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

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**Form S-3**

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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**ENTEROMEDICS INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**48-1293684**  
(I.R.S. Employer  
Identification No.)

**2800 Patton Road**  
**St. Paul, Minnesota 55113**  
**(651) 634-3003**  
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Greg S. Lea**  
**Chief Financial Officer and Secretary**  
**2800 Patton Road**  
**St. Paul, Minnesota 55113**  
**(651) 634-3003**  
(Name, address, including zip code, and telephone number, including area code, of agent for service)

*Copy to:*

**Kenneth L. Cutler**  
**Michael W. Clausman**  
**Dorsey & Whitney LLP**  
**50 South Sixth Street, Suite 1500**  
**Minneapolis, Minnesota 55402**  
**(612) 340-2600**

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**Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.**

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

## [Table of Contents](#)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered(1)	Proposed maximum offering price per unit(2)	Proposed maximum aggregate offering price(2)	Amount of registration fee
Common Stock (\$0.01 par value per share)	15,000,000(3)	\$3.36	\$50,400,000	\$2,813
Common Stock (\$0.01 par value per share)	6,000,000(4)	\$3.36	\$20,160,000	\$1,125
<b>Total</b>	<b>21,000,000</b>	<b>\$3.36</b>	<b>\$70,560,000</b>	<b>\$3,938</b>

- (1) Pursuant to Rule 416(a), this amount also covers additional securities that may become issuable as a result of stock splits, stock dividends or similar transactions.
- (2) Estimated solely for purposes of computing the registration fee pursuant to Rule 457(c), based on the average of the high and low sales prices of the registrant's common stock on August 31, 2009, as reported on the NASDAQ Global Market.
- (3) Represents the aggregate number of shares of common stock of the registrant which may be offered and sold from time to time by the registrant.
- (4) Represents the aggregate number of shares of common stock of the registrant which may be offered and sold from time to time by the selling stockholders named in the prospectus.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission becomes effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Subject to completion, dated September 3, 2009

## PROSPECTUS

21,000,000 Shares



Common Stock

We may from time to time offer and sell up to an aggregate of 15,000,000 shares of our common stock, par value \$0.01 per share, pursuant to this prospectus at prices and on terms to be determined at or prior to the time of sale. In addition, the selling stockholders named in this prospectus may offer and sell up to 6,000,000 shares of common stock owned by the selling stockholders, at prices and on terms to be determined at or prior to the time of sale. We will not receive any proceeds from the sale of shares by the selling stockholders.

This prospectus provides a general description of the common stock we and the selling stockholders may offer. Each time we sell common stock, we will provide the specific terms of such offering and the manner in which we will offer and sell the common stock in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus and the applicable prospectus supplement carefully before you invest in our common stock. This prospectus may not be used to consummate a sale of common stock unless accompanied by the applicable prospectus supplement.

We and the selling stockholders may from time to time offer and sell our respective shares of common stock, in the same offering or in separate offerings, to or through underwriters, dealers and agents or directly to purchasers. If any agents or underwriters are involved in the sale of our common stock, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions or discounts.

Our common stock is quoted on the NASDAQ Global Market under the symbol "ETRM." On September 1, 2009, the closing price of our common stock as reported on the NASDAQ Global Market was \$3.35 per share. As of September 1, 2009, the aggregate market value of our outstanding common stock held by non-affiliates, or the public float, was approximately \$51,121,610, which was calculated based on 15,260,182 shares of outstanding common stock held by non-affiliates and on a price per share of \$3.35, the closing price of our common stock on September 1, 2009. Pursuant to General Instruction I.B.6 of Form S-3, in no event will we sell our common stock in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below \$75.0 million. We have not offered any securities pursuant to General Instruction I.B.6 of Form S-3 during the 12 calendar months prior to and including the date of this prospectus.

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 3 of this prospectus and in the documents we file with the Securities and Exchange Commission that are incorporated by reference in this prospectus before making a decision to purchase our stock.

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

The date of this prospectus is \_\_\_\_\_, 2009.

**TABLE OF CONTENTS**

<a href="#">ABOUT THIS PROSPECTUS</a>	1
<a href="#">ENTEROMEDICS INC.</a>	2
<a href="#">RISK FACTORS</a>	3
<a href="#">CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS</a>	19
<a href="#">USE OF PROCEEDS</a>	20
<a href="#">SELLING STOCKHOLDERS</a>	20
<a href="#">PLAN OF DISTRIBUTION</a>	23
<a href="#">DESCRIPTION OF COMMON STOCK</a>	25
<a href="#">LEGAL MATTERS</a>	28
<a href="#">EXPERTS</a>	28
<a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>	29
<a href="#">INCORPORATION OF DOCUMENTS BY REFERENCE</a>	29

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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) utilizing a “shelf” registration process. Under this shelf registration process, we may offer and sell from time to time up to an aggregate of 15,000,000 shares of our common stock at prices and on terms to be determined at or prior to the time of sale. In addition, this prospectus may be used by the selling stockholders named in this prospectus to offer and sell up to 6,000,000 shares of our common stock as described under the heading “Selling Stockholders.”

This prospectus provides you with a general description of the common stock we and the selling stockholders may offer. Each time we sell common stock under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in the prospectus supplement. You should read both this prospectus and any prospectus supplement, including all documents incorporated herein or therein by reference, together with additional information described under “Where You Can Find More Information” and “Incorporation of Documents by Reference.”

We have not authorized any dealer, salesman or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and the accompanying prospectus supplement. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or the accompanying prospectus supplement. This prospectus and the accompanying prospectus supplement do not constitute an offer to sell or the solicitation of an offer to buy any common stock other than the registered common stock to which they relate, nor do this prospectus and the accompanying prospectus supplement constitute an offer to sell or the solicitation of an offer to buy common stock in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus and the accompanying prospectus supplement is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying prospectus supplement is delivered or common stock is sold on a later date.

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, ENTEROMEDICS and MAESTRO each registered with the United States Patent and Trademark Office, and have received a Notice of Allowance and a third extension of time to file a Statement of Use on our application to register the mark EMPOWER. In addition, the marks VBLOC, MAESTRO and ENTEROMEDICS are the subject of either a trademark registration or application for registration in Australia, Brazil, China, Mexico, the European Community, Saudi Arabia, the United Arab Emirates and Switzerland.

**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, independent of, and prior to, substantial weight loss. 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.

