



## 7,129,018 Shares of Common Stock

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This prospectus relates to 7,129,018 shares of common stock, par value \$0.01 per share, of EnteroMedics Inc., of which 3,734,709 shares of common stock may be issuable upon exercise of warrants issued to the selling stockholders named in this prospectus. The shares will be sold from time to time by the selling stockholders named in this prospectus. The selling stockholders may sell or otherwise dispose of the shares from time to time through public or private transactions or through other means described in the section entitled “Plan of Distribution” beginning on page 27. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying market prices determined at the time of sale or at negotiated prices. In addition, this prospectus covers the issuance of any shares of common stock to a subsequent holder of a warrant upon exercise of that warrant. Each warrant represents the right to purchase one share of our common stock.

We will receive no part of the proceeds from sales made under this prospectus. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants. We are paying the expenses incurred in registering the shares, but all selling and other expenses incurred by the selling stockholders will be borne by the selling stockholders.

Our common stock is quoted on the NASDAQ Capital Market under the symbol “ETRM.” On January 27, 2011, the last sale price of our common stock as reported on the NASDAQ Capital Market was \$2.68 per share.

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**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.**

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**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.**

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The date of this prospectus is February 10, 2011.

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission (SEC). The prospectus relates to 7,129,018 shares of our common stock which the selling stockholders named in this prospectus may sell from time to time. We will not receive any of the proceeds from these sales. We have agreed to pay the expenses incurred in registering these shares, including legal and accounting fees.

These shares have not been registered under the securities laws of any state or other jurisdiction as of the date of this prospectus. The selling stockholders should not make an offer of these shares in any state where the offer is not permitted. Brokers or dealers should confirm the existence of an exemption from registration or effect a registration in connection with any offer and sale of these shares.

You should rely only on the information contained or incorporated by reference in this prospectus or any supplement to this prospectus. We have not authorized anyone to provide you with different information or to make representations not contained in this prospectus. This prospectus is neither an offer to sell nor a solicitation of an offer to buy any securities other than those registered by this prospectus, nor is it an offer to sell or a solicitation of an offer to buy securities where an offer or solicitation would be unlawful. You should not assume that the information contained in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front cover of those documents.

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<sup>®</sup>, ENTEROMEDICS<sup>®</sup> and MAESTRO<sup>®</sup> each registered with the United States Patent and Trademark Office, and have received a Notice of Allowance and fourth extension of time to file a Statement of Use on our application to register the mark EMPOWER<sup>™</sup>. 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 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.

Unless otherwise stated, the information presented in this prospectus reflects a 1-for-6 reverse split of our outstanding common stock that was effected on July 9, 2010. The net loss per share basic and diluted for each of the years ended December 31, 2010, 2009 and 2008 as adjusted to reflect the reverse split was \$(2.06), \$(6.42) and \$(13.50), respectively. The number of shares used to compute the basic and diluted net loss per share for the same years as adjusted to reflect the reverse split was 8,420,000, 4,974,000 and 2,806,000, respectively.

**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 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 an acceleration of the timing of 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.

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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 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.

## RISK FACTORS

*An investment in our common stock involves a high degree of risk. You should carefully consider the risk factors described below, together with the other information included in our Annual Report on Form 10-K before you decide to invest in our common stock. Additional risks and uncertainties not presently known to us or that we do not currently believe are important to an investor, if they materialize, also may adversely affect the Company.*

### **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 September 30, 2010, we had experienced net losses during the development stage of \$146.6 million. Our net loss applicable to common stockholders for the nine months ended September 30, 2010 was \$13.4 million and for the fiscal years ended December 31, 2009, 2008 and 2007 was \$31.9 million, \$37.9 million and \$28.6 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 \$10.1 million

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for the nine months ended September 30, 2010 and \$24.7 million, \$33.7 million and \$23.4 million for the fiscal years ended December 31, 2009, 2008 and 2007, respectively. Our cash used in operations beyond September 30, 2010 will largely depend on our regulatory path forward. If we obtain adequate funding and launch the approved clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity, ReCharge, we would expect research and development expenditures to increase in support of that study in addition to the continued follow-up on existing trials, such as VBLOC-DM2 ENABLE and EMPOWER. In 2011 and the years following, we expect that our cash used in operations will be significant, and we will 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 on going 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 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 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 next-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



