$ —	$ —	$(200,172,412)	$ 11,874,671

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Consolidated Statements of Cash Flows

	Years ended December 31,			Period from December 19, 2002 (inception) to December 31, 2012
	2012	2011	2010	
Cash flows from operating activities:				
Net loss	$ (23,460,103)	$ (25,997,322)	$ (17,347,387)	$ (200,041,444)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation	226,990	303,972	375,756	2,487,028
Loss on sale of equipment	767	1,269	52,622	74,894
Stock-based compensation	4,225,322	2,892,696	2,564,226	18,688,488
Amortization of commitment fees, debt issuance costs and original issue discount	207,310	234,740	387,861	4,093,933
Amortization of short-term investment premium or discount	4,719	3,261	—	(300,071)
Change in value of warrant liability	—	—	(158,834)	3,840,622
Change in operating assets and liabilities:				
Accounts receivable	(52,406)	—	—	(52,406)
Inventory	(202,584)	(1,068,623)	—	(1,271,207)
Prepaid expenses and other current assets	233,145	(368,261)	47,805	(571,654)
Other assets	(813,063)	(176,985)	(60,348)	(1,050,396)
Accounts payable	(224,562)	367,491	(109,950)	76,578
Accrued expenses	(2,699,761)	3,834,999	460,455	3,673,609
Accrued interest payable	74,857	37,329	123,187	689,500
Net cash used in operating activities	(22,479,369)	(19,935,434)	(13,664,607)	(169,662,526)
Cash flows from investing activities:				
Decrease (increase) in restricted cash	—	6,327,031	(6,527,031)	(200,000)
Purchases of short-term investments available for sale	—	(5,007,980)	—	(19,890,213)
Maturities of short-term investments available for sale	1,000,000	4,000,000	—	19,854,414
Purchases of short-term investments held to maturity	—	—	—	(22,414,130)
Maturities of short-term investments held to maturity	—	—	—	22,750,000
Purchases of property and equipment	(76,394)	(252,274)	(2,592)	(2,907,616)
Net cash provided by (used in) investing activities	923,606	5,066,777	(6,529,623)	(2,807,545)
Cash flows from financing activities:				
Proceeds from stock options exercised	12,666	2,164	23,697	215,684
Proceeds from warrants exercised	6,137,095	129,689	—	6,454,436
Proceeds from sale of common stock and warrants for purchase of common stock	5,050,000	14,520,000	35,044,283	119,404,439
Common stock financing costs	(367,871)	(1,214,071)	(2,538,412)	(9,846,301)
Payment to shareholders for fractional shares upon reverse stock split	—	—	—	(355)
Proceeds from sale of Series A, B and C convertible preferred stock	—	—	5,838,211	63,766,564
Series A, B and C convertible preferred stock financing costs	—	—	(60,679)	(1,658,662)
Proceeds from notes payable and convertible notes payable	5,347,807	—	—	47,993,774
Repayments on notes payable	(752,841)	(921,997)	(1,889,904)	(31,178,928)
Debt issuance costs	(50,000)	—	—	(371,799)
Net cash provided by financing activities	15,376,856	12,515,785	36,417,196	194,778,852
Net (decrease) increase in cash and cash equivalents	(6,178,907)	(2,352,872)	16,222,966	22,308,781
Cash and cash equivalents:				
Beginning of period	28,487,688	30,840,560	14,617,594	—
End of period	$ 22,308,781	$ 28,487,688	$ 30,840,560	$ 22,308,781
Supplemental disclosure:				
Interest paid	$ 619,668	$ 450,751	$ 738,794	$ 7,672,568
Noncash investing and financing activities:				
Cancellation of Alpha Medical, Inc. Series A convertible preferred stock and common stock	$ —	$ —	$ —	$ (661,674)
Issuance of Beta Medical, Inc. Series A convertible preferred stock in exchange for Alpha Medical, Inc. Series A convertible preferred stock and common stock	—	—	—	661,674
Value of warrants issued with debt and for debt commitment	237,349	—	289,257	4,070,532
Value of warrants issued with sale of common and preferred stock offerings	—	—	794,869	1,684,832
Cashless exercise of warrants	—	—	—	5,244,778
Conversion of notes and interest payable to Series B and C convertible preferred shares	—	—	—	6,980,668
Options issued for deferred compensation	—	—	—	10,898
Common stock issued to Mayo Foundation and for deferred compensation	—	—	—	1,770,904
Reclassification of warrant liability	—	—	312,751	2,932,766
Conversion of convertible preferred stock to common stock	—	—	33,943	51,132

See accompanying notes to consolidated financial statements.

EnteroMedics Inc.
(A development stage company)

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 is in the development stage, as defined by the Accounting Standards Codification. Since inception the Company has devoted substantially all of its resources to recruiting personnel, developing its product technology, obtaining patents to protect its intellectual property and raising capital, and only recently has derived revenues from its primary business activity. 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.

In November 2007, the Company completed its initial public offering of common stock (IPO), issuing a total of 914,975 shares for net proceeds of approximately $39.1 million after expenses and underwriters' discounts and commissions, and including the exercise of the underwriters' over-allotment option.

Since inception, EnteroMedics has incurred losses through December 31, 2012 totaling approximately $200.0 million 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. See Notes 7 and 8 for additional discussion of financing activities.

(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.

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.

EnteroMedics Inc.
(A development stage company)

Notes to Consolidated Financial Statements (Continued)

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, cash equivalents and restricted cash. Cash, cash equivalents and restricted cash 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, cash equivalents or restricted cash.

Most of the products developed by the Company will require approval from the U.S. Food and Drug Administration (FDA) or corresponding foreign regulatory agencies prior to commercial sales. There can be no assurance the Company's products will receive the necessary approvals. If the Company is denied approval or approval is delayed, it will have a material adverse impact on the Company.

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.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. The fair values of investments in debt and equity securities are disclosed in Note 3. The fair value of the Company's long-term debt is approximately $10.0 million as of December 31, 2012 based on the present value of estimated future cash flows using a discount rate commensurate with borrowing rates available to the Company. If measured at fair value in the consolidated financial statements, long-term debt (including the current portion) would be classified as Level 2 in the fair value hierarchy.

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. Under terms of the Company's notes payable agreements (see Note 7), in the event of default, the lender has the right to enforce account control agreements and restrict the Company's access to their cash and investment accounts.

Restricted Cash

The Company had $200,000 in a cash collateral money market account as of December 31, 2012 and 2011. 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 standby letter of credit is to be maintained through October 1, 2013. 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.

EnteroMedics Inc.
(A development stage company)

Notes to Consolidated Financial Statements (Continued)

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 (deficit) 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 three to seven years. 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 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

EnteroMedics Inc.
(A development stage company)

Notes to Consolidated Financial Statements (Continued)

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, 2012 and 2011 (see Note 10). The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the consolidated statements of operations.

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. The difference from reported net loss for the years ended December 31, 2012 and 2011 related entirely to changes in unrealized gains (losses) on available-for-sale investments. There was no difference from reported net loss for the year ended December 31, 2010.

Revenue Recognition

The Company recognizes revenue 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. The Company sells products internationally through distributors and recognizes revenue upon sale to the distributor as these sales are considered to be final and 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. The Company does not provide for rights of return to customers on product sales and therefore does not record a provision for returns.

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, 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 $278,987, $271,105 and $306,181 for the years ended December 31, 2012, 2011 and 2010, respectively, and $2,443,269 for the period from December 19, 2002 (inception) to December 31, 2012.

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.

Effective January 1, 2009, the Company adopted new authoritative accounting guidance regarding the financial reporting for outstanding equity-linked financial instruments. As a result of this change in accounting

EnteroMedics Inc.
(A development stage company)

Notes to Consolidated Financial Statements (Continued)

guidance, the Company assessed any outstanding equity-linked financial instruments and concluded that warrants issued in November 2008 with a recorded value of $1.4 million on December 31, 2008 were to be reclassified from equity to a liability. The cumulative effect of the change in accounting principle on January 1, 2009 was a $130,968 increase to the deficit accumulated during development stage. See Note 7 for details.

Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for stock-based employee compensation using the intrinsic value method and recognized the expense over the option vesting period. The intrinsic value method is calculated as the difference, if any, between the fair value of the Company's stock and the exercise price on the date of the grant. The Company also followed the minimum value disclosure provisions.

Effective January 1, 2006, the Company adopted the fair value method of accounting for share-based payments, which superseded the previous accounting method, and 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. The Company adopted the new provisions using the prospective transition method, which requires that for nonpublic entities that used the minimum value method for either pro forma or financial statement recognition purposes, to apply the new accounting provisions only to option grants or modifications to existing options that occur after the required effective date. For options granted prior to January 1, 2006, the Company has continued to apply the intrinsic value provisions on any remaining unvested awards. All option grants valued after January 1, 2006 are expensed on a straight-line basis over the vesting period.

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.

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, unvested common shares subject to repurchase 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.

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The following table sets forth the computation of basic and diluted net loss per share for the years ended December 31, 2012, 2011 and 2010:

	Years ended December 31,		
	2012	2011	2010
Numerator:			
Net loss	$ (23,460,103)	$ (25,997,322)	$ (17,347,387)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares outstanding	39,536,500	30,205,447	8,419,575
Weighted-average unvested common shares subject to repurchase	—	—	—
Denominator for net loss per common share—basic and diluted	39,536,500	30,205,447	8,419,575
Net loss per share—basic and diluted	$ (0.59)	$ (0.86)	$ (2.06)

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,		
	2012	2011	2010
Stock options outstanding	7,835,533	3,470,908	812,515
Warrants to purchase common stock	21,216,447	23,923,301	22,224,718

Recently Issued Accounting Standards

In June 2011, the Financial Accounting Standards Board issued guidance on the presentation of comprehensive income in financial statements. Entities are required to present total comprehensive income either in a single, continuous statement of comprehensive income, or in two separate, but consecutive, statements. The Company adopted this standard during the first quarter of 2012 and presents net loss and other comprehensive loss in two separate, but consecutive, statements. The adoption of this standard did not have a material effect on the Company's financial statement disclosures.

There have been no other significant changes in recent accounting pronouncements during the year ended December 31, 2012.

(3) 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.

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Notes to Consolidated Financial Statements (Continued)

- Level 2—Quoted prices for similar assets and liabilities, 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 include U.S. treasury securities. 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 as of December 31, 2012 and did not hold any short-term investments classified as held to maturity as of December 31, 2012 and 2011.

The following table sets forth by level, within the fair value hierarchy, the Company's financial assets accounted for at fair value as of December 31, 2011. Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

All short-term investments at December 31, 2011 were classified as available for sale and as Level 2 as follows:

	Significant Other Observable Inputs Level 2
U.S. agency securities	$ 1,005,411
Total	$ 1,005,411

The amortized cost and fair value of short-term investments available for sale, and the related gross unrealized gains and losses, were as follows at December 31, 2011:

		Gross Unrealized		
	Cost	Gains	Losses	Fair value
U.S. agency securities	$1,004,719	$ 692	$ —	$1,005,411
Total	$1,004,719	$ 692	$ —	$1,005,411

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Notes to Consolidated Financial Statements (Continued)

(4) Inventory

From inception until December 2011, 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 (TGA), 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 $862,000 and $228,000 of long-term inventory, primarily consisting of raw materials, as of December 31, 2012 and 2011, respectively.

Current inventory consists of the following as of:

	December 31,	
	2012	2011
Raw materials	$ 198,647	$ 376,580
Work-in-process	1,051,286	692,043
Finished goods	21,274	—
Inventory	$ 1,271,207	$ 1,068,623

(5) Property and Equipment

Property and equipment consist of the following as of:

	December 31,	
	2012	2011
Furniture and equipment	$ 2,143,025	$ 1,996,462
Computer hardware and software	489,478	474,236
Leasehold improvements	46,754	32,258
	2,679,257	2,502,956
Less accumulated depreciation and amortization	(2,069,585)	(1,872,602)
Property and equipment, net	$ 609,672	$ 630,354

(6) Accrued Expenses

Accrued expenses consist of the following as of:

	December 31,	
	2012	2011
Professional service related expenses	$ 2,229,057	$ 4,898,360
Payroll related expenses	1,099,713	1,169,941
Other expenses	344,839	305,069
Accrued expenses	$ 3,673,609	$ 6,373,370

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Notes to Consolidated Financial Statements (Continued)

(7) Notes Payable

Notes payable consists of the following as of:

	December 31, 2012	December 31, 2011
Growth capital loan dated April 16, 2012 (net discount of $316,028 at December 31, 2012)	$ 9,683,972	$ —
Growth capital loan dated November 18, 2008 (net discount of $216,711 at December 31, 2011)	—	5,188,323
Less current portion	(3,000,000)	(2,307,162)
Total long-term debt	$ 6,683,972	$ 2,881,161

November 18, 2008 Debt Facility with Silicon Valley Bank, Venture Lending & Leasing V, Inc. and Compass Horizon Funding Company LLC

On November 18, 2008, the Company entered into a Loan and Security Agreement (the Prior Loan Agreement) with Silicon Valley Bank (SVB), Venture Lending & Leasing V, Inc. (a private equity fund under the management of Western Technology Investment (WTI)) and Compass Horizon Funding Company LLC (Horizon and, collectively with SVB and WTI, the Lenders), in an aggregate principal amount of up to $20.0 million. On November 21, 2008, SVB and WTI each funded a term loan in the aggregate principal amount of $10.0 million and $5.0 million, respectively. The additional $5.0 million term loan was automatically funded by Horizon on April 28, 2009 when the trading price of the Company's common stock on the NASDAQ Global Market exceeded a target amount specified in the Prior Loan Agreement.

Interest-only payments were required on the term loans during a period beginning on the term loan funding date and continuing through June 30, 2009, followed thereafter by equal monthly payments of principal and interest over the remaining term of the term loan. Amounts borrowed under the Prior Loan Agreement had an annual interest rate equal to 12.0% during the period of interest-only payments, and thereafter, at a rate of 11.0% per annum for the remainder of the term. Per the Prior Loan Agreement, the Company was also required to make a final payment in an aggregate amount equal to 5.0% of the term loans funded by the Lenders (the Final Payment Fee).

The debt financing was collateralized by a first security priority lien on all of the Company's assets, excluding intellectual property. The Company entered into account control agreements in order to perfect the Lenders' first security interest in the Company's cash and investment accounts.

On December 1, 2009, the Company voluntarily prepaid both the WTI and Horizon term loans in full. Both WTI and Horizon released their right to future interest when the term loans were paid in full.

During 2010 and 2011, the Company and SVB entered into four amendments to the Prior Loan Agreement, which modified the payment terms, annual interest rate and financial covenants. A brief summary of the four amendments is provided below.

On February 8, 2010, the Company and SVB entered into the First Amendment to the Prior Loan Agreement, which reduced the annual interest rate from 11.0% to a fixed annual rate of 10.0%, payable monthly, revised the liquidity financial covenant and added a New Capital Transaction covenant.

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Notes to Consolidated Financial Statements (Continued)

On July 8, 2010, the Company and SVB entered into a Second Amendment to the Prior Loan Agreement, which modified the repayment terms of the loan such that interest only payments were required through December 31, 2010 followed by 30 equal payments of principal and interest, increased the annual interest rate from 10.0% to a fixed annual rate of 11.0%, payable monthly, revised the liquidity financial covenant and added additional New Capital Transaction requirements.

