

**PROSPECTUS SUPPLEMENT**  
(To Prospectus dated May 6, 2010)



**8,800,000 Shares of Common Stock**  
**Warrants to Purchase 1,760,000 Shares of Common Stock**

We are offering 8,800,000 shares of our common stock, par value \$0.01 per share, together with warrants to purchase 1,760,000 shares of common stock in this offering. This prospectus supplement also covers the shares of common stock issuable from time to time upon the exercise of these warrants. Each share of common stock sold in this offering will be sold with a warrant to purchase 0.20 of a share of common stock at an exercise price of \$1.90 per share (115% of the aggregate offering price of a share and corresponding warrant). Each share and corresponding warrant will be sold at an aggregate public offering price of \$1.65.

Our common stock is listed on the NASDAQ Capital Market under the symbol "ETRM." We do not intend to list the warrants to be sold in this offering on any securities exchange. On September 22, 2011, the last reported sale price of our common stock on the NASDAQ Capital Market was \$1.86 per share. As of September 23, 2011, the aggregate market value of our outstanding common stock held by non-affiliates (the public float) was approximately \$58.2 million, which was calculated based on 21,074,940 shares of outstanding common stock held by non-affiliates and on a price per share of \$2.76, the closing price of our common stock on July 25, 2011. 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 supplement.

**Investing in our securities involves risks. See "[Risk Factors](#)" beginning on page S-9 of this prospectus supplement.**

|                                  | Per Share and<br>Corresponding<br>Warrant | Total         |
|----------------------------------|---|---------------|
| Public offering price            | \$ 1.65                                   | \$ 14,520,000 |
| Underwriting discounts           | \$ 0.099                                  | \$ 871,200    |
| Proceeds, before expenses, to us | \$ 1.551                                  | \$ 13,648,800 |

In addition to the underwriting discount, we have agreed to pay up to \$125,000 of the fees and expenses of the underwriter in connection with this offering. See "Underwriting" beginning on page S-32 of this prospectus supplement.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

The underwriter expects to deliver the shares of common stock and warrants to the purchasers on or about September 28, 2011.

**Craig-Hallum Capital Group**

The date of this prospectus supplement is September 23, 2011.

TABLE OF CONTENTS

|   | <u>Page</u> |
|---|-------------|
| <b>Prospectus Supplement</b>  |             |
| <a href="#">About this Prospectus Supplement</a>                          | S-1         |
| <a href="#">Prospectus Supplement Summary</a>                             | S-2         |
| <a href="#">The Offering</a>  | S-7         |
| <a href="#">Risk Factors</a>  | S-9         |
| <a href="#">Cautionary Statement Regarding Forward-Looking Statements</a> | S-28        |
| <a href="#">Use of Proceeds</a>   | S-29        |
| <a href="#">Dilution</a>  | S-30        |
| <a href="#">Description of the Warrants</a>                               | S-31        |
| <a href="#">Underwriting</a>  | S-32        |
| <a href="#">Legal Matters</a>   | S-33        |
| <a href="#">Experts</a>   | S-33        |
| <a href="#">Where You Can Find More Information</a>                       | S-33        |
| <a href="#">Incorporation of Documents by Reference</a>                   | S-34        |
| <b>Prospectus</b>   |             |
| <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> | 22          |
| <a href="#">USE OF PROCEEDS</a>   | 22          |
| <a href="#">RATIO OF EARNINGS TO FIXED CHARGES</a>                        | 22          |
| <a href="#">SELLING STOCKHOLDERS</a>                                      | 23          |
| <a href="#">DESCRIPTION OF COMMON STOCK</a>                               | 26          |
| <a href="#">DESCRIPTION OF PREFERRED STOCK</a>                            | 30          |
| <a href="#">DESCRIPTION OF DEBT SECURITIES</a>                            | 32          |
| <a href="#">DESCRIPTION OF SECURITIES WARRANTS</a>                        | 46          |
| <a href="#">DESCRIPTION OF UNITS</a>                                      | 48          |
| <a href="#">PLAN OF DISTRIBUTION</a>                                      | 48          |
| <a href="#">LEGAL MATTERS</a>   | 49          |
| <a href="#">EXPERTS</a>   | 49          |
| <a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>                       | 50          |
| <a href="#">INCORPORATION OF DOCUMENTS BY REFERENCE</a>                   | 50          |

### **About this Prospectus Supplement**

This prospectus supplement is a supplement to the accompanying prospectus dated May 6, 2010 that is also a part of this document. This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission (SEC) using a “shelf” registration process. Under the shelf registration process, from time to time, we may sell any of the securities described in the accompanying prospectus in one or more offerings. In this prospectus supplement, we provide you with specific information about the terms of this offering. Both this prospectus supplement and the accompanying prospectus include important information about us, our securities and other information you should know before investing in our securities. This prospectus supplement also adds, updates and changes information contained in the accompanying prospectus. To the extent that any statement that we make in this prospectus supplement is inconsistent with the statements made in the accompanying prospectus, the statements made in the accompanying prospectus are deemed modified or superseded by the statements made in this prospectus supplement. You should read both this prospectus supplement and the accompanying prospectus as well as the additional information described under the headings “Incorporation of Documents by Reference” on page S-34 and “Where You Can Find More Information” on page S-33 of this prospectus supplement before investing in our securities.

You should rely only on the information contained in this prospectus supplement, the accompanying prospectus, the documents we have incorporated by reference in this prospectus supplement and the accompanying prospectus and any free writing prospectus we might provide you. We have not, and the underwriter has not, authorized anyone to provide you with different information. We are not making an offer of shares of our securities in any state where the offer or sale is not permitted. You should not assume that the information provided by this prospectus supplement, the accompanying prospectus, as well as the information we have previously filed with the SEC that is incorporated by reference herein, is accurate as of any date other than the date of each of these documents. Our business, financial condition, results of operations and prospects may have changed since those dates.

For purposes of this prospectus supplement and the accompanying prospectus, references to the terms “we,” “us,” “our,” “EnteroMedics,” and “the Company” refer to EnteroMedics Inc., a Delaware corporation, and our subsidiary, unless the context otherwise requires.

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

## Prospectus Supplement Summary

*This summary highlights selected information about us, this offering and information appearing elsewhere in this prospectus supplement, in the accompanying prospectus and in the documents we incorporate by reference. This summary is not complete and does not contain all the information you should consider before investing in our securities pursuant to this prospectus supplement and the accompanying prospectus. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this prospectus supplement and the accompanying prospectus, including "Risk Factors" beginning on page S-9 of this prospectus supplement and the other information that we incorporated by reference herein.*

### **Our Business**

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 delivers VBLOC therapy. We believe VBLOC therapy limits the expansion of the stomach, helps control hunger sensations between meals, reduces the frequency and intensity of stomach contractions and produces 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. We believe that our Maestro System will allow bariatric surgeons to help obese patients who are concerned about the risks and complications associated with gastric banding and gastric bypass surgery. In addition, data from our VBLOC-DM2 ENABLE trial outside the United States demonstrates that VBLOC therapy may hold promise in improving the obesity-related co-morbidities of diabetes and hypertension. We are conducting, or plan to conduct, further studies in each of these co-morbidities to assess VBLOC therapy's potential in addressing multiple indications.

### **Our Solution**

Our proprietary Maestro System delivers VBLOC therapy via two small electrodes that are laparoscopically implanted and placed in contact with the trunks of the vagus nerve just above the junction between the esophagus and the stomach, near the diaphragm. By intermittently blocking, or interrupting, naturally occurring neural impulses on the vagus nerves, our therapy is designed to reduce hunger feelings between meals, limit the expansion of the stomach during eating and reduce the frequency and intensity of stomach contractions. In addition, we believe VBLOC therapy also reduces the absorption of calories by decreasing the secretion of digestive enzymes. The resulting physiologic effects of VBLOC therapy are intended to produce a feeling of early and prolonged fullness following smaller meal portions and, by intermittently blocking the vagus nerve and allowing it to return to full function between therapeutic episodes, we have limited the body's natural tendency to circumvent the therapy, all of which we believe will result in long-term weight loss.

We have designed our Maestro System to address a significant market opportunity that exists for a safe, effective and less-invasive therapy that is intended to address the underlying causes of hunger and obesity. Our Maestro System is designed to offer each of the following benefits, which we believe will lead to the adoption of VBLOC as the therapy of choice for obesity:

- preserves normal anatomy;
- allows continued ingestion and digestion of most foods;

- may be implanted on an outpatient basis and adjusted non-invasively;
- offers a favorable safety profile; and
- targets multiple factors that contribute to hunger and obesity.

We believe existing options for the treatment of obesity have seen limited adoption to date due to efficacy and safety concerns and a range of potential side effects.