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review an application for approval of our Maestro System with greater scrutiny, which could cause that process to be lengthier and more involved than that for products without such characteristics. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our inability to demonstrate safety or effectiveness to the FDA's satisfaction;
- the data from our preclinical studies and clinical trials may be insufficient to support approval;
- the facilities of our third-party manufacturers or suppliers may not meet applicable requirements;
- our 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 next-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.***

We recently obtained an approved Investigational Device Exemption (IDE) for a pivotal trial using our next-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 receipt of adequate funding and 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.

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The commencement of our trial could be delayed for a variety of reasons, including:

- obtaining adequate funds to support the trial cost;
- 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
- 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;

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

Besides requiring physician adoption, market acceptance of our Maestro System will depend on successfully communicating the benefits of our VBLOC therapy to three additional constituencies involved in deciding whether to treat a particular patient using such therapy: (1) the potential patients themselves; (2) institutions such as hospitals, where the procedure would be performed and opinion leaders in these institutions; and (3) third-party payors, such as private healthcare insurers and governmental payors, such as Medicare and Medicaid in the 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 next-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

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clinical trial sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, and we may be unable to obtain regulatory approval for, or successfully commercialize, our product.

***Assuming we receive regulatory approval for the Maestro System, modifications to the Maestro System may require additional approval from 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

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reimburse the cost of medical devices. Importantly, third-party payors are increasingly challenging the price of medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. We expect that third-party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our Maestro System and the related surgery and facility costs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our Maestro System will be impaired and our future revenue, if any, would be adversely affected. As such, even if we obtain regulatory clearance or approval for our Maestro System and begin to market it, the availability and level of third-party coverage and reimbursement could substantially affect our ability to commercialize our Maestro System and other products we may develop.

The efficacy, safety, ease of use and cost-effectiveness of our Maestro System and of any competing products will, in part, determine the availability and level of coverage and payment. In particular, we expect that securing coding, coverage and payment for our Maestro System will be more difficult if our clinical trials do not demonstrate a percentage of 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

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System in the United States. Failure by us or one of our manufacturers or suppliers to comply with statutes and regulations administered by the FDA, CE authorities and other regulatory bodies, or failure to adequately respond to any observations, could result in enforcement actions against us or our manufacturers or suppliers, including, restrictions on our product or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

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

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

We 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.

***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.

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### ***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.

The occurrence of any one of these risks could negatively affect our business and results of operations generally. Additionally, operating in international markets also 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.



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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.

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

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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 16 issued U.S. patents, 12 of which pertain to treating gastrointestinal disorders, and 18 U.S. patent applications. We have 10 Australian applications, 11 European patent applications, 2 Chinese applications, 2 Indian applications, and 1 Japanese application. We also have 1 granted Australian patent, and two European patent applications we believe will be granted. In addition, we are the exclusive licensee to two U.S. patent applications 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

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enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the loss of the entire patent or the relevant portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Even if we were to prevail in any litigation, we cannot assure you that we can obtain an injunction that prevents our competitors from practicing our patented technology. Our competitors may independently develop similar or alternative technologies or products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies.

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

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

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

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

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

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our

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

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

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

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

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

### **Risks Relating to Ownership of Our Common Stock**

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

The trading price of our common stock has been highly volatile. Further, our common stock has a limited trading history. Since our public offering in November 2007 through October 31, 2010 our stock price has fluctuated from a low of \$1.52 to a high of \$64.62. The market price for our common stock will be affected by a number of factors, including:

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

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

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

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

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

Although our common stock is listed on the NASDAQ Capital Market, our common stock has experienced low trading volume. Reported average daily trading volume in our common stock for the three month period ended September 30, 2010, was approximately 99,800 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.