In 2008, we completed enrollment and implantation of subjects in our pivotal clinical study, the EMPOWER trial. The EMPOWER trial is a multi-center, randomized, double-blind, prospective, placebo-controlled pivotal study being conducted in the United States and selected international centers. Assuming that the data from the trial is positive, we plan to use data from our EMPOWER trial to support our premarket approval (PMA) application for the Maestro System, which we expect to submit in late 2009. If the U.S. Food and Drug Administration (FDA) grants us approval, we anticipate we will be able to commercialize the Maestro System in the United States in early 2011. In the event that the Maestro System receives FDA approval, we expect to recruit and retain personnel responsible for commercial operations, sales and marketing, customer service, reimbursement and technical service in order to support the commercial launch of our product. Given the time required to locate and train appropriate personnel, we expect to commence that process prior to actually receiving FDA approval. We will also need to increase production volumes of our products in connection with commercialization. We rely primarily on third-party manufacturers and suppliers to produce our products and will continue to select qualified suppliers and contract manufacturers that can supply products on a commercial scale according to our proprietary specifications.

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, 2008, we had a total of 53 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 securities 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 securities. 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 Business and Industry**

***We are a 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 development stage company with a limited operating history upon which you can evaluate our business. We currently do not have any products cleared or approved for commercialization or any other source of revenue, and we do not expect to have a commercialized product until at least early 2011. We have been engaged in research and development since our inception in 2002 and have invested substantially all of our time and resources in developing our VBLOC therapy, which we intend to commercialize initially in the form of our Maestro System. The success of our business will depend on our ability to obtain regulatory approval to market our Maestro System and any products we may develop in the future and our ability to create product sales, successfully introduce new products, establish our sales force and control costs, all of which we may be unable to do. If we are unable to successfully develop, receive regulatory approval for and commercialize our Maestro System for its indicated use, we may never generate revenue or be profitable and we may have to cease operations. Our lack of a significant operating history also limits your ability to make a comparative evaluation of us, our products and our prospects.

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

We have incurred losses in each year since our formation in 2002. As of December 31, 2008, we had a deficit accumulated during the development stage of \$101.3 million. Our net losses applicable to common stockholders for the fiscal years ended December 31, 2008, 2007 and 2006 were \$37.9 million, \$28.6 million and \$17.7 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) 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 have not received, and may never receive, approval from the FDA or the regulatory body in any other country to market our Maestro 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 on March 4, 2009. We plan initially to launch our product, if approved, in the United States, but ultimately will also seek to commercialize our Maestro System in 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

## [Table of Contents](#)

approval (PMA). The PMA process requires us to prove the safety and efficacy of our Maestro System to the FDA's satisfaction. This process can be expensive and uncertain, requires detailed and comprehensive scientific and human clinical data, generally takes one to three years after a PMA application is filed, and notwithstanding the effort and expense incurred, may never result in the FDA granting a PMA. Because VBLOC therapy represents a novel way to effect weight loss in the treatment of obesity, and because there is a large population of obese patients who might be eligible for treatment, it is possible that the FDA and other regulatory bodies will review an application for approval of our Maestro System with greater scrutiny, which could cause that process to be lengthier and more involved than that for products without such characteristics. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our inability to demonstrate safety or effectiveness to the FDA's satisfaction;
- the data from our preclinical studies and clinical trials may be insufficient to support approval;
- 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 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 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 above 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, 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 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.

***We may be unable to complete our EMPOWER pivotal trial or other 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.***

Our application for an investigational device exemption (IDE) for the EMPOWER pivotal trial, a randomized, prospective, placebo-controlled multi-center trial of our Maestro System in the United States, has been approved by the FDA. In 2008 we completed enrollment and implantation of subjects in the EMPOWER trial. Conducting a clinical trial of this size, which involves screening, assessing, testing, treating and monitoring patients at up to 13 sites across the country and two in Australia, and coordinating with patients and clinical institutions, is a complex and uncertain process.



## [Table of Contents](#)

The completion of the EMPOWER 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 complete our EMPOWER trial and our other clinical trials, these trials may not produce results that are sufficient to support approval of a PMA application.***

We will consider our Maestro System to be effective if the EMPOWER trial demonstrates an average of at least 17 percentage points of excess weight loss (EWL) between the active and control groups at 12 months, with a 97.5% confidence interval of 10 to 24 percentage points of EWL. The FDA has indicated to us that they believe that a 20 to 25 percentage point greater EWL than a control group, absent a known and statistically validated safety profile, is the appropriate efficacy criterion for the EMPOWER trial. Thus, there is a risk that, even if we achieve our endpoint of an average of at least 17 percentage points of EWL between the active and control groups at 12 months, with a 97.5% confidence interval of 10 to 24 percentage points of EWL, the FDA may not approve our Maestro System. To date, we have limited clinical data regarding the efficacy of our therapy at 12 months upon which to evaluate our ability to meet either our or the FDA's proposed efficacy endpoint. Our results and our ability to obtain approval from the FDA for our Maestro System may also depend on the measurement standards we use to evaluate the excess weight loss data. In addition, there is a risk that the FDA may require us to conduct a longer clinical trial, submit additional follow-up data, or engage in other costly and time consuming activities that may delay the FDA's approval of the Maestro System. If our clinical trials fail to produce sufficient data to support a PMA application, 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, to achieve sufficient data to support PMA, we need to perform more or larger clinical trials than planned.

## [Table of Contents](#)

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

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

- our Maestro System may not be accepted in the marketplace by physicians, patients and third-party payors;
- the price of our Maestro System, associated costs of the surgical procedure and treatment and the availability of sufficient third-party reimbursement for the procedure and therapy implantation and follow-up procedures;
- appropriate reimbursement 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;
- patient noncompliance with wearing the external components of the Maestro RF System may render VBLOC therapy less effective in achieving long-term weight loss;
- 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; 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 Medicare, 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 early 2011, 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 EMPOWER, and other third parties to manage the trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, to ensure compliance by patients with clinical protocols or comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for our product. Our agreements with clinical investigators and clinical trial sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, and we may be unable to obtain regulatory approval for, or successfully commercialize, our product.

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

The FDA requires 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-approved device that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use would require a supplemental IDE and possibly additional clinical studies and a separate PMA application. Product changes or revisions will require all the regulatory steps and associated risks discussed above including testing, an IDE supplement and clinical study. We may not be able to obtain approval of supplemental IDEs or PMAs 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.