## Clinical Development & Commercialization

### Clinical Development

We are currently evaluating the Maestro System in human clinical trials conducted in the United States and internationally. Based on our preliminary preclinical and clinical findings, we believe that our Maestro System has the potential to offer people with obesity a less invasive, safe and effective treatment. Below is a summary of our clinical trial results to date:

| Clinical Study  | Location | Number of Patients | Study Duration (Years) | Efficacy % Excess Weight Loss (EWL) <sup>(1)(2)</sup> |
|---|----------|--------------------|------------------------|---|
| <b>First Generation Maestro RF System – Powered by an external battery and controller</b> |          |                    |                        |   |
| VBLOC-1   | OUS      | 31                 | 0.5                    | 14.2% (6 months)                                      |
| VBLOC-RF2   | OUS      | 38                 | 3                      | 23.0% (2 years)                                       |
| EMPOWER   | US       | 294                | 2/5                    | 19.8% (2.5 years) <sup>(3)</sup>                      |
| <b>Second Generation Maestro RC System – Powered by an internal rechargeable battery</b>  |          |                    |                        |   |
| VBLOC-RC1   | OUS      | 5                  | 1/5                    | 25.9% (1 year)  |
| VBLOC-DM2   | OUS      | 28                 | 1/5                    | 24.6% (1.5 years)                                     |
| ReCharge  | US       | ~234               | 1/5                    | Enrolling <sup>(4)</sup>                              |

- (1) Excess weight represents the difference between a subject’s actual weight and the subject’s weight assuming a BMI of 25, which is considered healthy. EWL is reported as the percentage of excess weight that is lost by the subject.
- (2) EWL results reported for the following numbers of patients: VBLOC-RF2, 18 patients; EMPOWER, 107 patients; VBLOC-DM2, 22 patients.
- (3) For the EMPOWER trial, the average EWL at 12 months was 16.6% EWL (BMI) from implant (12.1% from initiation, MetLife) for the treatment arm and 16.4% EWL (BMI) from implant (12.0% from initiation, MetLife) for the control arm.
- (4) The first implant for our ReCharge trial occurred in May 2011.

On October 2, 2009, we announced preliminary results from our first pivotal clinical study, the EMPOWER trial, a multi-center, randomized, double-blind, prospective, placebo-controlled pivotal study being conducted in the United States and selected international centers. Initial results from the trial indicated that the study did not meet its primary and secondary efficacy endpoints in that the weight loss for the treatment arm was not statistically different from the control arm in which therapy was turned off. The study did meet its safety endpoint. Our further review of the data suggests that: (i) patients that used the device for the prescribed amount of time (9 hours) had clinically meaningful weight-loss; (ii) both the treatment and control arm subjects experienced comparable, significant, dose-dependent EWL at 12 months; and (iii) there was an unanticipated therapeutic effect in the control group.

In October 2010, we received an unconditional approval from the U.S. Food and Drug Administration (FDA) for a pivotal trial using our second generation fully implantable Maestro Rechargeable (RC) System, the ReCharge trial, a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in approximately 234 morbidly obese subjects enrolled at up to 12 U.S. centers. All patients in the study will receive an implanted device and will be randomized in a 2:1 allocation to treatment or control groups. The control group will receive a non-functional device during the study period. All patients are expected to participate in a weight management counseling program.

### **Commercialization**

We have begun the enrollment process for the ReCharge trial and in May 2011 announced that the first patient had been implanted in the ReCharge trial. We expect completion of all implants by the end of 2011. Assuming that we successfully enroll and implant the trial, conclude the 12-month blinding period at the end of 2012 and achieve favorable results, we plan to use data from that trial to support a premarket approval (PMA) application for the Maestro System, which we expect to submit after analyzing and compiling the clinical data. We anticipate that we will be able to commercialize the Maestro System in the United States in late 2013 at the earliest.

We have begun to take the initial steps necessary to commercialize the Maestro RC System in Australia and other countries, which includes applying for European CE Mark certification and Australian Therapeutic Goods Administration (TGA) approval. During the first quarter of 2011 we received European CE Mark certification of the Maestro RC System and are currently in the application process with the TGA for supply in Australia of the Maestro RC System and intend to commercialize the device following receipt of that approval, which we anticipate to occur during the fourth quarter of 2011. We also continue to explore select European markets to commercialize the Maestro RC System.

On March 28, 2011, we entered into a multi-year distribution agreement with Device Technologies Australia Pty Limited (Device Technologies) appointing Device Technologies as our exclusive distributor of the Maestro RC System in Australia and New Zealand during the term of the agreement.

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

### **Our Strategy**

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

- achieve regulatory approval for VBLOC therapy using our Maestro System;
- drive the adoption and endorsement of VBLOC therapy through obesity therapy experts;

- commercialize our products using a distribution network or direct sales and marketing effort outside the United States;
- commercialize our products using a direct sales and marketing effort within the United States;
- identify appropriate coding, obtain coverage and payment for the Maestro System;
- expand and protect our intellectual property position; and
- leverage our VBLOC technology for other disease states.

## **The Obesity Epidemic**

### ***United States***

Obesity has been identified by the U.S. Surgeon General as the fastest growing cause of disease and death in the United States. Currently, the Centers for Disease Control and Prevention (CDC) estimates that there are more than 72 million obese adults in the United States, having a Body Mass Index (BMI) of 30 or higher. BMI is calculated by dividing a person's weight in kilograms by the square of their height in meters. It is estimated that by 2015, over 40% of American adults could be obese. According to data from the U.S. Department of Health and Human Services, almost 80% of adults with a BMI above 30 have an obesity-related disease or disorder, also called a co-morbidity, and almost 40% have two or more of these co-morbidities.

As of 2000, the Department of Health and Human Services estimated the overall economic costs of obesity in the United States to be \$117 billion per year. In an abstract sponsored and co-authored by the CDC, it was noted that in 2008 these costs could have risen to \$147 billion per year.

### ***International***

Obesity is also a significant health problem outside of the United States, with as many as 400 million people worldwide estimated to be obese and 1.6 billion adults estimated to be overweight, according to the World Health Organization (WHO). WHO predicts that approximately 2.3 billion adults will be overweight and more than 700 million people worldwide will be obese by 2015.

In Australia, 62% of all adults are either overweight (37%) or obese (25%) and by 2025 as many as 7.2 million Australians could be obese. The cost of obesity exceeds \$21 billion annually and the current Federal Minister has elevated obesity to a national priority. The rate of bariatric surgical procedures performed in Australia has grown by 800% over the last decade with approximately 13,900 bariatric surgeries performed in Australia in 2008 (less than 2% of that total are gastric bypass).

## **Intellectual Property**

As of the date of this prospectus supplement, we have 18 issued U.S. patents, 14 of which pertain to treating gastrointestinal disorders, and 17 U.S. patent applications. We have four granted European patents and three granted Australian patents. We also have eight Australian patent applications, nine European patent applications, three Chinese patent applications, three Indian patent applications and two Japanese patent applications. In addition, we are the exclusive licensee to one U.S. patent and one patent application owned by Mayo Foundation for Medical Education and Research, which are unrelated to our VBLOC therapy.

## **Risks Associated with Our Business**

Our business is subject to numerous risks discussed more fully in the section entitled "*Risk Factors*" beginning on page S-9 of this prospectus supplement. 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 have incurred losses since inception and we anticipate that we will continue to incur increasing losses for the foreseeable future. We have not received, and may never receive, approval from the FDA or the regulatory body in any country other than the European Community to market our Maestro System for the treatment of obesity. If we obtain regulatory approval for our Maestro System, our efforts to commercialize our product may not succeed or may encounter delays which could significantly harm our ability to generate revenue. In addition, we may be unable to complete our ReCharge, EMPOWER 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 in the United States and impair our financial position.

**Our Corporate Information**

We were incorporated in Minnesota in December 2002 under the name Beta Medical, Inc. In 2003 we changed our name to EnteroMedics Inc. and in 2004 we reincorporated in Delaware. Our principal executive offices are located at 2800 Patton Road, St. Paul, Minnesota 55113, and our telephone number is (651) 634-3003. Our website address is [www.enteromedics.com](http://www.enteromedics.com). The information on, or that may be accessed through, our website is not a part of, or incorporated by reference, in this prospectus supplement. As used in this prospectus supplement, references to “we,” “our,” “us” and “EnteroMedics” refer to EnteroMedics Inc. and its subsidiary unless the context requires otherwise.



**The Offering**

|   |  |
|---|--|
| Securities offered by us  | 8,800,000 shares of common stock together with warrants to purchase 1,760,000 shares of common stock   |
| Offering price  | \$1.65 per share of common stock and corresponding warrant to purchase 0.20 of a share of common stock   |
| Description of the warrants                                       | <p>The warrants are exercisable at an exercise price of \$1.90 per share (115% of the aggregate offering price for a share of common stock and corresponding warrant) for a period of five years beginning on the closing date of this offering. The warrants do not allow for cashless exercise. Subject to compliance with any applicable securities laws, any portion of a warrant will be transferable upon surrender of the warrant. Holders of warrants issued in this offering will not be permitted to exercise those warrants for an amount of common stock that would result in the holder owning more than 19.99% of our common stock outstanding after the exercise.</p> <p>We will have the right to redeem the warrants issued in this offering, in whole or in part, at a redemption price of \$0.01 per warrant at any time after any date on which the closing price of our common stock, as reported on the principal exchange or trading facility on which it is then traded, has equaled or exceeded \$1.00 more than the exercise price of the warrants for ten consecutive trading days. We are required to provide 30 days' prior written notice to the warrant holders of our intention to redeem the warrants; provided, that we may not provide this notice until the earlier to occur of (a) 30 days following the date we initially release the results of the blinded portion of our ReCharge trial or (b) June 30, 2013. We will not have the right to redeem a warrant if the holder's exercise of such warrant would result in the holder owning more than 19.99% of our common stock outstanding after the exercise. See "Description of the Warrants."</p> |
| Common stock to be outstanding after this offering <sup>(1)</sup> | 36,698,527 shares  |
| Use of proceeds   | We intend to use the net proceeds of this offering to continue work toward regulatory approval of our product in the United States, for international commercialization efforts, for clinical and product development activities and for other working capital and general corporate purposes. See "Use of Proceeds."  |
| Risk factors  | Investing in our securities involves a high degree of risk. Please see "Risk Factors" beginning on page S-9 of this prospectus supplement and the discussion of risk factors contained in our annual, quarterly and current reports filed with the SEC under the Securities Exchange Act of 1934, as amended (the Exchange Act), which are incorporated by reference into this prospectus supplement, to read about certain factors you should consider before deciding whether to invest in the securities offered by this prospectus supplement and the accompanying prospectus.   |
| NASDAQ Capital Market Symbol                                      | ETRM   |

- (1) The number of shares of our common stock that will be outstanding immediately after this offering is based on 27,898,527 shares outstanding as of June 30, 2011 and excludes:
- 22,217,523 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2011 at a weighted average exercise price of \$2.60 per share;
  - 1,986,991 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2011 at a weighted average exercise price of \$3.80 per share;
  - 2,247,746 shares of our common stock reserved for future issuance under our 2003 Stock Incentive Plan, as amended, as of June 30, 2011; and
  - 1,760,000 shares of our common stock issuable upon the exercise of the warrants to be sold in this offering.

