



17,020,000 Shares of Common Stock

This prospectus relates to 17,020,000 shares of common stock, par value \$0.01 per share, of EnteroMedics Inc., which are issuable upon the exercise of outstanding warrants to purchase common stock (Warrants) issued in our public offering which closed on December 14, 2010.

In order to obtain the shares of common stock, the holders of the Warrants must pay an exercise price of \$2.19 per share, subject to adjustment. The Warrants are exercisable beginning 181 days after December 14, 2010, the closing date of our public offering, and ending on the fifth anniversary of the date on which the exercise period begins. The Warrants do not allow for cashless exercise.

We will receive all of the proceeds from the exercise of the Warrants.

Our common stock is quoted on the NASDAQ Capital Market under the symbol "ETRM." On March 4, 2011, the last sale price of our common stock as reported on the NASDAQ Capital Market was \$2.67 per share.

Investing in our common stock involves risks. You should consider carefully the risks and uncertainties set forth in the section entitled "[Risk Factors](#)" beginning on page 4 of this prospectus and in the documents we file with the Securities and Exchange Commission that are incorporated by reference in this prospectus before making a decision to purchase our stock.

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

The date of this prospectus is April 8, 2011.

TABLE OF CONTENTS

ENTEROMEDICS INC.	1
THE OFFERING	3
RISK FACTORS	4
CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS	23
USE OF PROCEEDS	23
DETERMINATION OF OFFERING PRICE	23
DILUTION	23
PLAN OF DISTRIBUTION	24
LEGAL MATTERS	24
EXPERTS	24
WHERE YOU CAN FIND MORE INFORMATION	24
INCORPORATION OF DOCUMENTS BY REFERENCE	25

Unless the context otherwise requires, the terms “we,” “us,” “our,” “EnteroMedics,” and “the Company” refer to EnteroMedics Inc., a Delaware corporation, and our subsidiary.

All references in this prospectus to “\$,” “U.S. Dollars” and “dollars” are to United States dollars.

In the United States we have registered trademarks for VBLOC® and ENTEROMEDICS®, each registered with the United States Patent and Trademark Office, an approved Statement of Use for Maestro® and have received a fifth extension of time to file a Statement of Use on our application to register the mark EMPOWER™. In addition, 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 VBLOC is registered in Switzerland. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are registered in Mexico. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM are the subject of pending trademark applications in the United Arab Emirates. This prospectus contains other trade names and trademarks and service marks of EnteroMedics and of other companies.

ENTEROMEDICS INC.

We are a development stage medical device company focused on the design and development of devices that use neuroblocking technology to treat obesity, its associated co-morbidities, 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 controls much of the activity of the stomach, intestines and pancreas and plays a role in food processing. Our initial product under development is the Maestro System, which uses VBLOC therapy to limit the expansion of the stomach, help control hunger sensations between meals, reduce the frequency and intensity of stomach contractions and produce a feeling of early and prolonged fullness. Based on our understanding of vagal nerve function and nerve blocking from our preclinical studies and the results of our initial clinical trials, we believe the Maestro System may offer obese patients a minimally-invasive treatment alternative 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 the obesity-related co-morbidities of diabetes and hypertension. We are conducting, or plan to conduct, feasibility studies in each of these co-morbidities to assess VBLOC therapy's potential in addressing multiple indications.

We are currently evaluating the Maestro System in human clinical trials conducted 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.

On October 2, 2009, we announced preliminary results from our first pivotal clinical study, the EMPOWER trial, a multi-center, randomized, double-blind, prospective, placebo-controlled pivotal study being conducted in the United States and selected international centers. Initial results from the trial indicated that the study 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. Our further review of the data suggests that: (i) patients that used the device for the prescribed amount of time (39 hours) had clinically meaningful weight-loss; (ii) both the treatment and control arm subjects experienced comparable, significant, dose-dependent EWL at 12 months; and (iii) there was an unanticipated therapeutic effect in which a low-intensity blocking signal introduced VBLOC therapy in human subjects in the control group. In January 2010, we met with the U.S. Food and Drug Administration (FDA) to discuss the EMPOWER trial results and the regulatory process going forward. Based on this discussion, in March we submitted an Investigational Device Exemption (IDE) for a pivotal trial of our second generation fully implantable Maestro Rechargeable (RC) System. In October 2010, we received an unconditional approval from the FDA for this trial, the ReCharge trial, a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in 234 morbidly obese subjects enrolled at up to 12 U.S. centers. All patients in the study will receive an implanted device and will be randomized in a 2:1 allocation to treatment or control groups. The control group will receive a functional, but non-active device that will deliver no charge to the vagus nerve during the study period. All patients are expected to participate in a weight management program.