### ***Our directors and executive officers hold substantial control over us 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 October 31, 2010), approximately 30.1% of our outstanding common stock immediately following the closing of our December 2010 public offering. Our executive officers, directors and affiliated entities, if acting together, would 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 significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

Sales of substantial amounts of our common stock by us or by our stockholders, announcements of the proposed sales of substantial amounts of our common stock or the perception that substantial sales may be made, could cause the market price of our common stock to decline. We may issue additional shares of our common stock in follow-on offerings to raise additional capital or in connection with acquisitions or corporate alliances and we plan to issue additional shares to our employees, directors or consultants in connection with their services to us. All of the currently outstanding shares of our common stock are freely tradable under federal and state securities laws, except for shares held by our directors, officers and certain greater than five percent stockholders, which may be subject to volume limitations, and shares of common stock acquired upon conversion of the preferred stock issued in connection with our recent private placement offering. 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

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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.

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.

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***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 of the proceeds from the sale of the shares by any of the selling stockholders.

## SELLING STOCKHOLDERS

We are registering the shares of common stock covered by this prospectus on behalf of the selling stockholders named in the table below. Selling stockholders, including their transferees, pledgees or donees or their successors (all of whom may be selling stockholders), may from time to time offer and sell pursuant to this prospectus any or all of the shares. When we refer to “selling stockholders” in this prospectus, we mean those persons listed in the table below, as well as their transferees, pledgees or donees or their successors.

We issued a warrant to purchase 340,400 shares of common stock to Craig-Hallum Capital Group LLC (Craig-Hallum) in a private placement transaction pursuant to the Underwriting Agreement dated December 8, 2010 (the Underwriting Agreement) between us and Craig-Hallum. The warrant was issued in partial consideration for Craig-Hallum’s services as the underwriter of our public offering of common stock and warrants to purchase common stock, which closed on December 14, 2010 (the public offering), for a purchase price of \$100. The warrant has an exercise price of \$2.19 per share, which equals 125% of the aggregate offering price for a share of common stock and corresponding warrant issued in our public offering. The warrant will be exercisable beginning 181 days after the closing date of the public offering and ending five years after the effectiveness date of the registration statement for the public offering, which was December 8, 2010.

We issued 3,394,309 shares of Series A Non-Voting Convertible Preferred Stock (Preferred Stock) together with warrants to purchase 3,394,309 shares of common stock to the selling stockholders pursuant to Securities Purchase Agreements entered into on September 29, 2010 (the Securities Purchase Agreements) in a private placement transaction with several accredited investors (the Private Placement). The purchase price per share of the Preferred Stock was \$1.72, which equaled the consolidated closing bid price of our common stock as reported by the NASDAQ Stock Market on September 29, 2010. The Preferred Stock automatically converted to common stock on a 1:1 basis immediately following the closing of the public offering in accordance with its terms. The warrants have an exercise price of \$2.15 per share, which equals 125% of the consolidated closing bid price of our common stock as reported by the NASDAQ Stock Market on September 29, 2010. The warrants will be exercisable beginning 181 days from the issuance date of the warrants and ending on the fifth anniversary of the date on which the exercise period begins.

The following table sets forth certain information provided to us by the selling stockholders and reflects holdings as of December 31, 2010. Except as set forth in the table below, none of the selling stockholders has had a material relationship with us within the past three years. The number of shares in the column “Number of Shares Registered for Sale Hereby” represents all of the shares, including shares issuable upon the exercise of warrants, that each selling stockholder may offer under this prospectus. The information is based on information provided to us by or on behalf of the selling stockholders in a selling stockholder questionnaire. The selling stockholders may sell some, all or none of their shares. In addition, the selling stockholders may have sold, transferred or otherwise disposed of all or a portion of their shares since the date on which they provided the information regarding their shares in transactions exempt from the registration requirements of the Securities Act. For purposes of the table below, we have assumed that the selling stockholders will sell all of their shares offered pursuant to this prospectus and that any other shares of our common stock beneficially owned by the selling stockholders will continue to be beneficially owned.