On November 4, 2010, the Company and SVB entered into a Third Amendment (the Third Amendment) to the Prior Loan Agreement, which modified the New Capital Transaction covenant, suspended the liquidity financial covenant and required the Company to maintain a blocked cash collateral account with funds equal to the principal balance outstanding.

On March 3, 2011, the Company entered into a Fourth Amendment (the Fourth Amendment) to the Prior Loan Agreement with SVB. The Fourth Amendment modified the repayment terms of the term loan such that beginning April 1, 2011 through September 30, 2011, the Company was required to make interest only monthly payments on the term loan. Then, beginning on October 1, 2011, the remaining balance due on the term loan started to amortize over 30 equal payments of principal and interest, payable monthly. In addition, the Fourth Amendment amended the interest rate due effective March 1, 2011 on the remaining principal amount of the term loan from 11.0% to a fixed annual rate of 6.25%, payable monthly. The Fourth Amendment reinstated the liquidity financial covenant and eliminated SVB's springing lien on the Company's intellectual property, the New Capital Transactions requirement and the requirement of the Third Amendment to maintain a blocked cash collateral account with funds equal to the principal balance outstanding.

Warrants Issued

The Prior Loan Agreement required the issuance of warrants to the Lenders with an aggregate exercise price equal to 11.0% of the loan commitment. The warrants give the Lenders the option to purchase either (i) shares of the Company's common stock with a per share exercise price equal to $9.51, or (ii) shares of the Company's stock (including common stock) issued in an equity financing that occurred within 18 months after November 18, 2008 at the per share price of the stock sold in the financing. On November 18, 2008 (i) SVB was issued a warrant to purchase an aggregate number of shares equal to $1,100,000 divided by the per share exercise price of the warrant, (ii) WTI was issued a warrant to purchase an aggregate number of shares equal to $550,000 divided by the per share exercise price of the warrant, and (iii) Horizon received a warrant to purchase an aggregate number of shares equal to $55,000 divided by the per share exercise price of the warrant. On April 28, 2009 Horizon was issued an additional warrant to purchase an aggregate number of shares equal to $495,000 divided by the per share exercise price of the warrant in connection with the additional $5.0 million term loan that was automatically funded by Horizon pursuant to the Prior Loan Agreement.

On November 18, 2008, the Company issued a total of 179,328 common stock warrants with an exercise price of $9.51 per share and a ten year life to the Lenders, or a calculated fair value of $1.4 million. This fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 78.9%, dividend rate of 0%, risk-free interest rate of 3.54% and a ten year life. The exercise price of the common stock warrants issued on November 18, 2008 was adjusted to $6.90, the price per share sold in an equity financing that closed on February 24, 2009, resulting in an additional 67,773 common stock warrants for the Lenders. On April 28, 2009, the Company issued a total of 49,460 common stock warrants with an exercise price of $10.01 per share and a ten year life to Horizon, or a calculated fair value of $542,144. This fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 99.1%, dividend rate of 0%, risk-free interest rate of 3.00% and a ten year life. The exercise price of the common stock warrants issued to Horizon on both November 18, 2008 and April 28, 2009 was further adjusted to $4.80, the price per share sold in

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Notes to Consolidated Financial Statements (Continued)

an equity financing that closed October 7, 2009, resulting in an additional 57,152 common stock warrants for Horizon. The exercise price of Horizon's outstanding common stock warrants was further adjusted to $3.90, the price per share sold in an equity financing that closed January 20, 2010 (see Note 8), resulting in an additional 26,442 common stock warrants for Horizon.

As discussed in Note 2, effective January 1, 2009, as a result of a change in accounting guidance, the Company revalued the warrants issued in November 2008 and reclassified them from equity to a liability. The fair value of the warrant liability on January 1, 2009 was $1.5 million and the change in fair value was recorded as an increase to the deficit accumulated during development stage. This fair value was calculated using a weighted-average Black-Scholes valuation model and the following assumptions: volatility of 79.6%, dividend rate of 0%, risk-free interest rate of 2.24% and a remaining life of 9.88 years.

As of December 31, 2009, Horizon had outstanding 114,583 common stock warrants with an exercise price of $4.80 per share. The fair value of the warrant liability associated with these warrants was $471,585 as of December 31, 2009. This fair value was calculated using a weighted-average Black-Scholes valuation model and the following assumptions: volatility between 103.9% and 104.8%, dividend rate of 0%, risk-free interest rate of 3.84% and a remaining life between 8.89 and 9.33 years. The Company recorded a decrease of $119,904 in the change in value of the warrant liability for the year ended December 31, 2009 for this portion of the warrant liability.

As of December 31, 2010, Horizon had outstanding 141,025 common stock warrants with an exercise price of $3.90 per share. The fair value of the warrant liability associated with these warrants was $312,751 as of May 18, 2010, the date on which the warrants' down round protection expired. This Level 3 fair value was calculated using a weighted-average Black-Scholes valuation model and the following assumptions: volatility between 113.25% and 113.33%, dividend rate of 0%, risk-free interest rate of 3.38% and a remaining life between 8.51 and 8.95 years. As a result of the down round protection expiring, on May 18, 2010 the Company recorded a decrease of $158,834 in the change in value of the warrant liability for the year ended December 31, 2010 and reclassified the warrant liability to equity.

On July 8, 2010, per the terms of the Second Amendment to the Prior Loan Agreement, SVB was issued a warrant to purchase 150,642 shares of the Company's common stock with an exercise price of $2.10 per share.

Warrants Exercised

On September 29, 2009, SVB completed a cashless exercise of the warrants issued to them as part of the Prior Loan Agreement. SVB held a total of 159,420 common stock warrants with an exercise price of $6.90 per share. The cashless exercise of the warrants resulted in the Company issuing 125,470 shares of its common stock. The fair value of the warrant liability on the date of exercise was $4.8 million. This fair value was calculated using a weighted-average Black-Scholes valuation model and the following assumptions: volatility of 108.0%, dividend rate of 0%, risk-free interest rate of 3.29% and a remaining life of 9.14 years. As a result of the warrants being exercised, the warrant liability was reclassified to equity with $3.8 million being recorded as a change in value of the warrant liability for the year ended December 31, 2009.

On October 2, 2009, WTI completed a cashless exercise of the warrants issued to them as part of the Prior Loan Agreement entered into on November 18, 2008. WTI held a total of 79,710 common stock warrants with an exercise price of $6.90 per share. The cashless exercise of the warrants resulted in the Company issuing 59,248 shares of its common stock. The fair value of the warrant liability on the date of exercise was $494,652. This fair value was calculated using a weighted-average Black-Scholes valuation model and the following assumptions:

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Notes to Consolidated Financial Statements (Continued)

volatility of 108.0%, dividend rate of 0%, risk-free interest rate of 3.22% and a remaining life of 9.13 years. As a result of the warrants being exercised, the warrant liability was reclassified to equity with $1,210 being recorded as a change in value of the warrant liability for the year ended December 31, 2009. WTI also completed a cashless exercise of an additional 24,990 common stock warrants with an exercise price of $23.64 per share. The cashless exercise of the warrants resulted in the Company issuing 2,996 shares of its common stock. These warrants were not included as part of the warrant liability.

April 16, 2012 Debt Facility with Silicon Valley Bank

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

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 the outstanding debt of approximately $4.7 million. The term loan requires 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 Final Payment Fee from the Prior Loan Agreement will be due on September 1, 2015. The Company may voluntarily prepay the term loan in full, but not in part, and any voluntary or mandatory prepayment is subject to applicable prepayment premiums and will also include the final payment fee. The Company is required to comply with certain financial covenants that require the Company to generate certain minimum amounts of revenue from the sale of its Maestro System and to implant certain minimum numbers of Maestro Systems during cumulative quarterly measurement periods beginning with the period ended March 31, 2013 and ending with the period ending June 30, 2015. If the Company fails to meet the financial covenants, the term loan will be in default. The Company does not anticipate that it will be able to meet the financial covenants for the period ending March 31, 2013.