***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.***

Physicians tend to be slow to change their medical treatment practices because of the time and skill required to learn a new procedure and 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.

## [Table of Contents](#)

***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, and private healthcare insurers, to adequately cover and reimburse the cost of medical devices. Importantly, third-party payors are increasingly challenging the price of medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. We expect that third-party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our Maestro System and the related surgery and facility costs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our Maestro System will be impaired and our future revenue, if any, would be adversely affected. As such, even if we obtain FDA 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 EMPOWER trial does 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 the FDA and other regulatory bodies. In particular we and our manufacturers and suppliers are required to comply with 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. We and

## [Table of Contents](#)

our third-party manufacturers and suppliers have not yet been inspected by the FDA and will have to successfully complete such inspections before we receive regulatory approvals for our Maestro System. Failure by us or one of our manufacturers or suppliers to comply with statutes and regulations administered by the FDA 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 (MDR) regulations that require us to report to the FDA 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 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. Furthermore, we may later discover previously unknown problems with our products, including medically serious device related events. For example, we do not have long-term data on the safety of the Maestro System. Thus, there is a risk that long-term use of our Maestro System could cause injuries or harm, including possible damage to the vagus nerve. Any discovery of previously unknown problems with our product, including medically serious device related events, may result in restrictions on such products, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

***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, 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 obtain regulatory approval from the FDA to use different suppliers or components.

## [Table of Contents](#)

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

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

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

We do not have a sales organization and have no experience as a company in sales, marketing and distribution of our product. To generate sales we will need to 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.

***We may 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 commercialization efforts.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on research and development, including conducting clinical trials for our Maestro System. Even before we receive regulatory approval to market our Maestro System, we expect to spend significant funds commercializing the product, including development of a direct sales force. In 2008, our cash used in operations was \$33.7 million. We expect cash used in operations to decrease in 2009 due to the completion of enrollment and implantation in our EMPOWER trial during 2008. In the years following 2009, we expect that our cash used in operations will be significant, and we may need additional funds to complete the development and commercialization of our Maestro System. After, and possibly prior to, such time we may need to raise substantial additional capital to: continue our research and development programs; commercialize our Maestro System, if approved by the FDA; and fund our operations in general.

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;

## Table of Contents

- 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 acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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

### ***We 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 rapidly expand our operations and grow our research and development, product development and administrative operations. Our growth will require hiring a significant 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

## [Table of Contents](#)

significant strain on our management and financial and operational resources. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems and procedures. Our ability to effectively manage growth depends on our success in attracting and retaining highly qualified personnel, for which the competition may be intense. If we fail to manage these challenges effectively, our business could be harmed.

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

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

We have \$5 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 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



## [Table of Contents](#)

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

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

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

### ***We 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.***

We completed our initial public offering in November 2007. As a public company, we incur significant expenses that we did not incur as a private company. The obligations of being a public company, including substantial public reporting and auditing obligations, require significant expenditures, place additional demands on our management and require the hiring of additional personnel. Section 404 of the Sarbanes-Oxley Act of 2002 and the SEC rules and regulations implementing such act require us to conduct an annual evaluation of our internal control over financial reporting. This process increases our legal and financial compliance costs, and makes some activities more difficult, time consuming or costly. If we fail to have an effectively designed and operating system of internal control, we may be unable to comply with the requirements of Section 404 in a timely manner.

The Sarbanes-Oxley Act of 2002 has required us to adopt new corporate governance, securities disclosure and compliance practices. In response to the requirements of that act, the SEC and the NASDAQ Stock Market have enacted new rules. Compliance with these new rules has increased our legal, financial and accounting costs, and we expect these increased costs to continue indefinitely. These laws and regulations may also make it more difficult for us to attract and retain qualified members of our board of directors or members of senior management.

### ***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

## [Table of Contents](#)

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.

### ***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.

### **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. As of March 12, 2009, we had six issued U.S. patents, two of which pertain to treating gastrointestinal disorders, 23 U.S. patent applications (including two provisional applications), four pending international patent applications (PCT) and seven national stage patent applications, including four European applications, in foreign jurisdictions. 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 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

## [Table of Contents](#)

portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Even if we were to prevail in any litigation, we cannot assure you that we can obtain an injunction that prevents our competitors from practicing our patented technology. Our competitors may independently develop similar or alternative technologies or products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies.

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

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

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

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

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

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not

## [Table of Contents](#)

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 Related to Our Securities

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

The trading price of our common stock has been highly volatile. Further, our common stock has a limited trading history. Since our public offering in November 2007 through February 27, 2009 our stock price has fluctuated from a low of \$0.83 to a high of \$10.77. 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 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.

## [Table of Contents](#)

### ***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, approximately 61.8% of our outstanding common stock as of February 27, 2009. Our executive officers, directors and affiliated entities, if acting together, would be able to control or 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 issued in connection with our recent private placement offering. 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, as of December 31, 2008 certain holders of an aggregate of 10,997,940 shares of our common stock and warrants to purchase our common stock 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:

- our board of directors will be authorized, without prior stockholder approval, to create and issue preferred stock which could be used to implement anti-takeover devices;
- advance notice will be required for director nominations or for proposals that can be acted upon at stockholder meetings;
- our board of directors will be classified such that not all members of our board are elected at one time, 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;
- stockholder action by written consent will be prohibited;
- special meetings of the stockholders will be permitted to be called only by the chairman of our board of directors or by a majority of our board of directors; and

## [Table of Contents](#)

- stockholders will not be permitted to accumulate their votes for the election of directors; and stockholders will be permitted to amend our bylaws only upon receiving a majority of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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

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

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. The payment of dividends on our common stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. 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

Unless otherwise indicated in the prospectus supplement, we intend to use the net proceeds from the sale of common stock under this prospectus for pre-commercialization efforts, ongoing clinical trials, working capital and other general corporate purposes. We will set forth in the particular prospectus supplement our intended use for the net proceeds we receive from the sale of our common stock under such prospectus supplement. We will not receive any proceeds from the sale of common stock by the selling stockholders.

## SELLING STOCKHOLDERS

The selling stockholders named in the table below may from time to time offer and sell pursuant to this prospectus and any applicable prospectus supplement up to 6,000,000 shares of our common stock. 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.