## Risk Factors

*An investment in our securities involves a high degree of risk. You should carefully consider the risk factors set forth below and in the accompanying prospectus and the additional risk factors contained in our annual, quarterly and current reports, as well as any amendments thereto, as filed with the SEC under the Exchange Act, before deciding whether to invest in our securities. Additional risks and uncertainties that are not yet identified may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.*

### **Risks Related to Our Financial Condition and Capital Requirements**

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

We are a clinical development stage company with a limited operating history upon which you can evaluate our business. We currently do not have any products cleared in the United States or approved for commercialization or any other source of revenue, and we do not expect to have a commercialized product earlier than the fourth quarter of 2011 outside the United States and not until late 2013 within the United States, if at all. We have been engaged in research and development and clinical trials since our inception in 2002 and have invested substantially all of our time and resources in developing our VBLOC therapy, which we intend to commercialize initially in the form of our Maestro System. The success of our business will depend on our ability to obtain regulatory approval to market our Maestro System and any products we may develop in the future and our ability to create product sales, successfully introduce new products, establish our sales force and control costs, all of which we may be unable to do. If we are unable to successfully develop, receive regulatory approval for and commercialize our Maestro System for its indicated use, we may never generate revenue or be profitable and we may have to cease operations. Our lack of a significant operating history also limits your ability to make a comparative evaluation of us, our products and our prospects.

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

We have incurred losses in each year since our formation in 2002. As of June 30, 2011, we had experienced net losses during the development stage of \$161.2 million. Our net loss applicable to common stockholders for the fiscal years ended December 31, 2010, 2009 and 2008 was \$17.3 million, \$31.9 million and \$37.9 million, respectively. We have funded our operations to date principally from the sale of our securities and through the issuance of indebtedness. Development of a new medical device, including conducting clinical trials and seeking regulatory approvals, is a long, expensive and uncertain process. If our Maestro System is approved for marketing by the FDA, Australian Therapeutic Goods Administration (TGA) or regulatory authority of another country we expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our general and administrative expenses to increase as we continue to add the infrastructure necessary to support operating as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur significant and increasing operating losses for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with developing new medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on research and development, including conducting current and future clinical trials for our Maestro System, and initiating the commercialization of our product. Cash used in operations was \$13.7 million, \$24.7 million and \$33.7 million for the fiscal years ended December 31, 2010, 2009 and 2008, respectively. We

## [Table of Contents](#)

expect that our cash used in operations will continue to be significant in the upcoming years, and we may eventually need to raise additional capital to continue our research and development programs, commercialize our Maestro System in Australia or the United States, if approved by the TGA or FDA, respectively, or other countries, and fund our ongoing operations.

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

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

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

Additional capital may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we complete may contain terms that are not favorable to us or our stockholders. Issuing public equity or debt securities may also be more costly or time-consuming for us because the aggregate market value of our common stock held by non-affiliates (public float) is less than \$75.0 million (calculated in accordance with the SEC rules and regulations), which limits the size of offerings we may make using a Form S-3 registration statement to 1/3 of our public float for any twelve month period. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

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

As a public company, we incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial

controls and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations result in increased legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure. In particular, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. We have incurred and continue to expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. Moreover, if we do not comply with the requirements of Section 404, or if we identify deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

#### **Risks Associated with Development and Commercialization of Our Maestro System**

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

We do not have the necessary regulatory approvals to market our Maestro System in the United States or in any foreign market other than the European Community for which we received CE Mark approval for our Maestro RF System in March 2009 and for our Maestro RC System in March 2011. We plan initially to launch our product, if approved, in countries outside the United States. We are in the application process with the TGA for supply in Australia of the Maestro RC System and intend to commercialize the device following receipt of that approval, which we anticipate to occur during the fourth quarter of 2011.

In order to market our Maestro System outside of the United States, we will need to establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries may differ from that required to obtain FDA approval. The regulatory approval process in other countries may also include all of the risks detailed below regarding FDA approval in the United States. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. While we have received the European CE Mark for our Maestro RF System and our Maestro RC System, we cannot assure you when, or if, we will be able to commence sales in the European Economic Area or obtain approval to market our Maestro System in other countries outside the United States.

We cannot market our product in the United States unless it has been approved by the FDA. The FDA approval process involves, among other things, successfully completing clinical trials and obtaining a premarket approval (PMA). The PMA process requires us to prove the safety and efficacy of our Maestro System to the FDA's satisfaction. This process can be expensive and uncertain, requires detailed and comprehensive scientific and human clinical data, generally takes one to three years after a PMA application is filed, and notwithstanding the effort and expense incurred, may never result in the FDA granting a PMA. Because VBLOC therapy represents a novel way to effect weight loss in the treatment of obesity, and because there is a large population of obese patients who might be eligible for treatment, it is possible that the FDA and other regulatory bodies will review an application for approval of our Maestro System with greater scrutiny, which could cause that process to be lengthier and more involved than that for products without such characteristics. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our inability to demonstrate safety or effectiveness to the FDA's satisfaction;

## Table of Contents

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

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

We may not obtain the necessary regulatory approvals to market our Maestro System in the United States or anywhere else. Even if we obtain approval, the FDA or other regulatory authorities may require expensive or burdensome post-market testing or controls. Any delay in, failure to receive or maintain, or significant limitation on approval for our Maestro System could prevent us from generating revenue or achieving profitability and we may be forced to cease operations.

***The preliminary results of the blinded segment of our EMPOWER trial were not sufficient to support approval of a PMA application, and this has delayed regulatory approval of our Maestro System.***

In September 2009, we completed the blinded segment of our EMPOWER pivotal trial, a randomized, prospective, placebo-controlled multi-center trial of our Maestro System in the United States. Based on our initial analysis, the EMPOWER trial did not meet its primary and secondary efficacy endpoints in that the weight loss for the treatment arm was not statistically different from the control arm in which therapy was turned off. The study did meet its safety endpoint. The inability to achieve our primary and secondary efficacy endpoints in the EMPOWER trial has delayed our timeline for achieving regulatory approval of the Maestro System in the U.S. and caused us to need additional capital to fund a new pivotal trial. We may never be able to produce sufficient data to support a PMA application with the FDA or commercialize a product in the U.S.

***We may be unable to enroll and complete ReCharge, a pivotal trial using our second generation Maestro RC System, or other clinical trials, or we may experience significant delays in completing our clinical trials, which could prevent or delay regulatory approval of our Maestro System and impair our financial position.***

In October 2010, we obtained an unconditional Investigational Device Exemption (IDE) for a pivotal trial using our second generation Maestro RC System. Assuming that we successfully enroll and implant the trial and achieve favorable results, we plan to use data from that trial to support a PMA application for the Maestro System. We have begun the enrollment process for the ReCharge trial and in May 2011 announced that the first patient had been implanted in the ReCharge trial. Conducting a clinical trial of this size, which involves screening, assessing, testing, treating and monitoring patients at several sites across the country and possibly internationally, and coordinating with patients and clinical institutions, is a complex and uncertain process.

The completion of trial enrollment could be delayed for a variety of reasons, including:

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

## Table of Contents

Once the trial has begun, the completion of the trial, and our other ongoing clinical trials, could be delayed, suspended or terminated for several reasons, including:

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

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

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

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

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

- our Maestro System may not be accepted in the marketplace by physicians, patients and third-party payors;
- the price of our Maestro System, associated costs of the surgical procedure and treatment and the availability of sufficient third-party reimbursement for the procedure and therapy implantation and follow-up procedures;
- appropriate reimbursement and/or coding options may not exist to enable billing for the system implantation and follow-up procedures;
- we may not be able to sell our Maestro System at a price that allows us to meet the revenue targets necessary to generate revenue for profitability;
- the frequency and severity of any side effects of our VBLOC therapy;

## Table of Contents

- physicians and potential patients may not be aware of the perceived effectiveness and sustainability of the results of VBLOC therapy provided by our Maestro System;
- we, or the investigators of our product, may not be able to have information on the outcome of the trials published in medical journals;
- the availability and perceived advantages and disadvantages of alternative treatments;
- any rapid technological change may make our product obsolete;
- we may not be able to have our Maestro System manufactured in commercial quantities or at an acceptable cost;
- we may not have adequate financial or other resources to complete the development and commercialization of our Maestro System or to develop sales and marketing capabilities for our Maestro System; and
- we may be sued for infringement of intellectual property rights and could be enjoined from manufacturing or selling our products.

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

If our VBLOC therapy, or any other neuroblocking therapy for other gastrointestinal diseases and disorders that we may develop, does not achieve an adequate level of acceptance by the relevant constituencies, we may not generate significant product revenue and may not become profitable. The earliest we expect to be able to commercialize our Maestro System is the fourth quarter of 2011 outside the United States and not until late 2013 in the United States, if at all. If we are not successful in the commercialization of our Maestro System for the treatment of obesity we may never generate any revenue and may be forced to cease operations.