We will begin enrolling and implanting patients in the ReCharge trial and target the final implant to take place around the end of 2011 at the earliest. Assuming that we successfully enroll and implant the trial and achieve favorable results, we plan to use data from that trial to support a premarket approval (PMA) application for the Maestro System, which we expect to submit no earlier than the fourth quarter of 2012. We anticipate that we will be able to commercialize the Maestro System in the United States in late 2013 at the earliest.

We have begun to take the initial steps necessary to commercialize the Maestro RC System in Australia, which includes applying for European CE Mark certification and Australian Therapeutic Goods Administration (TGA) approval. We have applied for European CE Mark certification of the Maestro RC System and hope to

[Table of Contents](#)

receive approval in the first quarter of 2011. Once we receive European CE Mark certification, we intend to use that approval to file an application for approval and listing of the Maestro RC System with the TGA and intend to commercialize the device following receipt of that approval during the second half of 2011.

On October 21, 2010, we announced that we entered into a cooperation agreement with the Australian Institute of Weight Control (AIWC), a network of bariatric clinics specializing in laparoscopic weight loss surgery and clinical research for the morbidly obese. Under the cooperation agreement, we have designated AIWC and AIWC member clinics as authorized training and implantation centers for our products. AIWC will be the first clinics in Australia to implant the Maestro System when it has received approval by the TGA. The AIWC will work with us to provide research, communications, training and accreditation support related to the Maestro RC System in Australia and other international territories. In addition, the AIWC will work with us toward TGA approval of the Maestro RC System and collaborate on subsequent marketing and distribution efforts in Australia. The AIWC will also support our efforts in gaining reimbursement for the private sector through the Medical Services Advisory Committee (MSAC) in Australia.

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. As of December 31, 2010, we had a total of 29 employees, all of which are located in the United States. Our principal executive offices are located at 2800 Patton Road, St. Paul, Minnesota 55113, and our telephone number is (651) 634-3003.

THE OFFERING

Common stock offered under the Warrants	17,020,000 shares
Common stock outstanding before the offering ⁽¹⁾	27,892,388 shares
NASDAQ Capital Market symbol	ETRM
Number of Warrants	Warrants to purchase 17,020,000 shares of common stock
Exercise price	\$2.19 per share
Exercise period	The Warrants are exercisable beginning 181 days after December 14, 2010, the closing date of our public offering, and ending on the fifth anniversary of the date on which the exercise period begins.
Proceeds	Assuming all of the Warrants are exercised, we will receive gross proceeds of \$37,273,800.
Use of proceeds	We intend to use the proceeds of this offering to continue to work toward regulatory approval of our product in the United States, for international commercialization efforts, for clinical and product development activities and for other working capital and general corporate purposes.
Risk factors	You should read the “Risk Factors” beginning on page 4 of this prospectus for a discussion of the factors you should consider carefully before deciding whether to invest in the common stock offered by this prospectus.

⁽¹⁾ Based on the number of shares outstanding as of February 28, 2011.

RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risk factors described below, in addition to the other information contained in or incorporated by reference into this prospectus before you decide to exercise the Warrants. If any of the following risks were to occur, our business, financial condition or results of operations could be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical development stage company with a limited history of operations and no approved products, and we cannot assure you that we will ever have a commercialized product.

We are a clinical development stage company with a limited operating history upon which you can evaluate our business. We currently do not have any products cleared in the United States or approved for commercialization or any other source of revenue, and we do not expect to have a commercialized product earlier than the second half of 2011 outside the United States and not until late 2013 within the United States, 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 System. The success of our business will depend on our ability to obtain regulatory approval to market our Maestro 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 regulatory approval for and commercialize our Maestro 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, 2010, we had experienced net losses during the development stage of \$150.6 million. Our net loss applicable to common stockholders for the fiscal years ended December 31, 2010, 2009 and 2008 was \$17.3 million, \$31.9 million and \$37.9 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. If our Maestro System is approved for marketing by the U.S. Food and Drug Administration (FDA), Australian Therapeutic Goods Administration (TGA) or regulatory authority of another country 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 operating 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 \$13.7 million,

[Table of Contents](#)

\$24.7 million and \$33.7 million for the fiscal years ended December 31, 2010, 2009 and 2008, respectively. We expect that our cash used in operations will continue to be significant in the upcoming years, and we will eventually need to raise additional capital to continue our research and development programs, commercialize our Maestro System, if approved by the TGA or FDA, 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 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 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. Issuing public equity or debt securities may also be more costly or time-consuming for us because the aggregate market value of our common stock held by non-affiliates (public float) is less than \$75.0 million (calculated in accordance with the U.S. Securities and Exchange Commission (SEC) rules and regulations), which limits the size of offerings we may make using a Form S-3 registration statement to 1/3 of our public float for any twelve month period. 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 new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and NASDAQ have imposed various

[Table of Contents](#)

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 of 2002 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.