All of the shares of common stock being registered for resale by the selling stockholders were issued upon conversion of shares of preferred stock issued by us in one or more of the following private placements prior to our initial public offering in November 2007 (the IPO): (i) our Series A Preferred Stock financing, which had multiple closings in 2002 and 2003, (ii) our Series B Preferred Stock financing, which closed in 2005 and (iii) our Series C Preferred Stock financing, which had multiple closings in 2006. All of the shares of preferred stock issued in these private placements automatically converted into shares of our common stock upon the completion of our IPO. All of the selling stockholders’ shares included herein are being registered pursuant to the exercise of certain registration rights held by the selling stockholders. See “Description of Common Stock—Registration Rights.”

The following table sets forth certain information provided to us by the selling stockholders. 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 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.

<u>Selling Stockholders</u>	<u>Number of Shares Beneficially Owned Prior to Offering(1)</u>	<u>Number of Shares Registered for Sale Hereby(2)</u>	<u>Number of Shares to be Owned after Completion of the Offering(3)</u>	<u>Percent of Outstanding Shares to be Owned after Completion of the Offering(4)</u>
Donald C. Harrison, M.D.(5)(8)	766,328	4,177	391,974	1.3%
Aberdare II Annex Fund, L.P.(6)	2,339,024	141,076	2,197,948	7.2%
Aberdare Ventures II (Bermuda), L.P.(6)	30,641	16,016	14,625	*
Aberdare Ventures II, L.P.(6)	1,472,681	706,443	766,238	2.6%
Bay City Capital Fund IV Co-Investment Fund, L.P.(7)	5,329,232	28,361	3,985,092	12.9%
Bay City Capital Fund IV, L.P.(7)	5,329,232	1,315,779	3,985,092	12.9%
Charter Life Sciences, L.P.(8)	729,028	370,177	358,851	1.2%



## Table of Contents

<u>Selling Stockholders</u>	<u>Number of Shares Beneficially Owned Prior to Offering(1)</u>	<u>Number of Shares Registered for Sale Hereby(2)</u>	<u>Number of Shares to be Owned after Completion of the Offering(3)</u>	<u>Percent of Outstanding Shares to be Owned after Completion of the Offering(4)</u>
InterWest Partners IX, L.P.(9)	2,564,364	808,244	1,756,120	5.8%
MPM Asset Management Investors 2002 BV3(10)	111,785	33,240	78,545	*
MPM BioVentures III GmbH & Co. Beteiligungs KG(10)	478,143	142,180	335,963	1.1%
MPM BioVentures III L.P.(10)	380,435	113,125	267,310	*
MPM BioVentures III Parallel Fund L.P.(10)	170,940	50,830	120,110	*
MPM BioVentures III-QP L.P.(10)	5,658,252	1,682,538	3,975,714	12.9%
Onset V, L.P.(11)	958,734	514,337	444,397	1.5%
Mayo Foundation for Medical Education and Research(12)	769,529	73,477	696,052	2.3%

\* Less than one percent.

- (1) Represents all of the shares beneficially owned by the selling stockholder as of the date of the selling stockholder questionnaire provided by each holder and includes shares issuable upon the exercise of any warrants and/or stock options owned by the selling stockholder that are exercisable within 60 days of July 31, 2009.
- (2) The amounts in this column do not include any shares issuable pursuant to warrants or options, which may be beneficially owned by the selling stockholders as described in footnotes (5) through (12).
- (3) 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 from time to time pursuant to this prospectus, 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.
- (4) Based on 30,045,406 shares of common stock outstanding as of July 31, 2009.
- (5) Includes 18,958 and 1,015 shares issuable pursuant to options and warrants, respectively, held by Dr. Harrison, which are exercisable currently or within 60 days of July 31, 2009. Dr. Harrison is a member of our Board of Directors and a Managing Partner of CLS Management, LLC. See footnote (8).
- (6) Aberdare GP II, L.L.C. (Aberdare GP II) serves as the general partner of Aberdare II Ventures II, L.P. (Aberdare II), which holds 1,431,388 shares and 41,293 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009, Aberdare Ventures II (Bermuda), L.P. (Aberdare II Bermuda), which holds 29,704 shares and 937 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009, and Aberdare II Annex Fund, L.P. (Aberdare II Annex), which holds 1,720,467 shares and 618,557 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009. Aberdare GP II has voting and investment control of a total of 3,842,346 shares and warrants beneficially owned by Aberdare II, Aberdare II Bermuda and Aberdare II Annex, and may be deemed to own beneficially such shares. Paul Klingenstein, a member of our Board of Directors, is Manager of Aberdare GP II. Mr. Klingenstein has sole voting and dispositive power of 78,733 shares.
- (7) Bay City Capital Fund IV, L.P. (Fund IV) holds 4,337,102 shares and 861,126 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009. Bay City Capital Fund IV Co-Investment Fund, L.P. (Co-Investment IV) holds 93,484 shares and 18,562 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009. Fund IV, Co-Investment IV and Bay City Capital Management IV LLC (Management IV) each have shared voting power and shared dispositive power of a total of 4,430,586 shares and 879,688 warrants exercisable currently or within 60 days of July 31, 2009. Bay City Capital LLC (BCC) is the manager of Management IV, which is the general partner of Fund IV and

## Table of Contents

Co-Investment IV. BCC is also an advisor to Fund IV and Co-Investment IV. Carl Goldfischer, a Managing Director of BCC and a member of Management IV, is a member of our Board of Directors and has sole voting and dispositive power of 18,958 shares.