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

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



## [Table of Contents](#)

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

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

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

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

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

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

Healthcare providers generally rely on third-party payors, including governmental payors, such as Medicare and Medicaid in the U.S., and MSAC in Australia, as well as private healthcare insurers, to adequately cover and reimburse the cost of medical devices. Importantly, third-party payors are increasingly challenging the price of medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. We expect that third-party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our Maestro System and the related surgery and facility costs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our Maestro System will be impaired and our future revenue, if any, would be adversely affected. As such, even if we obtain regulatory

## [Table of Contents](#)

clearance or approval for our Maestro System and begin to market it, the availability and level of third-party coverage and reimbursement could substantially affect our ability to commercialize our Maestro System and other products we may develop.

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

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

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

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

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

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by our European Notified Body and the FDA and other regulatory bodies. In particular we and our manufacturers and suppliers are required to comply with ISO requirements, Good Manufacturing Practices (GMP), which for medical devices is called the Quality System Regulation (QSR), and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval. The FDA enforces the QSR through unannounced inspections and the CE system enforces its certification through inspections and audits as well. We and our third-party manufacturers and suppliers have not yet been inspected by the FDA but have received European ISO certification to standards ISO 13485:2003 and will have to continue to successfully complete such inspections to maintain regulatory approvals for sales outside the United States and will have to successfully complete such inspections before we receive regulatory approvals for our Maestro System in the United States. Failure by us or one of our manufacturers or suppliers to comply with statutes and regulations administered by the FDA, CE authorities and other regulatory bodies, or failure to adequately respond to any observations, could result in enforcement actions against us or our manufacturers or suppliers, including, restrictions on our product or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

If any of these actions were to occur it would harm our reputation and cause our product sales to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with

## [Table of Contents](#)

applicable regulatory requirements. If the FDA or any other regulatory body finds their compliance status to be unsatisfactory, our commercialization efforts could be delayed, which would harm our business and our results of operations.

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

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

***We may not be successful in our efforts to utilize our VBLOC therapy to treat co-morbidities associated with obesity and other gastrointestinal diseases and disorders.***

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

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

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

## [Table of Contents](#)

time, which could delay completion of our clinical trials or commercialization of our Maestro System. In addition, we may be required to use different suppliers or components to obtain regulatory approval from the FDA.

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

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

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

We do not have a sales organization and have no experience as a company in sales, marketing and distribution of our product. We have entered into an agreement with Device Technologies, a third-party distributor in Australia, to commence our commercial product launch. To generate sales and commence our commercial product launch in other geographic regions we may need to identify and enter into other third-party distributor agreements. There is no assurance that we can do so on economically acceptable terms or that if we do so, that third party will be successful in selling our product. In the rest of the world and the United States, we will also develop a sales and marketing infrastructure or contract with third parties to perform that function. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. Even if we obtain approval from the FDA to market our Maestro System, we may be unable to develop an effective sales and marketing organization on a timely basis, if at all. If we develop our own sales and marketing capabilities, our sales force will be competing with the experienced and well-funded marketing and sales organizations of our more established competitors. If we are unable to establish our own sales and marketing capabilities, we will need to contract with third parties to market and sell our product. In this event, our profit margins would likely be lower than if we performed these functions ourselves. In addition, we would necessarily be relying on the skills and efforts of others for the successful marketing of our product. If we are unable to establish and maintain effective sales and marketing capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

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

We intend to commercialize our products internationally, initially in Australia and the European Community, and subsequently in other international markets, if any, in which we obtain necessary regulatory approvals. Conducting international operations would subject us to unique risks, including:

- unfamiliar legal requirements with which we would need to comply;
- fluctuations in currency exchange rates;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;

## Table of Contents

- increased financial accounting and reporting burdens and complexities; and
- reduced or varied protection for intellectual property rights in some countries.

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

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

Our success depends on the services of our senior management and other key research and development employees. The loss of the services of one or more of our officers or key research and development employees could delay or prevent the successful completion of our clinical trials and the commercialization of our Maestro System. Upon receiving regulatory approval for our product, we expect to expand our operations and grow our research and development, product development and administrative operations. Our growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

### ***We may be unable to manage our growth effectively.***

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

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

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

We have \$5.0 million of product liability insurance, which covers the use of our Maestro System and VBLOC therapy in our clinical trials and any commercial sales, 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

## [Table of Contents](#)

attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our Maestro System and VBLOC therapy in the market.

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

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

If we are successful in achieving regulatory approval to market our Maestro System, our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs.

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

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as "qui tam" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "whistleblowers," may share in any amounts paid by the entity to the 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

## [Table of Contents](#)

federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations.

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

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

### **Risks Related to Intellectual Property**

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

Our commercial success depends in part on our ability to obtain protection in the United States and other countries for our Maestro System and VBLOC therapy by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. To date, we have 18 issued U.S. patents, 14 of which pertain to treating gastrointestinal disorders, and 17 U.S. patent applications. We have four granted European patents and three granted Australian patents. We also have eight Australian patent applications, nine European patent applications, three Chinese patent applications, three Indian patent applications and two Japanese patent applications. In addition, we are the exclusive licensee to one U.S. patent and one patent application owned by Mayo Foundation for Medical Education and Research, which are unrelated to our VBLOC therapy. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. We expect to incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third party's products or patents in litigation or administrative proceedings, including patent interferences or re-examinations. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the loss of the entire patent or the relevant portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Even if we were to prevail in any litigation, we cannot assure you that we can obtain an injunction that prevents our competitors from practicing our patented technology. Our competitors may



## [Table of Contents](#)

independently develop similar or alternative technologies or products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies.

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

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

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

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

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

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



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

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

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

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

## **Risks Relating to this Offering and Ownership of 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 September 22, 2011 our stock price has fluctuated from a low of \$1.52 to a high of \$64.62, as adjusted for the 1-for-6 reverse split of our common stock that was effected on July 9, 2010. The market price for our common stock will be affected by a number of factors, including:

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

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

## [Table of Contents](#)

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

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

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

Although our common stock is listed on the NASDAQ Capital Market, our common stock has experienced low trading volume. Reported average daily trading volume in our common stock for the three month period ended June 30, 2011, was approximately 50,891 shares. Although we believe that this offering will improve the liquidity for our common stock, there is no assurance that the offering will increase the volume of trading in our common stock. Limited trading volume subjects our common stock to greater price volatility and may make it difficult for you to sell your shares at a price that is attractive to you.

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

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

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

If you purchase securities in this offering, you will experience immediate dilution of \$0.73 per share of common stock purchased based on a public offering price of \$1.65 per share and corresponding warrant because the price that you pay will be substantially greater than the adjusted net tangible book value per share of common stock that you acquire. See the section entitled "Dilution" in this prospectus supplement for a more detailed description of this dilution.

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

Our executive officers and directors and entities affiliated with them beneficially own, in the aggregate (including options and warrants exercisable currently or within 60 days of June 30, 2011), approximately 37.0% of our outstanding common stock, and approximately 29.3% of our outstanding common stock immediately following the closing of this offering. Our executive officers, directors and affiliated entities, if acting together, could be able to influence significantly all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other significant corporate transactions. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as

## [Table of Contents](#)

part of a sale of our company and may affect the market price of our common stock. This concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

Sales of substantial amounts of our common stock by us or by our stockholders, announcements of the proposed sales of substantial amounts of our common stock or the perception that substantial sales may be made, could cause the market price of our common stock to decline. We may issue additional shares of our common stock in follow-on offerings to raise additional capital or in connection with acquisitions or corporate alliances and we plan to issue additional shares to our employees, directors or consultants in connection with their services to us. All of the currently outstanding shares of our common stock are freely tradable under federal and state securities laws, except for shares held by our directors, officers and certain greater than five percent stockholders, which may be subject to volume limitations. Following the expiration of lock-up agreements entered into for the benefit of the underwriter of this offering by certain holders of our common stock, including our directors and executive officers and their affiliated entities, 6,868,863 shares of our common stock will become eligible for sale in the public markets from time to time, subject to restrictions under the Securities Act of 1933, as amended (the Securities Act). The underwriter may, in its sole discretion and at any time, without notice, release all or any portion of the shares of common stock subject to the lock-up agreements for sale in the public and private markets prior to the expiration of the lock-up. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time and could reduce the market price of our common stock.

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

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

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

- the ability of our board of directors to create and issue preferred stock without stockholder approval, which could be used to implement anti-takeover devices;
- the authority for our board of directors to issue without stockholder approval up to 85,000,000 shares of common stock, that, if issued, would dilute the ownership of our stockholders;
- the advance notice requirement for director nominations or for proposals that can be acted upon at stockholder meetings;
- a classified and staggered board of directors, which may make it more difficult for a person who acquires control of a majority of our outstanding voting stock to replace all or a majority of our directors;
- the prohibition on actions by written consent of our stockholders;
- the limitation on who may call a special meeting of stockholders;
- the prohibition on stockholders accumulating their votes for the election of directors; and

## Table of Contents

- the ability of stockholders to amend our bylaws only upon receiving a majority of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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

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

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

***There is currently no established trading market for the warrants and we do not expect that one will develop.***

The warrants to be sold in this offering will not be listed on the NASDAQ Capital Market or any other securities exchange and there is currently no established trading market for the warrants. We do not intend to make a market in the warrants and do not expect that one will develop. Therefore, you may have to hold the warrants you purchase in this offering until such time, if any, as you wish to exercise the warrants or we redeem them.