The Company has 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 has entered into a negative pledge arrangement with SVB pursuant to which it has agreed not to encumber any of its intellectual property without SVB’s prior written consent. Pursuant to the Loan Agreement, SVB has the right 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. To date, SVB has not exercised this right.

Pursuant to the Loan Agreement, on April 16, 2012, the Company issued SVB a warrant to purchase 106,746 shares of common stock, exercisable for ten years from the date of grant, at an exercise price of $2.34 per share.

The Company was in compliance with all financial covenants related to the Loan Agreement.

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Scheduled debt principal payments are as follows as of December 31, 2012:

Years Ending December 31:	
2013	$ 3,000,000
2014	4,000,000
2015	3,000,000
	10,000,000
Less original issue discount	(316,028)
Notes payable, net	$ 9,683,972

(8) Stock Sales

Registered Direct Offering—January 2010

On January 14, 2010, the Company entered into a securities purchase agreement with certain institutional investors for the sale of 1,239,717 shares of its common stock in a registered direct offering, at a purchase price of $3.90 per share. On January 20, 2010, the offering closed and the Company received gross proceeds of $4.8 million before deducting offering expenses.

Private Placement—September 2010

On September 29, 2010, the Company entered into securities purchase agreements with several accredited investors, including certain directors and officers of the Company (see Note 13), for the sale of 3,394,309 shares of its Series A Non-Voting Convertible Preferred Stock (Preferred Stock) and 3,394,309 common stock warrants (Up Front Warrants) in a private placement transaction (the Private Placement), at a purchase price of $1.72 per share and $0.125 per warrant, respectively. On September 30, 2010, the Private Placement closed and the Company received gross proceeds of $6.3 million before deducting offering expenses.

The Up Front Warrants purchased have an exercise price per share of $2.15, or 125% of the original purchase price of the Preferred Stock and became exercisable on March 29, 2011.

On December 14, 2010, immediately following the completion of the public offering discussed below, all of the Company's outstanding Series A Non-Voting Convertible Preferred Stock automatically converted on a 1:1 basis into 3,394,309 shares of common stock in accordance with its terms.

Public Offering—December 2010

On December 14, 2010, the Company closed a public offering, selling 17,020,000 shares of common stock together with warrants to purchase an additional 17,020,000 shares of common stock at an aggregate price of $1.75 per share and corresponding warrant, for gross proceeds of $29.8 million before deducting offering expenses. This includes the full exercise of the over-allotment option by Craig-Hallum Capital Group LLC (the Underwriter) of 2,220,000 shares of common stock together with warrants to purchase 2,220,000 shares of common stock. Certain directors and officers of the Company participated in the public offering (see Note 13). The warrants have an exercise price of $2.19 per share of common stock and became exercisable on June 13, 2011.

Pursuant to the terms of the Underwriting Agreement, the Company issued a warrant to purchase 340,400 shares of the Company's common stock at an exercise price of $2.19 per share to the Underwriter (the Underwriter Warrant). The Underwriter purchased the Underwriter Warrant from the Company for $100 as

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partial compensation for its services as underwriter to the Company in connection with the Company's public offering. The Underwriter Warrant became exercisable on June 13, 2011 and the exercise period will end five years from December 8, 2010, the date of effectiveness of the Registration Statement. The Underwriter Warrant does not allow for cashless exercise. The fair value of the Underwriter Warrant on the date of issuance was $794,869. This fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility 126.3%, dividend rate of 0%, risk-free interest rate of 2.08% and a five year life.

Public Offering—September 2011

On September 28, 2011, the Company closed a public offering, selling 8,800,000 shares of common stock, together with warrants to purchase approximately 1,760,000 shares of common stock at an aggregate price of $1.65 per share and corresponding warrant, for gross proceeds of $14.5 million before deducting offering expenses. Certain directors of the Company participated in the public offering (see Note 13).

The warrants have an exercise price of $1.90 per share of common stock and are exercisable for a period of five years from September 28, 2011. 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. The warrants may be redeemed in whole or in part at the option of the Company, at a redemption price of $0.01 per warrant at any time after any date on which the closing sale price of the common stock, as reported on the principal exchange or trading facility on which it is then traded, has equaled or exceeded $1.00 more than the exercise price of the warrants for 10 consecutive trading days. The Company is required to provide 30 days' prior written notice to the warrantholder of the Company's intention to redeem the warrant; provided, that the Company may not provide this notice until the earlier of (i) 30 days following the date the Company initially releases the results of the blinded portion of the ReCharge trial or (ii) June 30, 2013. The Company may not redeem any portion of a warrant if, had the holder exercised that portion of the warrant in lieu of redemption, it would have resulted in such holder owning more than 19.99% of the common stock outstanding after such exercise.

Registered Direct Offering—April 2012

On April 16, 2012, the Company entered into a securities purchase agreement with a current investor for the sale of 2,271,705 shares of its common stock in a registered direct offering, at a purchase price of $2.223 per share. On April 20, 2012, the offering closed and the Company received gross proceeds of $5.0 million before deducting estimated offering expenses.

Common Stock Purchase Agreement—October 2012

On October 4, 2012, the Company entered into a Common Stock Purchase Agreement (the Purchase Agreement) with Terrapin Opportunity, L.P. (Terrapin) pursuant to which the Company may sell up to the lesser of $45.0 million of its common stock or 8,312,122 shares of its common stock over an approximately 24-month period pursuant to the terms of the Purchase Agreement. The Company is not obligated to utilize any portion of the facility and generally remains free to enter into and consummate other equity and debt financing transactions.

The Company will determine, at its sole discretion, the timing, the dollar amount and the price per share of each draw under this facility, subject to certain conditions. When and if the Company elects to utilize the facility by delivery of a draw down notice to Terrapin, the Company will issue shares to Terrapin at a discount ranging from 4.00% to 6.80% to the volume weighted average price of the Company's common stock over a preceding

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period of trading days (a Draw Down Period). The Purchase Agreement also provides that from time to time, at the Company's sole discretion, it may grant Terrapin an option to purchase additional shares of the Company's common stock during each Draw Down Period for an amount of shares specified by the Company based on the trading price of its common stock. Upon Terrapin's exercise of such an option, the Company will sell to Terrapin the shares subject to the option at a price equal to the greater of (i) the daily volume weighted average price of the Company's common stock on the day Terrapin notifies the Company of its election to exercise its option or (ii) the threshold price for the option determined by the Company, in each case less a discount ranging from 4.00% to 6.80%.

Terrapin is not required to purchase any shares at a pre-discounted purchase price below $1.25 per share, or any shares that would cause it to hold over 9.9% of the Company's common stock. Any shares sold under this facility will be sold pursuant to a shelf registration statement declared effective by the U.S. Securities and Exchange Commission on August 29, 2012. Subject to earlier termination under certain conditions, the Purchase Agreement will terminate on November 1, 2014.

No shares of common stock have been sold under the Purchase Agreement as of December 31, 2012.

On February 27, 2013, the Company completed an additional equity financing transaction (see Note 17).

(9) Convertible Preferred Stock

The Company's Amended and Restated Certificate of Incorporation, currently authorizes 5,000,000 shares of $0.01 par value convertible preferred stock. As of December 31, 2012 and 2011, there were no shares of convertible preferred stock issued or outstanding as all shares of Series A, Series B and Series C convertible preferred stock converted into shares of common stock upon completion of the Company's IPO utilizing the quotient obtained by dividing the original purchase price per share of $6.5593, $3.9430 and $8.0926 by $4.2379, $3.9430 and $8.0926 per share, respectively, and all shares of Series A convertible preferred stock issued with the September 29, 2010 private placement converted to common stock on a 1:1 basis upon the December 14, 2010 closing of the Company's public offering (see Note 8).