Risks Associated with Development and Commercialization of Our Maestro System

We have not received, and may never receive, approval from the FDA or the regulatory body in any other country to market our Maestro RC 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 the European Community for which we received CE Mark approval for our Maestro RF System on March 4, 2009. We plan initially to launch our product, if approved, in countries outside the United States. We are hoping to receive CE Mark approval on our second generation Maestro RC System in first quarter 2011 and immediately thereafter use that approval to seek approval from the TGA to market the system in Australia by the second half of 2011.

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 we have received the European CE Mark for our Maestro RF System, we cannot assure you when, or if, we will be able to commence sales in the European Economic Area 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. 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;

[Table of Contents](#)

- the facilities of our third-party manufacturers or suppliers may not meet applicable requirements;
- our compliance 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 could result in a more cautious approach by the FDA to clearances and approvals for devices such as ours.

We may not obtain the necessary regulatory approvals to market our Maestro System in the United States or anywhere else. 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 were not sufficient to support approval of a PMA application, and this has delayed regulatory approval of our Maestro System.

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 inability to achieve our primary and secondary efficacy endpoints in the EMPOWER trial has delayed our timeline for achieving regulatory approval of the Maestro System in the U.S. and caused us to need additional capital to fund a new pivotal trial. We may never be able to produce sufficient data to support a PMA application with the FDA or commercialize a product in the U.S.

We may be unable to enroll and complete a pivotal trial using our second generation Maestro RC System or other 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.

In October 2010, we obtained an unconditional Investigational Device Exemption (IDE) for a pivotal trial using our second generation Maestro RC System. Assuming that we successfully enroll and implant the trial and achieve favorable results, we plan to use data from that trial to support a PMA application for the Maestro System. We expect to commence the trial upon approval from the relevant institutional review boards at the various sites at which we intend to conduct the trial. Conducting a clinical trial of this size, 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 commencement of our trial could be delayed for a variety of reasons, including:

- reaching agreement on acceptable terms with prospective clinical trial sites;
- manufacturing sufficient quantities of our Maestro System;
- obtaining institutional review board approval to conduct the trial at a prospective site; and

[Table of Contents](#)

- obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the difficulty in getting patients to endure the implant for the control arm, and the eligibility criteria for the trial.

Once the trial has begun, the completion of the trial, and our other ongoing 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.

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

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.

If we obtain regulatory approval to market our Maestro System, our ability to generate revenue will depend upon the successful commercialization of this product. Our efforts to commercialize our Maestro 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;

[Table of Contents](#)

- 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 U.S., 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. The earliest we expect to be able to commercialize our Maestro System is the second half of 2011 outside the United States and not until late 2013 within the United States, if at all. If we are not successful in the commercialization of our Maestro 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, including a new pivotal trial using our second generation Maestro RC System, 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.

[Table of Contents](#)

Assuming we receive regulatory approval for the Maestro System, modifications to the Maestro System may require additional approval from the regulatory agencies such as FDA and TGA, which may not be obtained or may delay our commercialization efforts.

The FDA and TGA 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, the FDA can review a company's decision. Any modifications to an FDA- or TGA-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 U.S., 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.

[Table of Contents](#)

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 excess weight loss 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 (GMP), 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 unannounced inspections 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 have received European ISO certification to standards 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.

[Table of Contents](#)

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 are subject to medical device reporting regulations (MDR) that require us to report to the FDA and TGA or 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 co-morbidities 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 co-morbidities 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 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.

[Table of Contents](#)

If our device manufacturers or our suppliers are unable to provide an adequate supply of our product following the start 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 launch of the product or to meet future demand, if at all. 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 following commercialization. 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. To generate sales we will need to identify and enter into an agreement with a third-party distributor in Australia, our intended first market for product commercial launch. 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. In the rest of the world and the United States, we will also develop a sales and marketing infrastructure or contract with third parties to perform that function. 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.