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<u>Selling Stockholders<sup>(1)</sup></u>	<u>Number of Shares Beneficially Owned Prior to Offering<sup>(2)(3)</sup></u>	<u>Number of Shares Registered for Sale Hereby<sup>(3)</sup></u>	<u>Number of Shares to be Owned after Completion of the Offering<sup>(2)(4)</sup></u>	<u>Percent of Outstanding Shares to be Owned after Completion of the Offering<sup>(5)</sup></u>
Craig-Hallum Capital Group LLC <sup>(6)</sup>	340,400	340,400	—	—
MPM BioVentures III, L.P. <sup>(7)</sup>	141,172	78,846	62,326	*
MPM BioVentures III-QP, L.P. <sup>(7)</sup>	2,099,657	1,172,676	926,981	3.31%
MPM BioVentures III GmbH & Co. Beteiligungs KG <sup>(7)</sup>	177,428	99,096	78,332	*
MPM BioVentures III Parallel Fund, L.P. <sup>(7)</sup>	63,432	35,428	28,004	*
MPM Asset Management Investors 2002 BVIII LLC <sup>(7)</sup>	41,481	23,168	18,313	*
Bay City Capital Fund IV, LP <sup>(8)</sup>	5,704,952	3,183,414	2,521,538	9.00%
Bay City Capital Fund IV Co-Investment Fund, LP <sup>(8)</sup>	122,969	68,618	54,351	*
Aberdare II Annex Fund, L.P. <sup>(9)</sup>	1,202,846	813,008	389,838	1.39%
Charter Life Sciences, L.P. <sup>(10)</sup>	552,362	433,604	118,758	*
Nordea Specialized Investment Fund—Global Private Equity Fund	119,319	108,402	10,917	*
Paul H. Klingenstein <sup>(11)</sup>	48,685	33,050	15,635	*
Nicholas L. Teti, Jr. <sup>(12)</sup>	51,221	21,680	29,541	*
Mayo Clinic <sup>(13)</sup>	306,630	223,578	83,052	*
Rob Hopfner <sup>(14)</sup>	32,520	32,520	—	—
John H. Odden <sup>(15)</sup>	1,075	826	249	*
Ross S. Bersot <sup>(16)</sup>	42,493	27,100	15,393	*
DAFNA LifeScience Ltd. <sup>(17)</sup>	108,402	108,402	—	—
DAFNA LifeScience Market Neutral Ltd. <sup>(17)</sup>	82,384	82,384	—	—
DAFNA LifeScience Select Ltd. <sup>(17)</sup>	242,818	242,818	—	—
<b>Total</b>	<b>11,482,246</b>	<b>7,129,018</b>	<b>4,353,228</b>	<b>15.36%</b>

\* Less than one percent.

- (1) Information regarding the selling stockholders may change from time to time. Any such changed information will be set forth in supplements to this prospectus if required.
- (2) Includes shares subject to warrants exercisable currently or within 60 days of December 31, 2010 as follows: MPM BioVentures III, L.P., 8,325 shares; MPM BioVentures III-QP, L.P., 123,837 shares; MPM BioVentures III GmbH & Co. Beteiligungs KG, 10,463 shares; MPM BioVentures III Parallel Fund, L.P. 3,740 shares; MPM Asset Management Investors 2002 BVIII LLC, 2,445 shares; Bay City Capital Fund IV, LP, 134,557 shares; Bay City Capital Fund IV Co-Investment Fund, LP, 2,900 shares; Aberdare II Annex Fund, L.P., 103,093 shares; Mayo Clinic, 18,041 shares and Mr. Bersot, 687 shares. Includes shares subject to options exercisable currently or within 60 days of December 31, 2010 as follows: Mr. Klingenstein, 5,953 shares and Mr. Teti, 29,541 shares.
- (3) Includes shares offered by this prospectus which are issuable upon the exercise of warrants not exercisable currently or within 60 days of December 31, 2010 as follows: Craig-Hallum Capital Group LLC, 340,400 shares; MPM BioVentures III, L.P., 39,423 shares; MPM BioVentures III-QP, L.P., 586,338 shares; MPM BioVentures III GmbH & Co. Beteiligungs KG, 49,548 shares; MPM BioVentures III Parallel Fund, L.P. 17,714 shares; MPM Asset Management Investors 2002 BVIII LLC, 11,584 shares; Bay City Capital Fund IV, LP, 1,591,707 shares; Bay City Capital Fund IV Co-Investment Fund, LP, 34,309 shares; Aberdare II Annex Fund, L.P., 406,504 shares; Charter Life Sciences, L.P., 216,802 shares; Nordea Specialized Investment Fund—Global Private Equity Fund, 54,201 shares; Mr. Klingenstein, 16,525 shares; Mr. Teti, 10,840 shares; Mayo Clinic, 111,789 shares; Mr. Hopfner, 16,260 shares; Mr. Odden, 413 shares; Mr. Bersot, 13,550 shares; DAFNA LifeScience Ltd., 54,201 shares; DAFNA LifeScience Market Neutral Ltd., 41,192 shares; and DAFNA LifeScience Select Ltd., 121,409 shares.