(10) 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:

	2012	2011	2010
Computed 'expected' tax benefit	34.0%	34.0%	34.0%
Other permanent adjustments	-2.2%	-1.8%	-3.8%
Research and development credit	0.0%	1.6%	1.2%
Federal valuation allowance	-31.8%	-33.8%	-31.4%
	0.0%	0.0%	0.0%

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

	2012	2011
Deferred tax assets (liabilities):		
Start-up costs	$ 10,367,000	$ 10,751,000
Capitalized research and development costs	23,658,000	13,201,000
Reserves and accruals	3,447,000	2,299,000
Property and equipment	143,000	23,000
Research and development credit	486,000	462,000
Net operating loss carryforwards	9,185,000	5,127,000
Total gross deferred tax assets	47,286,000	31,863,000
Valuation allowance	(47,286,000)	(31,863,000)
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 described below).

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, 2012 and 2011.

As of December 31, 2012, the Company has generated U.S. federal net operating loss carryforwards of approximately $70.6 million. Of this amount, approximately $22.5 million is available after the application of Section 382 limitations described below. 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 2032.

The 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 the Company's built-in items of deduction, including capitalized start-up costs and research and development costs. During 2011, the Company 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. The Company's 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. The Section 382 limitation and accompanying recognized built-in loss limitation is currently estimated to result in the expiration of $48.1 million of the Company's gross federal net operating loss carryforward, as well as a write-off of $5.9 million of capitalized start-up costs, $14.2 million of capitalized research and development costs, $1.5 million of property and equipment and $2.4 million of research and development credits.

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As of December 31, 2012 and 2011, 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.

The Company is subject to federal examinations for the years 2009 forward. There are no tax examinations currently in progress.

(11) 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, 2012 and 2011, according to the Plan, 12,300,000 and 4,300,000 shares, respectively, 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.

On September 27, 2012, a special meeting of stockholders was held and the stockholders approved the Amended and Restated 2003 Stock Incentive Plan which (i) authorized an additional 8,000,000 shares for issuance under the Plan, (ii) extended the term of the Plan to September 27, 2022, (iii) gave the Compensation Committee the flexibility to cash out outstanding awards without participant consent in connection with a corporate transaction, (iv) modernized the provisions of the Plan with respect to Section 162(m) and Section 409A of the IRC of 1986, as amended and (v) made certain other clarification and administrative changes.

On May 5, 2011, the annual meeting of stockholders was held and the stockholders approved an amendment to the Plan to increase the number of shares authorized under the plan by 2,000,000.

On October 29, 2010, a special meeting of stockholders was held and the stockholders approved amendments to the Plan to (i) increase the number of shares authorized under the plan by 1,149,817 and (ii) allow for a one-time stock option exchange program.

The stock option exchange program was an offer by the Company to all of its employees (including executive officers) to exchange some or all of their outstanding options to purchase the Company's common stock for fewer new options with exercise prices equal to the closing price per share of the Company's common stock on the NASDAQ Capital Market on the date of grant (the Offer). A stock option was eligible for exchange if: (i) it had an exercise price of greater than $6.00 per share; (ii) it was not granted in connection with the performance of consulting services for the Company; (iii) it was held by an employee of the Company who was

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eligible to participate in the Offer; and (iv) it remained outstanding (i.e. unexpired and unexercised) as of the date of grant of the new options (such options are referred to herein as Eligible Options). There were 481,288 Eligible Options and on October 29, 2010, the Offer expired with a total of 481,288 shares of common stock underlying Eligible Options being validly tendered and not withdrawn. The Company granted new options to purchase 384,629 shares of the Company's common stock in exchange for the cancellation of the tendered Eligible Options. The exercise price of the new stock options is $1.90 and the new options vest such that one-third of the shares underlying the option were immediately vested on the date of grant and the remaining shares vested monthly for 24 months. Each new option is a non-qualified stock option for U.S. federal income tax purposes and has a term of seven years from the date of grant.

The Eligible Options were exchanged using the below exchange ratios, which were designed to result in the fair value of the new options being approximately equal in the aggregate to the fair value of the Eligible Options that were tendered for cancellation in the exchange offer.

If the Per Share Price of the Eligible Option was	The Exchange Ratio was (Eligible Option to New Option)
$6.00 to $9.99	1.03 to 1.00
$10.00 to $19.99	1.10 to 1.00
$20.00 to $29.99	1.20 to 1.00
$30.00 to $39.99	1.26 to 1.00
$40.00 and up	1.37 to 1.00

The exchange of options pursuant to the option exchange program is characterized as a modification of the existing option awards in accordance with the fair value method of accounting for share-based payments. However, no additional expense will be recognized as the modification was value neutral. To be value neutral, the fair value of the stock options tendered as calculated immediately prior to their tender must be at least equal to the fair value of the stock options received by employees in the option exchange program. Any previously unrecognized compensation expense from the tendered stock options and incremental compensation costs associated with the new stock options received in the option exchange program will be recognized over the appropriate vesting period.

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Stock option activity is as follows:

	Shares Available For Grant	Outstanding Options		
		Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Shares reserved at Plan inception	7,143	—	$ —	
Balance, December 31, 2003	7,143	—	—	
Shares reserved	73,260	—	—	
Options granted	(57,466)	57,466	2.76	
Options exercised	—	—	—	
Options cancelled	641	(641)	2.76	
Balance, December 31, 2004	23,578	56,825	2.76	
Shares reserved	113,148	—	—	
Options granted	(84,028)	84,028	2.76	
Options exercised	—	(4,926)	2.76	
Options cancelled	7,209	(7,209)	2.76	
Balance, December 31, 2005	59,907	128,718	2.76	
Shares reserved	94,449	—	—	
Options granted	(113,277)	113,277	6.90	
Options exercised	—	(14,498)	2.76	
Options cancelled	17,237	(17,237)	2.76	
Balance, December 31, 2006	58,316	210,260	5.00	
Shares reserved	362,183	—	—	
Options granted	(176,098)	176,098	45.78	
Options exercised	—	(5,851)	3.65	
Options cancelled	30,416	(30,416)	74.71	
Balance, December 31, 2007	274,817	350,091	19.48	
Shares reserved	—	—	—	
Options granted	(221,838)	221,838	45.56	
Options exercised	—	(16,820)	3.89	
Options cancelled	89,019	(89,019)	38.69	
Balance, December 31, 2008	141,998	466,090	28.79	
Shares reserved	500,000	—	—	
Options granted	(692,645)	692,645	14.68	
Options exercised	—	(13,437)	2.79	
Options cancelled	149,736	(149,736)	31.20	
Balance, December 31, 2009	99,089	995,562	18.96	
Shares reserved	1,149,817	—	—	
Options granted	(423,789)	423,789	1.96	
Options exercised	—	(8,592)	2.76	
Options cancelled	598,244	(598,244)	25.29	
Balance, December 31, 2010	1,423,361	812,515	5.60	
Shares reserved	2,000,000	—	—	
Options granted	(2,716,464)	2,716,464	2.44	
Options exercised	—	(1,139)	1.90	
Options cancelled	56,932	(56,932)	3.21	
Balance, December 31, 2011	763,829	3,470,908	3.17	$ —
Shares reserved	8,000,000	—	—	
Options granted	(4,462,873)	4,462,873	3.35	
Options exercised	—	(5,219)	2.43	
Options cancelled	93,029	(93,029)	2.79	
Balance, December 31, 2012	4,393,985	7,835,533	$ 3.28	$1,359,840

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The options outstanding, vested and currently exercisable by exercise price at December 31, 2012:

	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 $2.00	1,038,826	7.4	$ 934,943	550,576	$ 1.90	$495,518
$2.01 to $3.00	2,265,026	8.0	424,897	1,009,550	2.63	168,963
$3.01 to $5.00	4,413,799	9.6	—	610,490	3.49	—
$5.01 to $10.00	4,166	6.1	—	4,166	8.40	—
> $10.00	113,716	5.3	—	113,716	23.99	—
	7,835,533		$1,359,840	2,288,498	$ 3.76	$664,481

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, 2012, 2011 and 2010 was calculated using the following assumptions, defined below:

	Years Ended December 31,		
	2012	2011	2010
Risk-free interest rates	0.24%–2.05%	0.26%–3.45%	2.82%–3.81%
Expected life	2.00 years–9.25 years	2.04 years–9.95 years	9.01 years–9.87 years
Expected dividends	0%	0%	0%
Expected volatility	63.48%–142.25%	79.50%–123.80%	113.25%–127.93%

Stock-based compensation expense charged to operations on options granted to nonemployees for the years ended December 31, 2012, 2011 and 2010 was $52,190, $75,614 and $33,204, respectively, and $1,609,601 for the period from December 19, 2002 (inception) to December 31, 2012.