If we attempt to commercialize our products outside of the United States, our business will be susceptible to risks associated with international operations.

We intend to commercialize our products internationally, initially in Australia, and subsequently in other international markets, if any, in which we obtain necessary regulatory approvals. Conducting international operations would 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.

[Table of Contents](#)

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 research and development 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, 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 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 \$5.0 million of product liability insurance, which covers the use of our Maestro System and VBLOC therapy in our clinical trials, which 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.

[Table of Contents](#)

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.

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 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 15 issued U.S. patents, 13 of which pertain to treating gastrointestinal disorders, and 20 U.S. patent applications. We have two granted European patents and one granted Australian patent. We also have 10 Australian patent applications, 11 European patent applications, three Chinese patent applications, three Indian patent applications and two Japanese patent applications. In addition, we are the exclusive licensee to one U.S. patent and one patent application 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

[Table of Contents](#)

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

[Table of Contents](#)

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 this Offering and 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, 2011 our stock price has fluctuated from a low of \$1.52 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;

Table of Contents

- 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.

[Table of Contents](#)

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, 2010, was approximately 142,305 shares. Although we believe that our December 2010 public offering will improve the liquidity for our common stock, there is no assurance that the offering 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.

We have broad discretion in the use of the proceeds of this offering and may apply the proceeds in ways with which you do not agree.

Substantially all of our proceeds from this offering will be used, as determined by management in its sole discretion, to continue work toward regulatory approval of our product in the United States, for international commercialization efforts, for clinical and product development activities and for working capital and other general corporate purposes. Our management will have broad discretion over the use and investment of the net proceeds of this offering. The failure of our management to apply these funds effectively could harm our business. You will not have the opportunity, as part of your investment decision, to assess whether our proceeds are being used appropriately. Pending application of our proceeds, they may be placed in investments that do not produce income or that lose value.

You will experience immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering.

If you purchase common stock in this offering, you will experience immediate dilution of \$0.70 per share because the price that you pay for our common stock will be greater than the net tangible book value per share of our common stock.

There must be a current prospectus and state registration in order for you to exercise the Warrants.

The Warrants can only be exercised if a current prospectus relating to the common stock underlying the Warrants is then in effect and if such securities are qualified for sale or exempt from qualification under the applicable securities laws of the states in which the various holders of Warrants reside. Although we will attempt to (i) maintain the effectiveness of a current prospectus covering the common stock underlying the Warrants and (ii) maintain the registration of such common stock under the securities laws of the states in which we initially qualify the common stock and Warrants in our public offering, there can be no assurance that we will be able to do so. We will be unable to issue common stock to those persons desiring to exercise their Warrants if a current prospectus covering the common stock issuable upon the exercise of the Warrants is not kept effective or if such shares are neither qualified nor exempt from qualification in the states in which the holders of the Warrants reside.

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, 2010), approximately 27.8% 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.

[Table of Contents](#)

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. Following the expiration of lock-up agreements entered into for the benefit of the underwriter of our December 2010 public offering by certain holders of our common stock, including our directors and executive officers and their affiliated entities, 7,184,078 shares of our common stock will become eligible for sale in the public markets from time to time, subject to restrictions under the Securities Act of 1933, as amended (the Securities Act). The underwriter may, in its sole discretion and at any time, without notice, release all or any portion of the shares of common stock subject to the lock-up agreements for sale in the public and private markets prior to the expiration of the lock-up. 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 warrant holders 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 85,000,000 shares of common stock, 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.

[Table of Contents](#)

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.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference may contain forward-looking statements with respect to the financial condition, results of operations, plans, objectives, future performance and business of EnteroMedics. Statements preceded by, followed by or that include the words such as “may,” “will,” “expect,” “anticipate,” “continue,” “estimate,” “project,” “believes” or similar expressions are intended to identify some of the forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and are included, along with this statement, for purposes of complying with the safe harbor provisions of that Act. These forward-looking statements involve risks and uncertainties. Actual results may differ materially from those contemplated by the forward-looking statements due to, among others, the risks and uncertainties described in this prospectus, including under “Risk Factors,” and the documents incorporated by reference in this prospectus. Any forward-looking statement contained in this prospectus and the documents incorporated by reference speaks only as of the date on which the statement is made, and EnteroMedics undertakes no obligation to update any forward-looking statement or statements to reflect events or circumstances that occur after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for EnteroMedics to predict all of the factors, nor can EnteroMedics assess the effect of each factor on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement.