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

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

### **Cautionary Statement Regarding Forward-Looking Statements**

This prospectus supplement 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 supplement, including under “Risk Factors,” and the documents incorporated by reference in this prospectus supplement. Any forward-looking statement contained in this prospectus supplement and the documents incorporated by reference speaks only as of the date on which the statement is made, and EnteroMedics undertakes no obligation to update any forward-looking statement or statements to reflect events or circumstances that occur after the date on which the statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time, and it is not possible for EnteroMedics to predict all of the factors, nor can EnteroMedics assess the effect of each factor on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statement.

### **Use of Proceeds**

We estimate that the net proceeds to us from the sale of the securities offered by us in this offering will be approximately \$13.3 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds of this offering to continue work toward regulatory approval of our product in the United States, for international commercialization efforts, for clinical and product development activities and for other working capital and general corporate purposes. We have not yet determined with certainty the manner in which we will allocate these net proceeds. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering. The amounts and timing of these expenditures will vary depending upon a number of factors, including FDA and foreign regulatory approval for our product, success of research and product development efforts, timing and success of initiating the commercialization of our product, future sales growth, cash generated from future operations and actual expenses to operate our business. Pending the uses described above, we intend to invest the net proceeds in United States government securities and other short-term, investment-grade, interest-bearing instruments.

## Dilution

A purchaser of our securities in this offering will be diluted to the extent of the difference between the price per share of our common stock and corresponding warrant in this offering and the net tangible book value per share of our common stock after this offering. As of June 30, 2011, our historical net tangible book value was \$20.4 million, or \$0.73 per share of common stock, based on 27,898,527 shares of our common stock outstanding at June 30, 2011. Our historical net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of our common stock outstanding as of June 30, 2011.

After giving effect to our sale in this offering of 8,800,000 shares of our common stock together with warrants to purchase 1,760,000 shares of our common stock at a public offering price of \$1.65 per share and corresponding warrant and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of June 30, 2011 would have been \$33.7 million, or \$0.92 per share of our common stock. This amount represents an immediate increase of net tangible book value to our existing stockholders of \$0.19 per share and an immediate dilution of \$0.73 per share to the new investors purchasing securities in this offering. The following table illustrates this per share dilution:

|   |               |
|---|---------------|
| Public offering price per share and corresponding warrant                           | \$1.65        |
| Historical net tangible book value per share at June 30, 2011                       | \$0.73        |
| Increase per share attributable to investors purchasing securities in this offering | <u>\$0.19</u> |
| Net tangible book value per share, as adjusted to give effect to this offering      | <u>\$0.92</u> |
| Dilution per share to investors in this offering                                    | <u>\$0.73</u> |

The above discussion and table are based on 27,898,527 shares outstanding as of June 30, 2011 and excludes:

- 22,217,523 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2011 at a weighted average exercise price of \$2.60 per share;
- 1,986,991 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2011 at a weighted average exercise price of \$3.80 per share;
- 2,247,746 shares of our common stock reserved for future issuance under our 2003 Stock Incentive Plan, as amended, as of June 30, 2011; and
- 1,760,000 shares of common stock issuable upon the exercise of warrants issued in this offering.

To the extent that outstanding options or warrants are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of additional equity, the issuance of these shares could result in further dilution to our stockholders.



### **Description of the Warrants**

We are offering 8,800,000 shares of our common stock, par value \$0.01 per share, together with warrants to purchase 1,760,000 shares of common stock in this offering. Each share of common stock sold in this offering will be sold with a warrant to purchase 0.20 of a share of common stock at an exercise price of \$1.90 per share (115% of the aggregate offering price of a share and corresponding warrant). The warrants are exercisable for a period of five years beginning on the closing date of this offering. The warrants do not allow for cashless exercise.

We will have the right to redeem the warrants issued in this offering, in whole or in part, at a redemption price of \$0.01 per warrant at any time after any date on which the closing price of our common stock, as reported on the principal exchange or trading facility on which it is then traded, has equaled or exceeded \$1.00 more than the exercise price of the warrants for ten consecutive trading days. We are required to provide 30 days' prior written notice to the warrant holders of our intention to redeem the warrants; provided, that we may not provide this notice until the earlier to occur of (a) 30 days following the date we initially release the results of the blinded portion of our ReCharge trial or (b) June 30, 2013. We will not have the right to redeem a warrant if the holder's exercise of such warrant would result in a holder owning more than 19.99% of our common stock outstanding after the exercise.

Subject to compliance with any applicable securities laws, any portion of a warrant may be transferred by the warrant holder upon surrender of the warrant.

The warrants will not be listed on the NASDAQ Capital Market or any other securities exchange and there is currently no established trading market for the warrants. We do not intend to make a market in the warrants and do not expect that one will develop. Therefore, the warrant holders may have to hold the warrants they purchase in this offering, until such time, if any, as they wish to exercise them or we redeem them. The warrant holders do not have the rights or privileges of holders of common stock and any voting rights until they exercise their warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the warrants, each holder will be entitled to one vote for each share held on record on all matters to be voted on by stockholders.

Pursuant to the terms of the warrants, warrant holders are not permitted to exercise the warrants for an amount of common stock that would result in a holder owning more than 19.99% of our common stock outstanding after the exercise.

We will not be required to issue any fractional shares of our common stock upon the exercise of a warrant. Instead, the number of shares of common stock exercised will be rounded down to the nearest whole number.

The exercise price and number of shares of common stock issuable on exercise of the warrants may be adjusted in certain circumstances including in the event of our recapitalization, reorganization, merger or consolidation.

We will attempt to maintain the effectiveness of a current prospectus covering the common stock issuable upon exercise of the warrants until the expiration of the warrants. However, we cannot assure you that we will be able to do so. If the prospectus relating to the common stock issuable upon the exercise of the warrants is not current or if the common stock is not qualified or exempt from qualification in the jurisdictions in which the holders of the warrants reside, the warrants may have no value.

## Underwriting

The underwriter named below has agreed to buy, subject to the terms of the underwriting agreement, the number of securities listed opposite its name below. The underwriter is committed to purchase and pay for all of the securities if any are purchased. The underwriting agreement also provides that if the underwriter defaults, this offering of our securities may be terminated.

| <u>Underwriter</u>         | <u>Number of<br/>Shares of<br/>Common Stock</u> | <u>Number of<br/>Shares of<br/>Common Stock<br/>Underlying<br/>Warrants</u> |
|----------------------------|---|---|
| Craig-Hallum Capital Group | 8,800,000                                       | 1,760,000   |

The underwriter has advised us that it proposes to offer the shares of common stock and corresponding warrants to the public at an aggregate price of \$1.65 per share and corresponding warrant. Each purchaser of a share of common stock will be required to purchase a corresponding warrant to purchase 0.20 of a share of common stock in this offering. The underwriter proposes to offer the securities to be sold in this offering to certain dealers at the same prices less an aggregate concession of not more than \$0.0594 for each share and corresponding warrant. After the offering, these figures may be changed by the underwriter.

The table below summarizes the underwriting discounts that we will pay to the underwriter. In addition to the underwriting discount, we have agreed to pay up to \$125,000 of the fees and expenses of the underwriter, which may include the fees and expenses of counsel to the underwriter. The fees and expenses of the underwriter that we have agreed to reimburse are not included in the underwriting discounts set forth in the table below.

The underwriter has not received and will not receive from us any other item of compensation or expense in connection with this offering considered by the Financial Industry Regulatory Authority to be underwriting compensation under its rule of fair price. The aggregate value of all compensation to be received by the underwriter in connection with this offering will not exceed 8% of the offering proceeds. The underwriting discount and other items of compensation the underwriter will receive were determined through arms' length negotiations between us and the underwriter.

|   | <u>Per Share and<br/>Corresponding<br/>Warrant</u> | <u>Total</u> |
|---|--|--------------|
| Underwriting discount to be paid to the underwriter by us | \$ 0.099   | \$871,200    |

We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be \$350,000. This includes \$125,000 of fees and expenses of the underwriter. These expenses are payable by us.

We have agreed to indemnify the underwriter against certain liabilities, including civil liabilities under the Securities Act, or to contribute to payments that the underwriter may be required to make in respect of those liabilities.

Our directors, officers and certain principal stockholders have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any shares of common stock or any securities convertible into or exchangeable for shares of common stock without the prior written consent of the underwriter for a period of 90 days after the date of this prospectus supplement. These "lock-up" agreements cover approximately an aggregate of 6,868,863 shares of our common stock and are subject to limited exceptions.

We have agreed to certain restrictions on our ability to sell additional shares of our common stock for a period of 90 days after the date of this prospectus supplement. We have agreed not to offer, sell, agree to sell, directly or indirectly, or otherwise issue or dispose of, any shares of common stock, securities convertible into or exchangeable for shares of common stock, or any related security or instrument, without the prior written consent of the underwriter. The agreement is subject to limited exceptions.

## [Table of Contents](#)

To facilitate the offering, the underwriter may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock during and after the offering. Specifically, the underwriter may over-allot or otherwise create a short position in the common stock for its own account by selling more shares than have been sold to it by us. The underwriter may elect to cover any such short position by purchasing shares of common stock in the open market. In addition, the underwriter may stabilize or maintain the price of the common stock by bidding for or purchasing shares of common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to broker-dealers participating in the offering are reclaimed if shares of common stock previously distributed in the offering are repurchased, whether in connection with stabilization transactions or otherwise. 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 imposition of a penalty bid may also affect the price of the common stock to the extent that it discourages resales of the common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on the NASDAQ Stock Market or otherwise and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriter (and selling group members) may also engage in passive market making transactions in the common stock on the NASDAQ Stock Market. Passive market making consists of displaying bids on the NASDAQ Stock Market limited by the prices of independent market makers and effecting purchases limited by those prices in response to order flow. Rule 103 of Regulation M promulgated by the SEC limits the amount of net purchases that each passive market maker may make and the displayed size of each bid. Passive market making may stabilize the market price of the common stock at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

The underwriter may facilitate the marketing of this offering online directly or through one of its affiliates. In those cases, prospective investors may view offering terms and a prospectus online and place orders online or through their financial advisors.