- (8) CLS Partners, L.P. is the General Partner of Charter Life Sciences, L.P. The General Partner of CLS Partners, L.P. is CLS Management, LLC (CLS Management). The Managing Partners of CLS Management are A. Barr Dolan, Fred M. Schwarzer, Dr. Nelson Teng and Dr. Donald C. Harrison. CLS Management has voting and investment power of the 712,544 shares and 16,484 warrants held by Charter Life Sciences, L.P., which are exercisable currently or within 60 days of July 31, 2009. Dr. Harrison is a member of our Board of Directors and has sole voting and dispositive power of 37,300 shares. See footnote (5).
- (9) InterWest Management Partners IX, LLC (IMP IX) is the General Partner of InterWest Partners IX, L.P. (IWP IX). Harvey B. Cash, Philip T. Gianos, W. Stephen Holmes III, Gilbert H. Kliman, Arnold L. Oronsky, Thomas L. Rosch and Michael B. Sweeney, each is a Managing Director of IMP IX, and Bruce A. Cleveland, Christopher B. Ehrlich, Linda S. Grais, Nina S. Kjellson, Khaled A. Nasr, and Douglas A. Pepper, each is a Venture Member of IMP IX. IMP IX has sole voting and sole dispositive power of 2,225,163 shares and 339,201 warrants exercisable currently or within 60 days of July 31, 2009. Each of the Venture Members and Managing Directors of IMP IX shares voting power and dispositive power of 2,225,163 shares and 339,201 warrants exercisable currently or within 60 days of July 31, 2009. The Venture Members and Managing Directors of IMP IX each expressly disclaim beneficial ownership of the shares, except to the extent of their pecuniary interest. From July 2006 until April 2009, Ellen Koskinas, a member of IMP IX and a former Venture Member of IMP IX, was a member of our Board of Directors. In addition, prior to the completion of our IPO in November 2007, IWP IX was an affiliate of EnteroMedics by virtue of its ownership of more than 10% of our then outstanding common stock.
- (10) MPM BioVentures III, L.P. (BV III) has the sole power to vote and sole power to dispose of 323,996 shares and 56,439 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009, MPM BioVentures III-QP, L.P. (BV III QP) has the sole power to vote and sole power to dispose of 4,818,855 shares and 839,397 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009, MPM BioVentures III Parallel Fund L.P. (BV III PF) has the sole power to vote and sole power to dispose of 145,580 shares and 25,360 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009, MPM BioVentures III GmbH & Co. Beteiligungs KG (BV III KG) has the sole power to vote and sole power to dispose of 407,210 shares and 70,933 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009, and MPM Asset Management Investors 2002 BVIII LLC (AM LLC) has the sole power to vote and sole power to dispose of 95,201 shares and 16,584 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009. MPM BioVentures III GP, L.P. (BV III GP) and MPM BioVentures III LLC (BV III LLC) each have shared power to vote and shared power to dispose of 6,687,770 shares and warrants beneficially owned. BV III GP and BV III LLC are the direct and indirect general partners of BV III QP, BV III, BV III PF and BV III KG. Luke Evnin, Ansbert Gadick, Nicholas Galakatos, Michael Steinmetz, Kurt Wheeler, Nicholas Simon III, and Dennis Henner each have shared power to vote and shared power to dispose of 6,799,555 shares and warrants beneficially owned. Dr. Evnin and Messrs. Gadick, Galakatos, Steinmetz, Wheeler, Simon and Henner are each a member of BV III LLC and a manager of AM LLC, and each disclaims 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 and has sole voting and dispositive power of 18,958 shares.
- (11) Onset V Management, LLC is the General Partner of Onset V, L.P. and has sole voting and investment power over the 958,734 shares held by Onset V, L.P. Terry L. Opendyck, Robert F. Kuhling, Jr., Susan A. Mason, F. Leslie Bottorff, David A. Lane and Raman Khanna are the Managing Directors of Onset V Management, LLC. Prior to the closing of our Private Placement on February 24, 2009, Onset V, L.P. beneficially owned more than 5% of our then outstanding common stock.
- (12) Includes 108,247 shares issuable pursuant to warrants exercisable currently or within 60 days of July 31, 2009. Mayo Foundation for Medical Education and Research and/or its affiliates have existing license agreements and consultant agreements with EnteroMedics, under which they have received equity, royalties

and/or other payments from us. Mayo Foundation for Medical Education and Research has an existing consulting agreement with one of our officers. In addition, consistent with Mayo conflict-of-interest policies and procedures, Mayo Clinic and/or its affiliates have participated in preclinical and clinical research activities sponsored by us. Harry N. Hoffman, III has voting and dispositive power with respect to these shares.

#### **PLAN OF DISTRIBUTION**

We or the selling stockholders named in this prospectus may offer and sell the common stock being offered hereby from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We or the selling stockholders may sell the common stock separately or together:

- through one or more underwriters or dealers in a public offering and sale by them;
- through agents; and/or
- directly to one or more purchasers.

We or the selling stockholders may distribute the common stock from time to time in one or more transactions:

- at a fixed price or prices, which may be changed;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

We or the selling stockholders may solicit directly offers to purchase the common stock being offered by this prospectus. We or the selling stockholders may also designate agents to solicit offers to purchase the common stock from time to time. We will name in a prospectus supplement any agent involved in the offer or sale of our common stock.

If we or the selling stockholders utilize a dealer in the sale of the common stock being offered by this prospectus, we or the selling stockholders will sell the common stock to the dealer, as principal. The dealer may then resell the common stock to the public at varying prices to be determined by the dealer at the time of resale.

If we or the selling stockholders utilize an underwriter in the sale of the common stock being offered by this prospectus, we will execute an underwriting agreement with the underwriter at the time of sale and we will provide the name of any underwriter in the prospectus supplement that the underwriter will use to make resales of the common stock to the public. In connection with the sale of the common stock, we or the purchasers of common stock for whom the underwriter may act as agent may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the common stock to or through dealers, and the underwriter may compensate those dealers in the form of discounts, concessions or commissions.

We will provide in the applicable prospectus supplement any compensation we or the selling stockholders will pay to underwriters, dealers or agents in connection with the offering of the common stock, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the common stock may be deemed to be underwriters within the meaning of the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the common stock may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof.

## [Table of Contents](#)

Shares of common stock sold by us that are covered by this prospectus will be listed on the NASDAQ Global Market, upon official notice of issuance. To facilitate the offering of common stock, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the common stock, which involve the sale by persons participating in the offering of more common stock than we sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option. In addition, these persons may stabilize or maintain the price of the common stock by bidding for or purchasing common stock in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if common stock sold by them is repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the common stock at a level above that which might otherwise prevail in the open market. The transactions may be discontinued at any time.

We or the selling stockholders may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the common stock from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

We or the selling stockholders may enter into derivative transactions with third parties, or sell common stock not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the parties may sell common stock covered by this prospectus and the applicable prospectus supplement, including short sale transactions. If so, the third party may use common stock pledged by us or others to settle those sales or to close out any related open borrowings of common shares, and may use common stock received from us in settlement of those derivatives to close out any related open borrowings of common shares. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be identified in the applicable prospectus supplement or a post-effective amendment to this registration statement.

The underwriters, dealers and agents may engage in transactions with us, or perform services for us, in the ordinary course of business.