Employee Stock-Based Awards Granted on or Subsequent to January 1, 2006

On January 1, 2006, the Company adopted the fair value method of accounting for the issuance of stock-based payments, using the prospective transition method. Under this transition method, beginning January 1, 2006, compensation cost recognized includes: (a) compensation cost for all stock-based awards granted prior to, but not yet vested as of December 31, 2005, based on the intrinsic value method, and (b) compensation cost for all stock-based payments granted or modified subsequent to December 31, 2005, based on the estimated grant-date fair value.

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, 2012, 2011 and 2010 was $3.19, $2.13 and $0.13 per share, respectively. The weighted average estimated fair value of the employee stock options granted for the year ended December 31, 2010, excluding options granted pursuant to the option exchange program, was $1.97 per share.

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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, 2012, 2011 and 2010:

	Years Ended December 31,		
	2012	2011	2010
Risk-free interest rates	0.90%–1.09%	1.13%–2.68%	0.89%–2.62%
Expected life	6.00 years–6.25 years	5.42 years–6.25 years	4.00 years–6.25 years
Expected dividends	0%	0%	0%
Expected volatility	137.58%–143.98%	114.80%–124.40%	113.20%–124.78%

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

Volatility. Since the Company was a private entity for most of 2007 and a limited amount of historical data regarding the volatility of its common stock is available, the expected volatility used for 2012, 2011 and 2010 is based on both the volatility of similar entities, referred to as "guideline" companies, and the Company's historical volatility. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

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.

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, 2012 there was $15.9 million of total unrecognized compensation costs related to non-vested stock option awards granted after January 1, 2006, which are expected to be recognized over a weighted-average period of 3.24 years.

The aggregate intrinsic value of stock options (the amount by which the market price of the stock on the date of exercise exceeded the exercise price of the option) exercised during the years ended December 31, 2012, 2011 and 2010, was $3,044, $588, and $12,385, respectively.

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(12) Warrants

Stock warrant activity is as follows:

	Common Shares	Price(1)	Series A Preferred Shares	Price(1)	Series B Preferred Shares	Price(1)	Series C Preferred Shares	Price(1)
Balance as of:								
December 31, 2002	—		—		—		—	
Granted	—		20,963	$ 5.46	3,916	$ 23.68	—	
Exercised	—		—		—		—	
Cancelled	—		—		—		—	
December 31, 2003	—		20,963	$ 5.46	3,916	$ 23.68	—	
Granted	—		—		16,859	$ 23.68	—	
Exercised	—		(20,963)	$ 8.95	—		—	
Cancelled	—		—		—		—	
December 31, 2004	—		—		20,775	$ 23.68	—	
Granted	28,385	$ 2.76	—		11,624	$ 23.68	—	
Exercised	—		—		—		—	
Cancelled	—		—		—		—	
December 31, 2005	28,385	$ 2.76	—		32,399	$ 23.68	—	
Granted	—		—		5,811	$ 23.68	24,605	$ 48.56
Exercised	—		—		—		—	
Cancelled	—		—		—		—	
December 31, 2006	28,385	$ 2.76	—		38,210	$ 23.68	24,605	$ 48.56
Granted	—		—		—		22,650	$ 48.56
Exercised	—		—		—		—	
Cancelled	—		—		—		—	
Converted upon close of IPO	85,465	$ 37.44	—		(38,210)	$ 23.68	(47,255)	$ 48.56
December 31, 2007	113,850	$ 28.79	—		—		—	
Granted(2)	179,328	$ 9.51	—		—		—	
Exercised	—		—		—		—	
Cancelled	—		—		—		—	
December 31, 2008	293,178	$ 17.00	—		—		—	
Granted(2)(3)	1,540,036	$ 7.86	—		—		—	
Exercised(3)	(264,120)	$ 8.49	—		—		—	
Cancelled(3)	(236,759)	$ 9.53	—		—		—	
December 31, 2009	1,332,335	$ 9.44	—		—		—	
Granted(2)(3)	21,046,376	$ 2.19	—		—		—	
Exercised	—		—		—		—	
Cancelled(3)	(153,993)	$ 5.78	—		—		—	
December 31, 2010	22,224,718	$ 2.60	—		—		—	
Granted(2)	1,759,997	$ 1.90	—		—		—	
Exercised	(59,219)	$ 2.19	—		—		—	
Cancelled	(2,195)	$ 23.68	—		—		—	
December 31, 2011	23,923,301	$ 2.55	—		—		—	
Granted(2)	106,746	$ 2.34	—		—		—	
Exercised	(2,813,600)	$ 2.18	—		—		—	
Cancelled	—		—		—		—	
December 31, 2012	21,216,447	$ 2.60	—		—		—	

(1) Represents weighted-average exercise price per share.
(2) See Notes 7 and 8 for discussions relating to the issuance of warrants in 2012, 2011, 2010, 2009 and 2008.
(3) See Note 7 for discussions relating to both the cashless exercises of warrants in 2009 and the cancellation and reissuance of warrants following down round equity financings.

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At December 31, 2012 and 2011, the weighted-average remaining contractual life of outstanding warrants was 3.33 and 4.32 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.

(13) Related Party Transactions

Private Placements

As discussed in Note 8, on September 29, 2010, the Company entered into securities purchase agreements for the sale of 3,394,309 shares of its Series A Non-Voting Convertible Preferred Stock and 3,394,309 common stock warrants, in a private placement transaction. The following directors and principal stockholders, each purchased shares of preferred stock at a price of $1.72 per share and common stock warrants at a price of $0.125 per share. The shares purchased, together with the proceeds, before expenses to the Company, are shown in the table below:

Beneficial Owner	Shares Purchased	Warrants Purchased	Net Proceeds, before expenses, to the Company
MPM Capital	704,607	704,607	$ 1,300,000
Bay City Capital	1,626,016	1,626,016	3,000,000
Aberdare Ventures	406,504	406,504	750,000
Charter Life Sciences	216,802	216,802	400,000
Paul Klingenstein	16,525	16,525	30,488
Nicholas L. Teti, Jr.	10,840	10,840	20,000

Luke Evnin, Ph.D. is a director of the Company and is a member of MPM BioVentures III LLC and a manager of MPM Asset Management Investors 2002 BVIII LLC. Carl Goldfischer, M.D. is a director of the Company and is a managing director of Bay City Capital LLC. Paul H. Klingenstein is a director of the Company and is a managing partner of the Aberdare Funds. Donald C. Harrison, M.D. served as a director of the Company until his resignation, effective May 5, 2011, and is a managing partner of Charter Life Sciences, L.P. Nicholas L. Teti, Jr. is a director of the Company.