### **Legal Matters**

The validity of the securities offered by this prospectus supplement will be passed upon for us by Dorsey & Whitney LLP, Minneapolis, Minnesota. The underwriter has been represented in connection with this offering by Faegre & Benson LLP, Minneapolis, Minnesota.

### **Experts**

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

### **Where You Can Find More Information**

We file annual, quarterly and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public through the Internet at the SEC's web site at [www.sec.gov](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.

## [Table of Contents](#)

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 supplement. When used in this prospectus supplement, 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 or incorporated by reference therein. This prospectus supplement, which constitutes a part of the registration statement, does not contain all of the information in the registration statement. This prospectus supplement 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 supplement, 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 supplement:

- Annual Report on Form 10-K for the year ended December 31, 2010;
- Quarterly Reports on Form 10-Q for the quarters ended March 31, 2011 and June 30, 2011;
- Current Reports on Form 8-K filed on January 11, 2011, March 28, 2011, May 10, 2011, June 14, 2011, July 8, 2011 and September 22, 2011; and
- the description of our common shares contained in any registration statement on Form 8-A that we have filed, and any amendment or report filed for the purpose of updating this description.

We also are incorporating by reference any future 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 supplement is a part and before the effective date of the registration statement and after the date of this prospectus supplement 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 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

**PROSPECTUS**



**\$35,000,000**

**Common Stock  
Preferred Stock  
Debt Securities  
Securities Warrants  
Units**

---

**5,191,756 Shares of Common Stock  
Offered by the Selling Stockholders**

We may from time to time offer to sell any combination of common stock, preferred stock, debt securities, securities warrants and units described in this prospectus in one or more offerings. The aggregate initial offering price of all securities sold under this prospectus will not exceed \$35,000,000.

In addition, the selling stockholders named in this prospectus may offer and sell up to 5,191,756 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 respective securities that we and the selling stockholders may offer. Each time we sell securities, we will provide the specific terms of the securities offered 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 any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

We and the selling stockholders may from time to time offer and sell our respective securities 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 any of these securities, the applicable prospectus supplement will provide the names of the agents or underwriters and any applicable fees, commissions or discounts.

Our common stock is traded on the NASDAQ Capital Market under the symbol "ETRM." On April 9, 2010, the closing price of our common stock as reported on the NASDAQ Capital Market was \$0.52 per share. As of April 9, 2010, the aggregate market value of our outstanding common stock held by non-affiliates (the public float) was approximately \$15.6 million, which was calculated based on 30,069,903 shares of outstanding common stock held by non-affiliates and on a price per share of \$0.52, the closing price of our common stock on April 9, 2010. 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 securities 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 securities.**

---

**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 May 6, 2010.

[Table of Contents](#)

**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> | 22 |
| <a href="#">USE OF PROCEEDS</a>   | 22 |
| <a href="#">RATIO OF EARNINGS TO FIXED CHARGES</a>                        | 22 |
| <a href="#">SELLING STOCKHOLDERS</a>                                      | 23 |
| <a href="#">DESCRIPTION OF COMMON STOCK</a>                               | 26 |
| <a href="#">DESCRIPTION OF PREFERRED STOCK</a>                            | 30 |
| <a href="#">DESCRIPTION OF DEBT SECURITIES</a>                            | 32 |
| <a href="#">DESCRIPTION OF SECURITIES WARRANTS</a>                        | 46 |
| <a href="#">DESCRIPTION OF UNITS</a>                                      | 48 |
| <a href="#">PLAN OF DISTRIBUTION</a>                                      | 48 |
| <a href="#">LEGAL MATTERS</a>   | 49 |
| <a href="#">EXPERTS</a>   | 49 |
| <a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>                       | 50 |
| <a href="#">INCORPORATION OF DOCUMENTS BY REFERENCE</a>                   | 50 |

---

## 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 any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$35,000,000. In addition, this prospectus may be used by the selling stockholders named in this prospectus to offer and sell up to 5,191,756 shares of our common stock as described under the heading “Selling Stockholders.”

This prospectus provides you with a general description of the respective securities that we and the selling stockholders may offer. Each time we sell securities 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 securities other than the registered securities 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 securities 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 securities are 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.

On October 2, 2009, we announced preliminary results from our pivotal clinical study, the EMPOWER trial; indicating that based on an initial analysis, the study did not meet its primary and secondary efficacy endpoints. We also announced that there were no therapy-related serious adverse events reported during the study. 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. We further announced on November 12, 2009, the ongoing detailed review suggests that vagal blocking therapy may promote safe and effective weight loss as an adjunct to behavioral support, diet and exercise in morbidly obese patients. The review further suggests that these effects were evident in both the treatment and control arms. We are continuing a comprehensive analysis of all clinical, statistical, and engineering data to understand this finding. Based on the analysis to date, the control arm of the trial, which was intended to be inactive, apparently provided a low-intensity blocking signal that introduced VBLOC therapy in human subjects.

In January 2010, we met with the U.S. Food and Drug Administration (FDA) to discuss the EMPOWER trial results and the regulatory process going forward. Based on this discussion, we recently submitted an Investigational Device Exemption (IDE) application for a clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity. Assuming that we obtain an approved IDE, successfully enroll and implant the trial and achieve favorable results, we plan to use data from that trial to support a premarket approval (PMA) application for the Maestro System, which we expect to submit no earlier than the second half of 2012. If the FDA grants us approval, we anticipate we will be able to commercialize the Maestro System in the United States no earlier than the second half of 2013. 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. 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, 2009, we had 34 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 earlier than the second half of 2013. 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. If we are unable to raise additional capital in the second half of 2010, we may be unable to continue as a going concern.***

We have incurred losses in each year since our formation in 2002. As of December 31, 2009, we had a deficit accumulated during the development stage of \$133.2 million. Our net losses applicable to common stockholders for the fiscal years ended December 31, 2009, 2008 and 2007 were \$31.9 million, \$37.9 million and \$28.6 million, respectively. We have funded our operations to date principally from the sale of our securities and through the issuance of indebtedness. Development of a new medical device, including conducting clinical trials and seeking regulatory approvals, is a long, expensive and uncertain process. If our Maestro System is approved for marketing by the 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.

Without additional capital, we may run out of cash in the second half of 2010, which has raised a substantial doubt about our ability to continue as a going concern. We have prepared our consolidated financial statements for the year ended December 31, 2009 on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities and other commitments in the normal course of business. The funding of our operations beyond the second half of 2010 will require additional investments in our company in the form of equity or debt financing or through collaboration, licensing or other similar arrangements. There is no assurance that we will be able to raise sufficient capital to continue as a going concern.

## [Table of Contents](#)

***If we are unable to comply with the continued listing requirements of the NASDAQ Capital Market, our common stock could be delisted, which could affect its market price and liquidity and reduce our ability to raise capital.***

We are required to meet certain qualitative and financial tests (including a minimum closing bid price for our common stock of \$1.00 per share) to maintain the listing of our common stock on the NASDAQ Capital Market. On November 13, 2009, we received a notice from the NASDAQ Stock Market (NASDAQ) advising that for the prior 30 consecutive business days, the minimum closing bid price of our listed securities had been below the minimum \$1.00 per share requirement for continued listing on the NASDAQ Global Market pursuant to NASDAQ Listing Rule 5450(a)(1). In anticipation of not regaining compliance with two other continued listing requirements of the NASDAQ Global Market prior to the expiration of their grace periods, we requested and were approved to transfer to the NASDAQ Capital Market, effective January 22, 2010. In connection with this transfer, we have been afforded the balance of our 180 calendar day grace period, until May 12, 2010, to regain compliance with the minimum closing bid price rule by having our stock price close at or above \$1.00 per share for a minimum of ten consecutive business days. If we are unable to regain compliance with the minimum closing bid price rule or are unable to maintain compliance with the other continued listing requirements of the NASDAQ Capital Market within specified periods and subject to permitted extensions, our common stock may be recommended for delisting (subject to any appeal we would file). If our common stock were delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting would also impair our ability to raise capital.

***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 for our Maestro RF System 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 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.

## [Table of Contents](#)

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 for our Maestro RF System, we cannot assure you when, or if, we will be able to commence sales in the European Economic Area or obtain approval to market our Maestro System in other countries outside the United States.

We may not obtain the necessary regulatory approvals to market our Maestro System in the United States or anywhere else. Even if we obtain approval, the FDA or other regulatory authorities may require expensive or burdensome post-market testing or controls. Any delay in, failure to receive or maintain, or significant limitation on approval for our Maestro System could prevent us from generating revenue or achieving profitability and we may be forced to cease operations.

***The preliminary results of the blinded segment of our EMPOWER trial may not be sufficient to support approval of a PMA application, and this will likely prevent or delay regulatory approval of our Maestro System and impair our financial position.***

In September 2009, we completed the blinded segment of our EMPOWER pivotal trial, a randomized, prospective, placebo-controlled multi-center trial of our Maestro System in the United States. Based on our initial analysis, the EMPOWER trial did not meet its primary and secondary efficacy endpoints; however, we are currently conducting a thorough analysis of the EMPOWER study data and have met with the FDA to discuss the EMPOWER trial results and the regulatory process going forward. Based on this discussion, we recently submitted an IDE application for a clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity. Even if we are able to obtain FDA approval of an IDE for a clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity, the inability to achieve our primary and secondary efficacy endpoints in the EMPOWER trial means that it will take us longer to ultimately commercialize a product and generate revenue, our financial projections may be impaired, and we may never be able to produce sufficient data to support a PMA application with the FDA or commercialize a product.