## DESCRIPTION OF COMMON STOCK

*The following summary of the terms of the common stock we may offer using this prospectus does not purport to be complete and is subject to and qualified in its entirety by reference to our Amended and Restated Certificate of Incorporation (certificate of incorporation) and Amended and Restated Bylaws (bylaws) copies of which have been previously filed by us with the SEC and are incorporated by reference in this prospectus. See “Incorporation of Documents by Reference.”*

### General

Our authorized capital stock consists of 85,000,000 shares of common stock, \$0.01 par value per share, and 5,000,000 shares of preferred stock, \$0.01 par value per share. As of June 30, 2009, we had 30,045,406 shares of common stock outstanding. As of June 30, 2009, we had an aggregate of 5,137,288 shares of common stock reserved for issuance upon exercise of outstanding stock options granted under our 2003 Stock Incentive Plan, and an aggregate of 9,236,046 shares of common stock reserved for issuance upon the exercise of outstanding stock warrants.

The holders of our common stock are generally entitled to one vote for each share held on all matters submitted to a vote of the stockholders and do not have any cumulative voting rights. Holders of our common stock are entitled to receive proportionally any dividends declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock.

The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of holders of shares of any series of preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, holders of our common stock are entitled to share ratably in all assets remaining after payment of all debts and other liabilities, subject to the prior rights of any outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. All outstanding shares of our common stock are validly issued, fully paid and nonassessable. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and nonassessable.

### Registration Rights

As of the date of this prospectus, the holders of approximately 10,997,940 shares of common stock have the right to require us to register these shares, together with other shares of common stock they hold, under the Securities Act under the circumstances set forth below. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. The following description of the terms and registration rights provisions of the investor rights agreement is intended as a summary only and is qualified in its entirety by reference to the investor rights agreement which has been previously filed by us with the SEC and is incorporated by reference in this prospectus. See “Incorporation of Documents by Reference.”

*Demand Registration Rights.* On no more than one occasion during any twelve-month period, the holders of at least 50% of our registrable shares have the right to request that we register all or a portion of the registrable shares then held by the requesting stockholders, provided that the shares requested to be registered have an aggregate value of at least \$5.0 million. Such a registration is referred to as a demand registration and we are required to use our best efforts to cause any such demand registration to become effective under the Securities Act. The demand registration rights will cease after we have effected two such demand registrations. In addition to the demand registration rights, the holders of registrable shares will have the right to request that we register on Form S-3 all or a portion of the registrable shares held by them, provided that the holders propose to sell registrable securities at an aggregate price of at least \$1.0 million (less any underwriter discounts or fees) pursuant to such registration statement on Form S-3. Such registration is referred to as a Form S-3 registration. We will not be obligated to effect a demand registration or a Form S-3 registration within 180 calendar days of the effective date of an immediately preceding Form S-3 registration of our securities.

## [Table of Contents](#)

*Incidental Registration Rights.* If we propose to register shares of our common stock under the Securities Act (other than a registration relating solely to the initial public offering of our securities, the sale of securities of participants in our stock option plan, a registration relating to a corporate reorganization or transaction under Rule 145 of the Securities Act, a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of registrable securities, or a registration in which the only common stock being registered is common stock issuable upon conversion of debt securities that are also being registered), the holders of registrable shares will have the right to require us to register all or a portion of the registrable shares then held by them. In the event that any registration in which the holders of registrable shares participate pursuant to the registration rights agreement is an underwritten public offering, the number of registrable shares to be included may, in specified circumstances, be limited due to market conditions.

The registration rights described in the investor rights agreement are subject to customary restrictions such as minimums, blackout periods and, if a registration is underwritten, any limitations on the number of shares to be included in the underwritten offering imposed by the managing underwriter. The investor rights agreement also contains customary indemnification and contribution provisions.

All expenses of registration under the investor rights agreement, including the legal fees of one counsel for the holders, but excluding underwriting discounts and commissions will be paid by us. The investor rights agreement is governed by Delaware law.

### **Anti-Takeover Effects of Delaware Law and Certain Provisions of our Certificate of Incorporation and Bylaws**

We have elected to be governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally will have an anti-takeover effect for transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for our common stock. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a three-year period following the time that the stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes, among other things, a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation’s voting stock. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or
- at or after the time the stockholder became interested, the business combination was approved by the board and authorized at a stockholder meeting by the affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

Our certificate of incorporation and bylaws provide for the board to be divided into three classes of directors serving staggered, three-year terms. The classification of the board has the effect of requiring at least two annual stockholder meetings, instead of one, to replace a majority of members of the board. Subject to the rights of the holders of any outstanding series of preferred stock, our certificate of incorporation will authorize only the board

## [Table of Contents](#)

to fill vacancies, including newly created directorships. Accordingly, this provision could prevent a stockholder from obtaining majority representation on the board by enlarging the board of directors and filling the new directorships with its own nominees. Our certificate of incorporation will also provide that directors may be removed by stockholders only for cause and only by the affirmative vote of holders of a majority of the outstanding shares of our voting stock.

Under our bylaws, any vacancy on our board of directors resulting from an enlargement of our board or the death, resignation, retirement, disqualification or other cause (other than removal for cause), may only be filled by vote of a majority of our directors then in office, even if less than a quorum. The limitations on the removal of directors and filling of vacancies could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, control of us.

The affirmative vote of the holders of at least a majority of our voting stock is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation or bylaws described in the prior two paragraphs.

Our certificate of incorporation provides that stockholders may not take any action by written consent in lieu of a meeting and our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting. In addition, our bylaws provide that only our board of directors or our chairman may call a special meeting of stockholders. Business transacted at any special meeting of stockholders must be limited to matters relating to the purpose stated in the notice of the special meeting.

To be “properly brought” before an annual meeting, the proposals or nominations must be:

- specified in the notice of meeting;
- brought before the meeting by or at the direction of our board of directors; or
- brought before the meeting by a stockholder entitled to vote at the meeting who has given to our corporate secretary the required advance written notice, in proper form, of the stockholder’s intention to bring that proposal or nomination before the meeting and who was a stockholder of record on the date on which notice is given.