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- (4) We do not know when or in what amounts the selling stockholders will offer shares for sale, if at all. The selling stockholders may sell any or all of the shares included in and offered by this prospectus. Because the selling stockholders may offer all or some of the shares pursuant to this offering, we cannot estimate the number of shares that will be held by the selling stockholders after completion of the offering. However, for purposes of this table, we have assumed that after completion of the offering, none of the shares included in and covered by this prospectus will be held by the selling stockholders.
- (5) Based on 27,892,388 shares of common stock outstanding as of December 31, 2010.
- (6) Craig-Hallum Capital Group LLC acted as underwriter for our public offering of common stock and warrants, which closed on December 14, 2010.
- (7) MPM BioVentures III GP, L.P. (BV III GP) and MPM BioVentures III LLC (BV III LLC) are the direct and indirect general partners of MPM BioVentures III, L.P. (BV III), MPM BioVentures III-QP, L.P. (BV III QP), MPM BioVentures III Parallel Fund L.P. (BV III PF), MPM Bio Ventures III GmbH & Co. Beteiligungs KG (BV III KG) and each has shared power to vote and shared power to dispose of the shares held by these funds. Luke Evnin, Ansbert Gadicke, Nicholas Galakatos, Michael Steinmetz, Kurt Wheeler, Nicholas Simon III, and Dennis Henner are each a member of BV III LLC and a manager of MPM Asset Management Investors 2002 BV III LLC (AM LLC) and each has shared power to vote and shared power to dispose of the shares held by these funds. Dr. Evnin and Messrs. Gadicke, Galakatos, Steinmetz, Wheeler, Simon and Henner, each disclaim beneficial ownership of all such shares except to the extent of his proportionate pecuniary interests therein. Dr. Evnin is a member of our Board of Directors.
- (8) Bay City Capital Fund IV, L.P. (Fund IV), Bay City Capital Fund IV Co-Investment Fund, L.P. (Co-Investment IV) and Bay City Capital Management IV LLC (Management IV), each have shared voting power and shared dispositive power of the shares held by each of these funds. Bay City Capital (BCC) is the manager of Management IV, which is the general partner of Fund IV and Co-Investment IV. BCC is also an advisor to Fund IV and Co-Investment IV. Management IV and BCC do not hold shares of common stock or warrants directly but each has sole voting and dispositive power, and are deemed to have beneficial ownership of the common stock and warrants owned by Fund IV and Co-Investment IV because of their roles as general partner and manager, respectively. Carl Goldfischer, a Managing Director of BCC and a member of Management IV, is a member of our Board of Directors.
- (9) Aberdare GP II, L.L.C. (Aberdare GP II), serves as the general partner of Aberdare II Annex Fund, L.P., and has voting and investment control of the shares owned by this fund, and may be deemed to own beneficially such shares. Paul H. Klingenstein, one of our directors, serves as Manager of Aberdare GP II.
- (10) Charter Life Sciences, L.P. beneficially owned more than 5% of our common stock prior to the closing of our initial public offering on November 20, 2007. Donald C. Harrison, M.D., one of our directors, serves as Managing Partner of Charter Life Sciences, L.P.
- (11) Mr. Klingenstein, one of our directors, serves as Manager of Aberdare GP II (see footnote (9) above).
- (12) Mr. Teti is a member of our Board of Directors and also served as a consultant to the Chief Executive Officer of the Company since April 2009.
- (13) Mayo Clinic and/or its affiliates have or have had license agreements and consultant agreements with the Company, under which they have received equity, royalties and/or other payments from the Company. Consistent with Mayo conflict-of-interest policies and procedures, Mayo Clinic and/or its affiliates have participated in pre-clinical and clinical research activities sponsored by the Company. Mayo Clinic and/or its affiliates own shares in the Company.
- (14) Mr. Hopfner is an employee of BCC.
- (15) Mr. Odden is an employee of Aberdare Ventures.
- (16) Mr. Bersot is an employee of BCC.
- (17) Nathan Fischel, MD, CFA and Fariba Ghodsian, Ph.D. exercise shared voting and dispositive power with respect to the shares held of record by DAFNA LifeScience Ltd., DAFNA LifeScience Market Neutral Ltd. and DAFNA LifeScience Select Ltd.