***We may be unable to receive approval for or complete a pivotal trial using our next-generation Maestro RC System 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.***

We recently submitted an IDE application for a clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity. Assuming that we obtain an approved IDE, successfully enroll and implant the trial and achieve favorable results, we plan to use data from that trial to support a PMA application for the Maestro System. We expect to commence the trial upon receipt of an IDE approval from the FDA and upon receipt of approval from the relevant institutional review boards at the various sites at which we would be conducting the trial. Conducting a clinical trial of this size, which involves screening, assessing, testing, treating and monitoring patients at several sites across the country and possibly internationally, and coordinating with patients and clinical institutions, is a complex and uncertain process.

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

- obtaining an IDE approval from the FDA with acceptable terms;
- reaching agreement on acceptable terms with prospective clinical trial sites;
- manufacturing sufficient quantities of our Maestro System;

## Table of Contents

- obtaining institutional review board approval to conduct the trial at a prospective site; and
- obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial.

Once the trial has begun, the completion of the trial, and our other ongoing clinical trials, could be delayed, suspended or terminated for several reasons, including:

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

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

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

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

- our Maestro System may not be accepted in the marketplace by physicians, patients and third-party payors;
- the price of our Maestro System, associated costs of the surgical procedure and treatment and the availability of sufficient third-party reimbursement for the procedure and therapy implantation and follow-up procedures;
- appropriate reimbursement coding options may not exist to enable billing for the system implantation and follow-up procedures;
- we may not be able to sell our Maestro System at a price that allows us to meet the revenue targets necessary to generate revenue for profitability;
- the frequency and severity of any side effects of our VBLOC therapy;
- physicians and potential patients may not be aware of the perceived effectiveness and sustainability of the results of VBLOC therapy provided by our Maestro System;

## Table of Contents

- we, or the investigators of our product, may not be able to have information on the outcome of the trials published in medical journals;
- the availability and perceived advantages and disadvantages of alternative treatments;
- any rapid technological change may make our product obsolete;
- we may not be able to have our Maestro System manufactured in commercial quantities or at an acceptable cost;
- we may not have adequate financial or other resources to complete the development and commercialization of our Maestro System; 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 in the second half of 2013, if at all. If we are not successful in the commercialization of our Maestro System for the treatment of obesity we may never generate any revenue and may be forced to cease operations.

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

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

## [Table of Contents](#)

***Assuming we receive regulatory approval for the Maestro System, modifications to the Maestro System may require additional approval from the 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, the perceived liability risks arising from the use of new products and procedures, and the uncertainty of third-party coverage and reimbursement. Physicians may not widely adopt our Maestro System and VBLOC therapy unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, that the use of our VBLOC therapy provides a safe and effective alternative to other existing treatments for obesity, including pharmaceutical solutions and bariatric surgical procedures.

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

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

Healthcare providers generally rely on third-party payors, including governmental payors, such as Medicare and Medicaid, 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.

## [Table of Contents](#)

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

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

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

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

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

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by 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 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,

## [Table of Contents](#)

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, clinical trials or commercialization of our product could be delayed. Alternatively, if we have to switch to a replacement manufacturer or replacement supplier for any of our product components, we may face additional regulatory delays, and the manufacture and delivery of our Maestro System could be interrupted for an extended period of time, which could delay completion of our clinical trials or commercialization of our Maestro System. In addition, we may be required to obtain regulatory approval from the FDA to use different suppliers or components.

***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



## [Table of Contents](#)

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on research and development, including conducting current and future clinical trials for our Maestro System. 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 2009, our cash used in operations was \$24.7 million. Our cash used in operations in 2010 and beyond will largely depend on our regulatory path forward. If the FDA grants us approval on an IDE application for a clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity we would expect research and development expenditures to increase in support of a new clinical trial in addition to the continued follow-up on existing trials, such as VBLOC-DM2 ENABLE and EMPOWER. In 2010 and the years following, we expect that our cash used in operations will be significant, and we will 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 ongoing operations.

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

- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our Maestro System and any products that we may develop;
- the rate of market acceptance of our Maestro System and VBLOC therapy and any other product candidates;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;

## Table of Contents

- 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. Issuing public equity or debt securities may also be more costly or time-consuming for us because our public float is less than \$75.0 million (calculated in accordance with the SEC rules and regulations), which limits the size of offerings we may make using a Form S-3 registration statement to 1/3 of our public float for any twelve month period. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products, or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

### ***We 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 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.

## Table of Contents

***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 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,

## [Table of Contents](#)

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.***

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure. In particular, we are required to perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. We have incurred and continue to expect to incur significant expense and devote substantial management effort toward ensuring compliance with Section 404. We currently do not have an internal audit function, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we do not comply with the requirements of Section 404, or if we identify deficiencies in our internal controls that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources.

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

The health care industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The obesity treatment market in which we operate has grown significantly in recent years and is expected to continue to expand as technology continues to evolve and awareness of the need to treat the obesity epidemic grows. Although we are not aware of any

## [Table of Contents](#)

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. To date, we have nine issued U.S. patents, seven of which pertain to treating gastrointestinal disorders, 22 U.S. patent applications, four pending international patent applications (PCT) and fourteen national stage patent applications, including seven 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 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

## [Table of Contents](#)

business operations. Even if we were to prevail in any litigation, we cannot assure you that we can obtain an injunction that prevents our competitors from practicing our patented technology. Our competitors may independently develop similar or alternative technologies or products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies.

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

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

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

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

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

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

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

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

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

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

## Risks Related to Ownership of 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 26, 2010 our stock price has fluctuated from a low of \$0.40 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 39.1% of our outstanding common stock as of February 26, 2010. Our executive officers, directors and affiliated entities, if acting together, would be able to influence significantly all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other significant corporate transactions. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may affect the market price of our common stock. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

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

## 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.

***Our Board of Directors has the power to issue series of preferred stock and to designate the rights and preferences of these series, which could adversely affect the voting power, dividend, liquidation and other rights of holders of our common stock.***

Under our amended and restated certificate of incorporation, our Board of Directors has the power to issue series of preferred stock and to designate the rights and preferences of those series. Therefore, our Board of Directors may designate a new series of preferred stock with the rights, preferences and privileges that the Board of Directors deems appropriate, including special dividend, liquidation and voting rights. The creation and designation of a new series of preferred stock could adversely affect the voting power, dividend, liquidation and other rights of holders of our common stock and, possibly, any other class or series of stock that is then in existence.

***Except for our common stock, there is no public market for the securities that we may offer using this prospectus.***

Except for our common shares, no public market exists for the securities that we may offer using this prospectus, and we cannot assure the liquidity of any market that may develop, the ability of the holders of the securities to sell their securities or the price at which the securities may be sold. Our common stock is traded on the NASDAQ Capital Market. We may not apply for listing of any other securities that we may offer using this prospectus on any securities exchange or for quotation through the NASDAQ system. Future trading prices of the securities will depend on many factors including, among others, prevailing interests rates, our operating results and the market for similar securities.

---

## [Table of Contents](#)

***Any debt securities that we may issue could contain covenants that may restrict our ability to obtain financing, and our noncompliance with one of these restrictive covenants could lead to a default on those debt securities and any other indebtedness.***

If we issue debt securities covered by this prospectus or any future indebtedness, those securities or future indebtedness may be subject to restrictive covenants, some of which may limit the way in which we can operate our business and significantly restrict our ability to incur additional indebtedness or to issue preferred stock. Noncompliance with any covenants under that indebtedness, unless cured, modified or waived, could lead to a default not only with respect to that indebtedness, but also under any other indebtedness that we may incur. If this were to happen, we might not be able to repay or refinance all of our debt.

***If we issue a large amount of debt, it may be more difficult for us to obtain financing, will increase the cost of our debt and may magnify the results of any default under any of our outstanding indebtedness.***

The issuance of debt securities could increase our debt-to-equity ratio or leverage, which may in turn make it more difficult for us to obtain future financing. In addition, the issuance of any debt securities will increase the amount of interest we will need to pay, except to the extent that the proceeds from the issuance of debt securities are used to repay other outstanding indebtedness. Finally, our level of indebtedness, and in particular any significant increase in it, may make us more vulnerable if there is a downturn in our business or the economy.

## 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 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 securities under this prospectus to fund clinical studies of our VBLOC therapy in obesity, hypertension and diabetes, and for working capital and other general corporate purposes. The prospectus supplement relating to a particular offering of securities by us will identify the use of proceeds for that offering. We will not receive any proceeds from the sale of common stock by the selling stockholders.

## RATIO OF EARNINGS TO FIXED CHARGES

Our ratio of earnings to fixed charges for each of the years indicated is as follows:

|   | Year Ended December 31, |            |            |            |            |
|---|-------------------------|------------|------------|------------|------------|
|   | 2005                    | 2006       | 2007       | 2008       | 2009       |
| Ratio of earnings to fixed charges                      | —                       | —          | —          | —          | —          |
| Deficiency of earnings available to cover fixed charges | \$(11,215)              | \$(17,690) | \$(28,575) | \$(37,874) | \$(31,929) |

For purposes of computing these ratios, earnings represent loss before income taxes plus fixed charges and fixed charges represent interest expense, amortization of commitment fees, debt issuance costs and original issue discount and the estimated interest component of rent expense.