USE OF PROCEEDS

We will not receive any amounts pursuant to this offering unless the Warrants are exercised. Assuming the exercise of all the Warrants, we will receive gross proceeds of \$37,273,800. We intend to use the proceeds, if any, from the exercise of the Warrants to continue to work toward regulatory approval of our product in the United States, for international commercialization efforts, for clinical and product development activities and for other working capital and general corporate purposes. Our management will have broad discretion in the application of the proceeds, and purchasers will be relying on the judgment of our management regarding the application of the proceeds of this offering. There is no assurance that the holders of the Warrants will elect to exercise any or all of the Warrants.

DETERMINATION OF OFFERING PRICE

The purchase price of the shares of common stock offered hereby is determined by reference to the exercise price of the Warrants. The exercise price of the Warrants to purchase 17,020,000 shares of common stock is \$2.19 per share. The exercise price of the Warrants was determined by us and our underwriter at the commencement of the public offering in which the Warrants were issued.

DILUTION

The difference between the exercise price per share of the common stock issuable under the Warrants, and the pro forma net tangible book value per share of our common stock after this offering constitutes the dilution to purchasers in this offering. As of December 31, 2010, our net tangible book value was \$29.7 million, or \$1.07 per share of common stock, based on 27,892,388 shares of our common stock outstanding as at December 31, 2010. Our net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of our common stock outstanding as of December 31, 2010. The information below assumes all of the warrants are exercised.

[Table of Contents](#)

The following table illustrates the dilution to the purchasers in this offering on a per-share basis as if the offering had occurred on December 31, 2010:

Offering price of the shares of common stock		\$2.19
Net tangible book value per share before this offering	\$1.07	
Increase attributable to purchasers in this offering	<u>\$0.42</u>	
Pro forma net tangible book value per shares after this offering		<u>\$1.49</u>
Dilution to purchasers in this offering		<u>\$0.70</u>

PLAN OF DISTRIBUTION

Pursuant to the terms of the Warrants, shares of our common stock will be issued to those Warrant holders who surrender their certificates representing the Warrants and provide payment of the exercise price to us. We do not know if or when the Warrants will be exercised. We also do not know whether any of the shares of common stock acquired upon exercise will be sold.

LEGAL MATTERS

Dorsey & Whitney LLP has issued a legal opinion as to the validity of the issuance of the shares of common stock offered under this prospectus.

EXPERTS

The consolidated financial statements incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2010 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is incorporated herein by reference (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the January 1, 2009 adoption of new authoritative accounting guidance regarding the financial reporting for outstanding equity-linked financial instruments), and have been so incorporated in reliance upon that report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public through the Internet at the SEC's web site at www.sec.gov. You may also read and copy any document we file with the SEC at the SEC's public reference room at 100 F Street N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information about its public reference facilities and their copy charges.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities offered by this prospectus. When used in this prospectus, the term "registration statement" includes amendments to the registration statement as well as the exhibits, schedules, financial statements and notes filed as part of the registration statement. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement. This prospectus omits information contained in the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and the securities offered by this prospectus, reference is made to the registration statement.

[Table of Contents](#)

Statements herein concerning the contents of any contract or other document are not necessarily complete and in each instance reference is made to the copy of such contract or other document filed with the SEC as an exhibit to the registration statement, each such statement being qualified by and subject to such reference in all respects.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them. This allows us to disclose important information to you by referencing those filed documents. We have previously filed the following documents with the SEC and are incorporating them by reference into this prospectus:

- Annual Report on Form 10-K for the year ended December 31, 2010;
- Current Reports on Form 8-K filed with the SEC on January 11, 2011 and March 28, 2011; and
- the description of our common shares contained in any registration statement on Form 8-A that we have filed, and any amendment or report filed for the purpose of updating this description.

We also are incorporating by reference any future filings made by us with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial filing of the registration statement of which this prospectus is a part and before the effective date of the registration statement and after the date of this prospectus until we sell all of the securities offered by this prospectus. The most recent information that we file with the SEC automatically updates and supersedes more dated information.

You can obtain a copy of any documents which are incorporated by reference in this prospectus or prospectus supplement, except for exhibits which are specifically incorporated by reference into those documents, at no cost, by writing or telephoning us at:

EnteroMedics Inc.
2800 Patton Road
St. Paul, Minnesota 55113
Attention: Secretary
(651) 634-3003



17,020,000 Shares of Common Stock

PROSPECTUS

April 8, 2011