## PLAN OF DISTRIBUTION

We are registering the shares covered by this prospectus to permit the selling stockholders to conduct public secondary trading of the shares from time to time after the date of this prospectus.

The selling stockholders and their successors, including their transferees, pledgees or donees or their successors (all of whom may be selling stockholders), may sell the shares directly to purchasers or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling stockholders or the purchasers of the shares. Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. The discounts, concessions or commissions as to any particular underwriter, broker-dealer or agent may be in excess of those customary in the types of transactions involved, except in the case of an agency transaction not in excess of a customary brokerage commission in compliance with NASDR Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with NASDR IM-2440. The selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. Notwithstanding the foregoing, in no event will the method of distribution of the shares take the form of an underwritten offering of such shares without our prior written agreement.

The shares may be sold in one or more transactions at:

- fixed prices;
- prevailing market prices at the time of sale;
- prices related to the prevailing market prices;
- varying prices determined at the time of sale; or
- negotiated prices.

These prices will be determined by the selling stockholders or by agreement between such selling stockholders and underwriters, broker-dealers or agents. The aggregate proceeds to the selling stockholders from the sale of the shares offered by them will be the purchase price of the shares less discounts and commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of shares to be made directly or through agents. We will not receive any of the proceeds from this offering.

The sales described in this prospectus may be effected in transactions:

- on any national securities exchange or quotation service on which the shares may be listed or quoted at the time of sale or in ordinary brokerage transactions in which the broker-dealer solicits purchasers;
- in the over-the-counter market;
- that are privately negotiated;
- that are a combination of any such methods of sale; or
- through any other method permitted by applicable law.

These transactions may include block trades in which the broker-dealer will attempt to sell the shares as an agent but may position and resell a portion of the block as a principal to facilitate the transaction. The transactions may also include crosses, which are transactions in which the same broker acts as an agent on both sides of the trade.

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In connection with the sale of the shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the shares to close out their short positions, or loan or pledge the shares to broker-dealers which in turn may sell the shares. The selling stockholders may also sell shares of the common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

Our outstanding common stock is listed for trading on the NASDAQ Capital Market.

In order to comply with the securities laws of some states, if applicable, the shares may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states, the shares may not be sold unless they have been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the shares may be “underwriters” within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profits they earn on any resale of the shares may be deemed to be underwriting discounts and commissions under the Securities Act. Selling stockholders who are “underwriters” within the meaning of Section 2(11) of the Securities Act will be subject to the prospectus delivery requirements of the Securities Act, including Rule 172 thereunder, and may be subject to statutory liabilities, including, but not limited to, liability under Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Securities Exchange Act of 1934, as amended (the Exchange Act). Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale shares may not simultaneously engage in market-making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed the selling stockholders of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

To our knowledge, there are currently no plans, arrangements or understandings between any selling stockholders and any underwriter, broker-dealer or agent regarding the sale of the shares. Selling stockholders may ultimately not sell all, and conceivably may not sell any, of the shares offered by them under this prospectus. In addition, we cannot assure you that a selling stockholder will not transfer, devise or gift the shares by other means not described in this prospectus. Furthermore, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 or Rule 144A of the Securities Act or any other available exemption may be sold under Rule 144 or Rule 144A or any other available exemption rather than pursuant to this prospectus.

To the extent required, the specific shares to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement to which this prospectus relates.

We originally issued the shares and warrants to the selling stockholders in two separate private placement transactions exempt from the registration requirements of the Securities Act. In connection with these private placement transactions, we agreed to register (i) 340,400 shares of common stock issuable upon exercise of the

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warrant issued to Craig-Hallum under applicable federal and state securities laws and (ii) 6,788,618 shares of common stock, including 3,394,309 shares of common stock issuable upon the exercise of warrants, held by the investors under applicable federal and state securities laws under specific circumstances and at specific times pursuant to the terms of the Underwriting Agreement and the Securities Purchase Agreements, respectively.