Public Offerings

As discussed in Note 8, on December 14, 2010, the Company closed a public offering, selling 17,020,000 shares of common stock together with warrants to purchase an additional 17,020,000 shares of common stock at an aggregate price of $1.75 per share and corresponding warrant. The following officers, directors and principal stockholder, each purchased shares of common stock and warrants at an aggregate price of $1.75 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	Net Proceeds, before expenses, to the Company
Bay City Capital	1,700,000	1,700,000	$ 2,975,000
Mark B. Knudson, Ph.D.	25,000	25,000	43,750
Greg S. Lea	10,000	10,000	17,500

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As discussed in Note 8, on September 28, 2011, the Company closed a public offering, selling 8,800,000 shares of common stock together with warrants to purchase approximately 1,760,000 shares of common stock at an aggregate price of $1.65 per share and corresponding warrant. The following principal stockholder, purchased shares of common stock and warrants at a price of $1.65 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	Net Proceeds, before expenses, to the Company
Bay City Capital	840,000	167,999	$ 1,386,000

Carl Goldfischer, M.D. is a director of the Company and is a managing director of Bay City Capital LLC. Mark B. Knudson, Ph.D. is the Company's President, Chief Executive Officer and Chairman of the Board. Greg S. Lea is the Company's Senior Vice President, Chief Financial Officer and Chief Operating Officer.

Consulting Agreement—Anthony Jansz

Effective June 1, 2011, the Company entered into a four year consulting agreement with Anthony Jansz, who is a member of the board of directors. Pursuant to the agreement, in exchange for consulting services provided, Mr. Jansz is entitled to receive a consulting fee of $96,000 AUD (approximately $100,000 USD as of December 31, 2012) per year and the reimbursement of reasonable expenses. Mr. Jansz also received an option to purchase 50,000 shares of common stock at $2.76 per share that vest in 48 equal monthly installments beginning on July 1, 2011. The full grant date fair value of the option grant was approximately $108,000.

On December 20, 2012, the Company entered into an amendment, effective October 1, 2012, to the consulting agreement with Anthony Jansz. Pursuant to the amendment, during the period from October 1, 2012 until June 30, 2013, Mr. Jansz agreed to commit additional time to performing consulting services for the Company. In exchange for these additional services, Mr. Jansz is entitled to receive a consulting fee of $12,000 AUD (approximately $12,000 USD as of December 31, 2012) per month from October 1, 2012 until June 30, 2013. Mr. Jansz also received an option to purchase 75,000 shares of the Company's common stock at $2.65 per share, which vests as follows: (A) 16,667 of such 75,000 shares vested on January 22, 2013, the date of grant; (B) 16,667 of such 75,000 shares will vest on January 22, 2014; (C) 16,666 of such 75,000 shares will vest on January 22, 2015; and (D) the remaining 25,000 of such 75,000 shares will vest upon the occurrence of both (i) the Company successfully obtaining full Australian reimbursement approval for both surgeon's fees and hospital fees for the VBLOC vagal blocking therapy and the Maestro Rechargeable System from the Australian Medical Services Advisory Committee prior to June 30, 2014 and (ii) the Company successfully obtaining device listing for the Maestro Rechargeable System on the Australian Prostheses List prior to June 30, 2014. The full grant date fair value of the option grant was approximately $153,000.

Total stock-based compensation expense recorded was approximately $23,000 and $10,000 for the years ended December 31, 2012 and 2011, respectively. In addition to the option grant, the Company paid Mr. Jansz approximately $195,000 and $67,000 in fees and expenses for consulting services provided during the years ended December 31, 2012 and 2011, respectively.

Consulting Agreement—Nicholas L. Teti, Jr.

On May 28, 2009, the Company entered into a one-year consulting agreement effective June 1, 2009 with Nicholas L. Teti, Jr., who is a member of the board of directors. Pursuant to the agreement, in exchange for

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consulting services provided, Mr. Teti was entitled to receive a consulting fee of $275,000 per year and the reimbursement of reasonable expenses. Mr. Teti also received an option to purchase 25,000 shares of common stock at $13.80 per share that vested in 36 equal monthly installments following the date of grant. The full grant date fair value of the option grant was approximately $314,000.

On February 10, 2010, the Company entered into a new agreement with Mr. Teti, which was effective as of February 1, 2010 and ended on July 30, 2010. In connection with entering into the new agreement, Mr. Teti and the Company agreed to terminate Mr. Teti's prior consulting agreement. However, the options that Mr. Teti received in connection with the prior agreement continued to vest in accordance with their terms. Pursuant to this agreement, in exchange for consulting services provided, Mr. Teti was entitled to receive a consulting fee of $15,417 per month and one-third of Mr. Teti's administrative assistant expenses. Mr. Teti also received an option to purchase 12,500 shares of common stock at $3.24 per share that vests such that one-third of the options vested immediately with the remainder vesting in 36 equal monthly installments following the date of grant.

On August 1, 2010, the Company entered into a new agreement with Mr. Teti, which was effective from August 1, 2010 through January 31, 2011. Pursuant to this agreement, in exchange for consulting services provided, Mr. Teti was entitled to receive a consulting fee of $7,000 per month and one-third of Mr. Teti's administrative assistant expenses.

On October 1, 2010, the Company amended the August 1, 2010 agreement with Mr. Teti, which was effective from October 1, 2010 through January 31, 2011. Pursuant to this agreement, in exchange for up to ten hours of consulting services provided per month, Mr. Teti was entitled to receive a consulting fee of $175 an hour. Reimbursement of Mr. Teti's administrative assistant expenses was eliminated with this amendment.

Total stock-based compensation expense recorded was approximately $32,000 for the year ended December 31, 2010. In addition to the option grant, the Company paid Mr. Teti approximately $184,000 in fees and expenses for consulting services rendered during the year ended December 31, 2010. There was no stock-based compensation expense recorded or other fees and expenses paid to Mr. Teti during the years ended December 31, 2012 and 2011.

(14) Commitments and Contingencies

Effective October 1, 2008 the Company entered into a seven-year non-cancelable operating lease agreement for office/warehouse space. The lease expires on September 30, 2015 with monthly base rent ranging from $19,570 to $24,643. Total rent expense recognized for the years ended December 31, 2012, 2011 and 2010 was $270,872, $270,872 and $270,872 respectively, and $1,623,928 for the period from December 19, 2002 (inception) to December 31, 2012. 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, 2012:

Years ending December 31:	
2013	$ 285,656
2014	291,369
2015	221,789
	$ 798,814

EnteroMedics Inc.
(A development stage company)

Notes to Consolidated Financial Statements (Continued)

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.

The Company is evaluating its product, 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.

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.

Under this agreement, the Company issued 36,630 shares of common stock to the Mayo Foundation in 2005 and recorded $100,000 as deferred compensation, which was amortized over the term of the five-year agreement and was fully amortized in 2010. In accordance with the agreement, upon the closing of the IPO in November 2007, the Company was also obligated to issue 34,341 shares of common stock as consideration to the Mayo Foundation and recorded a one-time stock-based compensation expense of $1.7 million. The stock-based compensation expense is recorded on the consolidated statements of operations as research and development expense.

The Mayo Foundation received an annual $250,000 retainer fee which commenced in 2005 and continued through January 2009. The annual retainer fee paid to the Mayo Foundation is recorded on the consolidated statements of operations as research and development expense.

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.

EnteroMedics Inc.
(A development stage company)

Notes to Consolidated Financial Statements (Continued)

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.

(15) 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, 2012, 2011 and 2010 and for the period from December 19, 2002 (inception) to December 31, 2012, the Company did not provide any matching of employees' contributions.