In addition to other applicable requirements, for a stockholder proposal or nomination to be properly brought before an annual meeting by a stockholder, the stockholder generally must have given notice in proper written form to our corporate secretary not less than 90 days nor more than 120 days prior to the first anniversary of the preceding year’s annual meeting of stockholders. In the event that no annual meeting was held in the previous year or the annual meeting is called for a date that is not within 30 days from the anniversary date of the preceding year’s annual meeting date, written notice by a stockholder in order to be timely must be received not later than the 10th day following the day on which the first public disclosure of the date of the annual meeting was made. Although our bylaws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our bylaws may have the effect of precluding the consideration of some business at a meeting if the proper procedures are not followed or may discourage or defer a potential acquiror from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Delaware law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation’s certificate of incorporation or bylaws, unless the certificate of incorporation or bylaws require a greater percentage. Our bylaws may be amended or repealed by a majority vote of our board of directors, subject to any limitations set forth in the bylaws, and may also be amended or repealed by the stockholders by the affirmative vote of the holders of a majority of the votes that all the stockholders would be entitled to cast in any annual election of directors. The majority stockholder vote would be in addition to any separate class vote that might in the future be required pursuant to the terms of any series of preferred stock that might be outstanding at the time any of these amendments are submitted to stockholders.

### **Liability Limitations and Indemnification**

Our bylaws provide that we must indemnify our directors and officers and that we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions. In addition, our certificate of incorporation provides that our directors will not be personally liable for monetary damages to us for breaches of their fiduciary duty as directors, except to the extent that the Delaware law statute prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

These provisions may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duties. These provisions may also have the effect of reducing the likelihood of derivative litigation against directors and officers, even though such an action, if successful, might otherwise benefit us and our stockholders. Furthermore, you may lose some or all of your investment in our common stock if we pay the costs of settlement or damage awards against our directors and officers under these provisions. We believe these provisions, the director and officer insurance we maintain, and the indemnification agreements we have entered into with our directors and officers are necessary to attract and retain talented and experienced directors and officers.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Wells Fargo Bank, National Association.

### **LEGAL MATTERS**

Dorsey & Whitney LLP will issue a legal opinion as to the validity of the common stock offered by this prospectus.

### **EXPERTS**

The consolidated financial statements incorporated in this prospectus by reference from our Annual Report on Form 10-K 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, 2006, adoption of the provisions of Financial Accounting Standards Board Statement No. 123(R), *Share-Based Payment*), 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 common stock 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 common stock 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, 2008;
- Quarterly Reports on Form 10-Q for the quarters ended March 31, 2009 and June 30, 2009;
- Current Reports on Form 8-K filed on January 29, 2009 (as amended by our Current Report on Form 8-K/A filed on February 10, 2009), February 10, 2009, February 25, 2009, April 3, 2009, April 29, 2009 (Except with respect to Item 2.02), May 11, 2009 and June 2, 2009; 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 information filed (rather than furnished) 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 the termination of the offering. 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

**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth the estimated costs and expenses in connection with the sale and distribution of the common stock being registered hereby, other than underwriting discounts and commissions. All of the amounts shown are estimates, except the Securities and Exchange Commission (SEC) registration fee. The expenses listed will be paid by EnteroMedics Inc.

SEC registration fee	\$ 3,938
Legal fees and expenses	50,000
Printing expenses	15,000
Accountants' fees and expenses	15,000
Transfer agent and registrar fees	5,000
Blue sky fees and expenses	5,000
Miscellaneous expenses	1,062
Total	<u>\$95,000</u>

**Item 15. Indemnification of Directors and Officers**

Article 6 of the amended and restated certificate of incorporation of EnteroMedics Inc. (the Company) provides that no director of the Company shall be personally liable to us or the Company's stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except for liability (i) for any breach of the director's duty of loyalty to the Company or its stockholders, (ii) for acts or omissions not in good faith or which involved intentional misconduct or a knowing violation of law, (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit.

Article 8 of the Company's bylaws provides that the Company will indemnify each person who was or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she, or a person of whom he or she is the legal representative, is or was a director or officer of the Company or is or was serving at the request of the Company as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee or agent or in any other capacity while serving as a director, officer, employee or agent (all such persons are referred to as an indemnitee), shall be indemnified and held harmless by the Company, against all expenses, liability and loss (including attorneys' fees, judgments, fines, penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if such indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. The Company's bylaws provide that the Company will indemnify any indemnitee seeking indemnity in connection with a proceeding (or part thereof) initiated by such person only if such proceeding (or part thereof) was authorized by the Company's board of directors. The Company will indemnify the indemnitee for expenses incurred in defending any such proceeding in advance of its final disposition to the extent not prohibited by law. Such indemnification will only be made if the indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Expenses must be advanced to an indemnitee under certain circumstances.

## [Table of Contents](#)

As a condition precedent to the right of indemnification, an indemnitee must give the Company notice of the action for which indemnity is sought and the Company must have the right to participate in such action or assume the defense thereof.

Article 8 of the Company's bylaws further provides that the indemnification provided therein is not exclusive, and provides that no amendment, termination or repeal of the relevant provisions of the Delaware law statute or any other applicable law will diminish the rights of any Indemnitee to indemnification under the Company's certificate of incorporation.

Section 145 of the Delaware law statute provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he or she is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses that the Court of Chancery or such other court shall deem proper.

The Company has director and officer insurance providing for indemnification for its directors and officers for certain liabilities and such insurance provides for indemnification of the Company's directors and officers for liabilities under the Securities Act of 1933, as amended.

### **Item 16.**      *List of Exhibits*

The exhibits filed with this registration statement are set forth on the exhibit index following the signature page and are incorporated by reference in their entirety into this item.

### **Item 17.**      *Undertakings*

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

## Table of Contents

*Provided, however,* that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5) or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii) or (x) for the purpose of providing the information required by Section 10(a) of the Securities Act shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however,* that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

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## Table of Contents

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of St. Paul, State of Minnesota, on September 3, 2009.

ENTEROMEDICS INC.