Under Section 4(t) of the Underwriting Agreement, we are obligated to keep the registration statement effective for a period of time at least equal to the term of Craig-Hallum's warrant plus two years following its expiration date. Under the registration rights provisions of the Securities Purchase Agreements, we are obligated to use our best efforts to keep the registration statement effective until the earlier of: (1) the first anniversary of the closing date, which was September 30, 2010; (2) the date on which the registrable securities may be sold pursuant to Rule 144 of the Securities Act without limitations on volume or manner of sales; or (3) such time as all registrable securities purchased by the selling stockholders in the offering have been sold pursuant to a registration statement or Rule 144 of the Securities Act.

The Securities Purchase Agreements also provide for cross-indemnification of the selling stockholders and us and our respective directors, officers and controlling persons against specific liabilities in connection with the offer and sale of the shares, including liabilities under the Securities Act. We have agreed, among other things, to pay all expenses of the registration statement to which this prospectus relates.

Pursuant to the terms of the Securities Purchase Agreements, we may suspend the use of this prospectus under certain circumstances relating to any request by the SEC or other federal or state governmental authority for amendments or supplements to the registration statement or for additional information, the issuance of any stop order suspending the effectiveness of the registration statement, the receipt of notice of the suspension of the qualification or exemption from qualification of the registrable securities for sale in any jurisdiction or any event which necessitates making changes to the registration statement, prospectus or any document incorporated or deemed to be incorporated by reference so that the registration statement or prospectus do not contain any untrue statement of a material fact or omit to state a material fact required to be stated necessary to make the statements contained therein not misleading. Such suspensions shall be considered "qualifying suspensions" provided the suspension period does not exceed 30 days individually, no more than two suspensions occur during any 12 month period and each suspension is separated by a period of at least 30 days. In the event a non-qualifying suspension occurs prior to the date when the selling stockholders may sell registrable securities pursuant to Rule 144 without limitations on volume or manner of sales, we are required to pay to the selling stockholders, beginning on the 10<sup>th</sup> business day after the effectiveness of the non-qualifying suspension and every 30<sup>th</sup> day thereafter that the non-qualifying suspension continues, a penalty amount equal to 1.5% of the purchase price paid by the selling stockholder for the registrable securities purchased and not previously sold; provided, however, that the aggregate penalty shall not exceed 5% of the purchase price paid by the selling stockholders for the registrable securities.

In the event that the SEC takes the position that some or all of the registrable securities may not be included in the registration statement because the inclusion of such registrable securities violates Rule 415 of the Securities Act or the instructions of Form S-3 and/or the registrable securities cannot be sold as an "at the market offering," we will remove from the registration statement the amount of shares necessary to comply with the requirements of Rule 415 and agree to any other restrictions or limitations on the registration and resale of the registrable securities that the SEC may require. Any such required "cut back" of the registrable securities will be allocated among the selling stockholders on a pro rata basis.

## LEGAL MATTERS

Dorsey & Whitney LLP will issue 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, 2009 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 an explanatory paragraph regarding going concern uncertainty), 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](http://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. 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, 2009;
- Quarterly Reports on Form 10-Q for the quarterly periods ended March 31, 2010, June 30, 2010 and September 30, 2010 (The June 30, 2010 and September 30, 2010 quarterly reports were filed as adjusted for the 1-for-6 reverse split of our outstanding common stock that was effected on July 9, 2010);
- Current Reports on Form 8-K filed with the SEC on January 15, 2010, January 20, 2010, January 21, 2010, February 10, 2010, February 12, 2010, February 23, 2010, March 15, 2010, March 17, 2010, April 19, 2010, May 11, 2010, May 19, 2010, June 29, 2010, July 13, 2010, August 2, 2010; October 5, 2010, October 22, 2010, October 29, 2010, November 1, 2010, December 9, 2010, December 10, 2010, December 14, 2010 and January 11, 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





**7,129,018 Shares of Common Stock**

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**PROSPECTUS**

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February 10, 2011

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