(16) Quarterly Data (unaudited)

The following table represents certain unaudited quarterly information for each of the eight quarters in the period ended December 31, 2012. 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
2012:				
Net loss	$(5,633)	$(4,954)	$(5,847)	$(7,027)
Basic and diluted net loss per share	$ (0.15)	$ (0.13)	$ (0.14)	$ (0.17)
2011:				
Net loss	$(5,086)	$(5,557)	$(7,298)	$(8,056)
Basic and diluted net loss per share	$ (0.18)	$ (0.20)	$ (0.26)	$ (0.22)

(17) Subsequent Event

On February 27, 2013, the Company closed a public offering, selling 13,770,000 shares of common stock, together with warrants to purchase approximately 5,508,000 shares of common stock at an aggregate price of $0.95 per share and corresponding warrant, for gross proceeds of $13.1 million before deducting offering expenses.

The warrants have an exercise price of $1.14 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.

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, 2012 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, 2012 utilizing the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework*. Based upon the evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2012.

Deloitte & Touche LLP, the Company's independent registered public accounting firm, has audited the consolidated financial statements and notes thereto included in Part II, Item 8 of this Annual Report on Form 10-K and, as part of its audit, has issued an attestation report on the effectiveness of the Company's internal control over financial reporting. The attestation report can be found on the following page as part of this Item 9A.

Report of Independent Registered Public Accounting Firm

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

We have audited the internal control over financial reporting of EnteroMedics Inc. and subsidiary (a development stage company) (the "Company") as of December 31, 2012, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with 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 (3) 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.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2012 and 2011, and the related statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012 and for the period from December 19, 2002 (date of inception) to December 31, 2012, of the Company and our report dated March 7, 2013 expressed an unqualified opinion on those consolidated financial statements.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, MN
March 7, 2013

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 2013 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, 2012 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	7,835,533(1)	$ 3.28	4,393,985(2)
Equity compensation plans not approved by security holders	—	—	—
Total	7,835,533	$ 3.28	4,393,985

(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, 2012.

(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, 2012 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 113 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/ MARK B. KNUDSON, PH.D.
Mark B. Knudson, Ph.D.
President and Chief Executive Officer

Dated: March 7, 2013

POWERS OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Mark B. Knudson 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/ MARK B. KNUDSON, PH.D. **Mark B. Knudson, Ph.D.**	President, Chief Executive Officer, Chairman and Director (principal executive officer)	March 7, 2013
/s/ GREG S. LEA **Greg S. Lea**	Senior Vice President, Chief Financial Officer and Chief Operating Officer (principal financial and accounting officer)	March 7, 2013
/s/ LUKE EVNIN, PH.D. **Luke Evnin, Ph.D.**	Director	March 7, 2013
/s/ CATHERINE FRIEDMAN **Catherine Friedman**	Director	March 7, 2013
/s/ CARL GOLDFISCHER, M.D. **Carl Goldfischer, M.D.**	Director	March 7, 2013
/s/ BOBBY I. GRIFFIN **Bobby I. Griffin**	Director	March 7, 2013
/s/ ANTHONY P. JANSZ **Anthony P. Jansz**	Director	March 7, 2013

Signature	Title	Date
/S/ PAUL H. KLINGENSTEIN **Paul H. Klingenstein**	Director	March 7, 2013
/S/ NICHOLAS L. TETI, JR. **Nicholas L. Teti, Jr.**	Director	March 7, 2013
/S/ JON T. TREMMEL **Jon T. Tremmel**	Director	March 7, 2013

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company and all amendments thereto. (Incorporated herein by reference to Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed on November 8, 2012 (File No. 1-33818)).
3.2	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)).
4.1	Amended and Restated Investors' Rights Agreement, dated as of July 6, 2006, by and between the Company and the parties named therein. (Incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.1	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 10.1 to the Company's Current Report on Form 8-K filed on November 24, 2008 (File No. 1-33818)).
10.2	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)).
10.3	First Amendment to Loan and Security Agreement, dated as of February 8, 2010, by and between Silicon Valley Bank and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 12, 2010 (File No. 1-33818)).
10.4	Second Amendment to Loan and Security Agreement, dated as of July 8, 2010, by and between Silicon Valley Bank and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 13, 2010 (File No. 1-33818)).
10.5	Third Amendment to Loan and Security Agreement, dated as of November 4, 2010, by and between Silicon Valley Bank and the Company. (Incorporated herein by reference to Exhibit 10.8 to the Company's Quarterly Report on Form 10-Q filed on November 8, 2010 (File No. 1-33818)).
10.6	Fourth Amendment to Loan and Security Agreement, dated as of March 3, 2011, by and between Silicon Valley Bank and the Company. (Incorporated herein by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K filed on March 7, 2011 (File No. 1-33818)).
10.7	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)).
10.8	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)).
10.9	Form of Securities Purchase Agreement, dated February 19, 2009, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 25, 2009 (File No. 1-33818)).
10.10	Form of Warrant, dated February 24, 2009, 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 February 25, 2009 (File No. 1-33818)).

Exhibit Number	Description of Document
10.11	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)).
10.12	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)).
10.13	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)).
10.14	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)).
10.15	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)).
10.16	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)).
10.17	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)).
10.18	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)).
10.19	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)).
10.20	Securities Purchase Agreement, dated as of April 16, 2012, between the Company and the purchasers identified on Schedule A thereto. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 17, 2012 (File No. 1-33818)).
10.21	Common Stock Purchase Agreement, dated as of October 4, 2012, by and between Terrapin Opportunity, L.P. and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 4, 2012 (File No. 1-33818)).
10.22	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)).
10.23	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)).
10.24†	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 September 28, 2012 (File No. 1-33818)).
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	Consulting Agreement, dated June 1, 2009, by and between the Company and Nicholas L. Teti, Jr. (Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2009 (File No. 1-33818)).
10.32	Consulting Agreement, dated as of February 1, 2010, by and between the Company and Nicholas L. Teti, Jr. (Incorporated herein by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K filed on March 29, 2010 (File No. 1-33818)).
10.33	Consulting Agreement, dated as of August 1, 2010, by and between the Company and Nicholas L. Teti, Jr. (Incorporated herein by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K filed on March 7, 2011 (File No. 1-33818)).
10.34	Consulting Agreement, dated as of October 1, 2010, by and between the Company and Augustus Advisors, Inc. (Incorporated herein by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K filed on March 7, 2011 (File No. 1-33818)).
10.35	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)).
10.36	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)).
10.37†	Executive Employment Agreement, dated June 22, 2005, by and between the Company and Mark B. Knudson. (Incorporated herein by reference to Exhibit 10.8 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
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)).

Exhibit Number	Description of Document
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)).
10.41†	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)).
10.42†	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)).
10.43†	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)).
10.44	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)).
10.45	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)).
10.46	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)).
10.47	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)).
10.48	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)).
10.49	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)).
10.50	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)).
10.51	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).

Exhibit Number	Description of Document
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, 2012, 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 (Deficit); (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.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-184181, 333-176174, 333-171244, 333-159592, and 333-149662 on Form S-8 and Registration Statement Nos. 333-183313, 333-171944, 333-170503, 333-171052, 333-166011, and 333-158516 on Form S-3 of our reports dated March 7, 2013, relating to the consolidated financial statements of EnteroMedics Inc. and subsidiary (the "Company") and the effectiveness of the Company's internal control over financial reporting, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2012.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, MN
March 7, 2013

EXHIBIT 31.1

CERTIFICATIONS

I, Mark B. Knudson, 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/ MARK B. KNUDSON, PH.D.

Mark B. Knudson, Ph.D.
President and Chief Executive Officer

Date: March 7, 2013

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
Senior Vice President, Chief Financial Officer
and Chief Operating Officer

Date: March 7, 2013

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, 2012 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Mark B. Knudson, 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/ MARK B. KNUDSON, PH.D.
Mark B. Knudson, Ph.D.
President and Chief Executive Officer

March 7, 2013

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, 2012 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
Senior Vice President, Chief Financial Officer
and Chief Operating Officer

March 7, 2013