By: /s/ Mark B. Knudson, Ph.D.  
Mark B. Knudson, Ph.D.  
President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Mark B. Knudson and Greg S. Lea, and each of them, his true and lawful attorneys-in-fact and agents, each acting alone, with the powers of substitution and revocation, for him and in his name, place and stead, in any and all capacities, to sign a Registration Statement on Form S-3, and any and all amendments (including post-effective amendments or any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933) thereto, relating to the offer and sale by EnteroMedics Inc. of up to an aggregate of 15,000,000 shares of its common stock and the offer and sale of up to 6,000,000 shares of common stock by the selling stockholders named in the prospectus, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all such attorneys-in-fact and agents or any of them, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the date indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Mark B. Knudson, Ph.D.</u> Mark B. Knudson, Ph.D.	President and Chief Executive Officer, Chairman and Director (principal executive officer)	September 3, 2009
<u>/s/ Greg S. Lea</u> Greg S. Lea	Senior Vice President and Chief Financial Officer (principal financial and accounting officer)	September 3, 2009
<u>/s/ Luke Evnin, Ph.D.</u> Luke Evnin, Ph.D.	Director	September 3, 2009
<u>/s/ Catherine Friedman</u> Catherine Friedman	Director	September 3, 2009
<u>/s/ Carl Goldfischer, M.D.</u> Carl Goldfischer, M.D.	Director	September 3, 2009

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[Table of Contents](#)

<u>/s/ Bobby I. Griffin</u> Bobby I. Griffin	Director	September 3, 2009
<u>/s/ Donald C. Harrison, M.D.</u> Donald C. Harrison, M.D.	Director	September 3, 2009
<u>/s/ Paul H. Klingenstein</u> Paul H. Klingenstein	Director	September 3, 2009
<u>/s/ Nicholas L. Teti, Jr.</u> Nicholas L. Teti, Jr.	Director	September 3, 2009
<u>/s/ Jon T. Tremmel</u> Jon T. Tremmel	Director	September 3, 2009

**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
1.1*	Form of Underwriting Agreement.
4.1	Form of Common Stock Certificate. (Incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended, filed with the Securities and Exchange Commission on August 14, 2007 (File No. 333-143265)).
4.2	Amended and Restated Investors' Rights Agreement, dated as of July 6, 2006, by and between the Registrant and the parties named therein. (Incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1, as amended, filed on May 25, 2007 (File No. 333-143265)).
5.1**	Opinion of Dorsey & Whitney LLP.
23.1**	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
23.2**	Consent of Dorsey & Whitney LLP (included in Exhibit 5.1 to this registration statement).
24.1**	Power of Attorney (included on signature page to this registration statement).

\* To be filed by amendment or by a report filed under the Securities Exchange Act of 1934, as amended, and incorporated by reference herein.

\*\* Filed herewith.



[Letterhead of Dorsey & Whitney LLP]

EnteroMedics Inc.  
2800 Patton Road  
St. Paul, MN 55113

Re: Registration Statement on Form S-3

Ladies and Gentlemen:

We have acted as counsel to EnteroMedics Inc., a Delaware corporation (the "Company"), in connection with a Registration Statement on Form S-3 (the "Registration Statement") relating to (i) the offering and sale by the Company from time to time of up to 15,000,000 shares of its common stock, par value \$0.01 per share (the "Common Stock"), and (ii) the offering and sale by certain selling stockholders identified in the Registration Statement from time to time of up to 6,000,000 shares of Common Stock (the "Selling Stockholders Shares").

We have examined such documents and have reviewed such questions of law as we have considered necessary and appropriate for the purposes of our opinions set forth below.

In rendering our opinions, we have assumed the authenticity of all documents submitted to us as originals, the genuineness of all signatures and the conformity to authentic originals of all documents submitted to us as copies. We have also assumed the legal capacity for all purposes relevant hereto of all natural persons. As to questions of fact material to our opinions, we have relied upon certificates of officers of the Company and of public officials.

Based on the foregoing, we are of the opinion that:

1. The Company has the authority pursuant to its Amended and Restated Certificate of Incorporation (the "Certificate") to issue up to 85,000,000 shares of Common Stock. Upon adoption by the Company's Board of Directors or a duly constituted and empowered committee thereof of resolutions in sufficient form and content under the Delaware General Corporation Law, as then in effect, and the Company's Certificate and Amended and Restated Bylaws (the "Bylaws"), as then in effect, to authorize a particular issuance of Common Stock and upon the due execution, issuance and delivery of certificates representing the Common Stock (or, if uncertificated, the making of valid book-entry notations in the stock register of the Company) and payment for such Common Stock in the manner contemplated by such resolutions and by the Registration Statement, the prospectus included therein (the "Prospectus") and the related prospectus supplement(s) (each, a "Prospectus Supplement"), such Common Stock will be validly issued, fully paid and nonassessable.
2. The Selling Stockholders Shares have been duly authorized and validly issued, and are fully paid and nonassessable.

The opinions set forth above are subject to the qualification and exception that, in rendering the opinions set forth above in paragraph 1, we have assumed that, at the time of the authentication and delivery of the Common Stock, (i) the applicable resolutions referred to above will not have been modified or rescinded, (ii) there will not have occurred any change in the law affecting the authorization, execution, delivery, validity or enforceability of the Common Stock, the Registration Statement and any required post-effective amendment thereto, (iii) the Registration Statement, the Prospectus and any and all Prospectus Supplements required by applicable law have all become effective under the Securities Act of 1933, as amended, and will continue to be effective, (iv) such Common Stock will be issued and sold with such terms and in such manner as is described in the Registration Statement (as amended from time to time), the Prospectus included therein (as amended from time to time) and any related Prospectus Supplement and in compliance with the Securities Act of 1933, as amended, the rules and regulations thereunder, and any applicable state securities laws, all as then in effect, (v) neither the issuance and sale of such Common Stock nor the compliance by the Company with the terms thereof will result in a violation of the Certificate or Bylaws of the Company as then in effect, any agreement or instrument then binding upon the Company or any order then in effect of any court or governmental body having jurisdiction over the Company, and (vi) the Company has a sufficient number of shares of Common Stock authorized under its Certificate as then in effect for the issuance of the Common Stock.

Our opinions expressed above are limited to the laws of the State of Delaware, and the federal laws of the United States of America.

We hereby consent to your filing of this opinion as an exhibit to the Registration Statement and to the reference to our firm under the caption "Validity of Securities" contained in the Prospectus constituting part of the Registration Statement.

Dated: September 3, 2009

Very truly yours,

/s/ Dorsey & Whitney LLP

KLC

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in this Registration Statement on Form S-3 of our report dated March 5, 2009, relating to the consolidated financial statements of EnteroMedics Inc. and subsidiary (the "Company") (which report expresses an unqualified opinion and includes an explanatory paragraph relating to the January 1, 2006, adoption of the provisions of Financial Accounting Standards Board Statement No. 123(R), *Share-Based Payment*), appearing in the Annual Report on Form 10-K of the Company for the year ended December 31, 2008, and the reference to us under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Deloitte & Touche LLP

Minneapolis, Minnesota

September 2, 2009