In each of the periods presented, there were insufficient earnings available to cover fixed charges. As a result, the ratio of earnings to fixed charges was less than 1.0 for these years. The deficiencies of earnings to fixed charges for these years are presented in the table above.

We have not included a ratio of earnings to combined fixed charges and preferred stock dividends because we do not have any preferred stock outstanding as of the date of this prospectus.

## 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 5,191,756 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 based on information provided to us by or on behalf of 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 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)                         | 782,033   | 4,177   | 407,679   | *  |
| Aberdare II Annex Fund, L.P.(6)                        | 2,339,024   | 141,076   | 2,197,948   | 4.9%   |
| 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   | 1.7%   |
| Bay City Capital Fund IV Co-Investment Fund, L.P.(7)   | 5,334,337   | 28,361  | 3,990,197   | 8.9%   |
| Bay City Capital Fund IV, L.P.(7)                      | 5,334,337   | 1,315,779   | 3,990,197   | 8.9%   |
| Charter Life Sciences, L.P.(8)                         | 729,028   | 370,177   | 358,851   | *  |
| MPM Asset Management Investors 2002 BV3(9)             | 111,785   | 33,240  | 78,545  | *  |
| MPM BioVentures III GmbH & Co. Beteiligungs KG(9)      | 478,143   | 142,180   | 335,963   | *  |
| MPM BioVentures III L.P.(9)                            | 380,435   | 113,125   | 267,310   | *  |
| MPM BioVentures III Parallel Fund L.P.(9)              | 170,940   | 50,830  | 120,110   | *  |
| MPM BioVentures III-QP L.P.(9)                         | 5,658,252   | 1,682,538   | 3,975,714   | 8.9%   |
| Onset V, L.P.(10)                                      | 958,734   | 514,337   | 444,397   | 1.0%   |
| Mayo Foundation for Medical Education and Research(11) | 498,311   | 73,477  | 424,834   | *  |

\* Less than one percent.

(1) Represents all of the shares beneficially owned by the selling stockholder as of the date of the information provided to us 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 February 26, 2010.

## Table of Contents

- (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 44,856,657 shares of common stock outstanding as of February 26, 2010.
- (5) Includes 24,063 and 1,015 shares issuable pursuant to options and warrants, respectively, held by Dr. Harrison, which are exercisable currently or within 60 days of February 26, 2010. 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 February 26, 2010, 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 February 26, 2010, 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 February 26, 2010. 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 83,838 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 February 26, 2010. 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 February 26, 2010. 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 February 26, 2010. Bay City Capital LLC (BCC) is the manager of Management IV, which is the general partner of Fund IV and Co-Investment IV. BCC is also an advisor to Fund IV and Co-Investment IV. 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 24,063 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 February 26, 2010. Dr. Harrison is a member of our Board of Directors and has sole voting and dispositive power of 53,005 shares. See footnote (5).
- (9) 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 February 26, 2010, 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 February 26, 2010, 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 February 26, 2010, 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 February 26, 2010, 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 February 26, 2010. MPM BioVentures III GP, L.P. (BV III GP) and MPM BioVentures III LLC (BV III LLC) each have

## Table of Contents

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 Evin, 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. Evin 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. Evin is a member of our Board of Directors and has sole voting and dispositive power of 24,063 shares.

- (10) 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. Opdendyk, 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.
- (11) Includes 108,247 shares issuable pursuant to warrants exercisable currently or within 60 days of February 26, 2010. 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.

## 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 March 31, 2010, we had 44,868,202 shares of common stock outstanding. As of March 31, 2010, we had an aggregate of 5,471,871 shares of common stock reserved for issuance upon exercise of outstanding stock options granted under our 2003 Stock Incentive Plan, and an aggregate of 8,152,878 shares of common stock reserved for issuance upon the exercise of outstanding common 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, certain of our holders of common stock and holders of warrants to purchase common stock have a right to require us to register their shares 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.



## [Table of Contents](#)

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.

*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.

## Table of Contents

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 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

---

## [Table of Contents](#)

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.

## DESCRIPTION OF PREFERRED STOCK

This section summarizes the general terms and provisions of the preferred stock that we may offer using this prospectus. This section is only a summary and does not purport to be complete. You must look at our certificate of incorporation and the relevant certificate of designation for a full understanding of all the rights and preferences of any series of preferred stock. Our certificate of incorporation and the certificates of designation have been or will be filed or incorporated by reference as exhibits to the registration statement of which this prospectus is a part. See “Where You Can Find More Information” for information on how to obtain copies.

A prospectus supplement will describe the specific terms of any particular series of preferred stock offered under that prospectus supplement, including any of the terms in this section that will not apply to that series of preferred stock, and any special considerations, including tax considerations, applicable to investing in that series of preferred stock.

### General

Pursuant to our certificate of incorporation, we currently have authorized 5,000,000 shares of preferred stock, \$0.01 par value per share. We do not have any shares of preferred stock outstanding as of the date of this prospectus.

Prior to issuance of shares of each series of our undesignated preferred stock, our Board of Directors is required by the Delaware General Corporate Law and our certificate of incorporation to adopt resolutions and file a Certificate of Designations with the Secretary of State of the State of Delaware, fixing for each such series the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series. Our Board of Directors could authorize the issuance of shares of preferred stock with terms and conditions which could have the effect of discouraging a takeover or other transaction which holders of some, or a majority, of such shares might believe to be in their best interests or in which holders of some, or a majority, of such shares might receive a premium for their shares over the then-market price of such shares.

Subject to limitations prescribed by the Delaware General Corporation Law, our certificate of incorporation and our bylaws, our Board of Directors is authorized to fix the number of shares constituting each series of preferred stock and the designations, powers, preferences, rights, qualifications, limitations and restrictions of the shares of such series, including such provisions as may be desired concerning voting, redemption, dividends, dissolution or the distribution of assets, conversion or exchange, and such other subjects or matters as may be fixed by resolution of the Board of Directors. Each series of preferred stock that we offer under this prospectus will, when issued, be fully paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

The applicable prospectus supplement(s) will describe the following terms of the series of preferred stock in respect of which this prospectus is being delivered:

- the title and stated value of the preferred stock;
- the number of shares of the preferred stock offered, the liquidation preference per share and the purchase price of the preferred stock;
- the dividend rate(s), period(s) and/or payment date(s) or the method(s) of calculation for dividends;
- whether dividends shall be cumulative or non-cumulative and, if cumulative, the date from which dividends on the preferred stock shall accumulate;
- the procedures for any auction and remarketing, if any, for the preferred stock;
- the provisions for a sinking fund, if any, for the preferred stock;
- the provisions for redemption, if applicable, of the preferred stock;

## Table of Contents

- any listing of the preferred stock on any securities exchange or market;
- the terms and conditions, if applicable, upon which the preferred stock will be convertible into common stock or another series of our preferred stock, including the conversion price (or its manner of calculation) and conversion period;
- the terms and conditions, if applicable, upon which preferred stock will be exchangeable into our debt securities, including the exchange price, or its manner of calculation, and exchange period;
- voting rights, if any, of the preferred stock;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs;
- any limitations on issuance of any series of preferred stock ranking senior to or on a parity with the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and
- any other specific terms, preferences, rights, limitations or restrictions on the preferred stock.

Unless otherwise specified in the prospectus supplement, with respect to dividend rights and rights upon our liquidation, dissolution or winding up, the preferred stock will rank:

- senior to all classes or series of our common stock, and to all equity securities issued by us the terms of which specifically provide that such equity securities rank junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of us;
- on a parity with all equity securities issued by us that do not rank senior or junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of us; and
- junior to all equity securities issued by us the terms of which do not specifically provide that such equity securities rank on a parity with or junior to the preferred stock with respect to dividend rights or rights upon the liquidation, dissolution or winding up of us (including any entity with which we may be merged or consolidated or to which all or substantially all of our assets may be transferred or which transfers all or substantially all of our assets).

As used for these purposes, the term “equity securities” does not include convertible debt securities.

### **Transfer Agent and Registrar**

The transfer agent and registrar for any series of preferred stock will be set forth in the applicable prospectus supplement.

### **Certain Provisions of Articles of Incorporation and Bylaws**

For a description of some additional provisions of our articles of incorporation and bylaws, see “Description of Common Stock—Anti-Takeover Effects of Delaware Law and Certain Provisions of our Certificate of Incorporation and Bylaws.”

## DESCRIPTION OF DEBT SECURITIES

This section describes the general terms and provisions of the debt securities that we may offer using this prospectus and the related indenture. This section is only a summary and does not purport to be complete. You must look to the relevant form of debt security and the related indenture for a full understanding of all terms of any series of debt securities. The form of debt security and the related indenture have been or will be filed or incorporated by reference as exhibits to the registration statement of which this prospectus is a part. See “Where You Can Find More Information” for information on how to obtain copies.

A prospectus supplement will describe the specific terms of any particular series of debt securities offered under that prospectus supplement, including any of the terms in this section that will not apply to that series, and any special considerations, including tax considerations, applicable to investing in those debt securities. In some instances, certain of the precise terms of debt securities you are offered may be described in a further prospectus supplement, known as a pricing supplement. If information in a prospectus supplement is inconsistent with the information in this prospectus, then the information in the prospectus supplement will apply and, where applicable, supersede the information in this prospectus.

The amount of debt securities we may offer using this prospectus will be limited to the amount of securities described on the cover of this prospectus that we have not already issued or reserved for issuance. We may also issue debt securities pursuant to the related indentures in transactions that are exempt from the registration requirements of securities laws. We will not consider those debt securities in determining the aggregate amount of securities issued under this prospectus.

### Description of Senior Debt Securities

#### General

This section summarizes the general terms and provisions of the senior debt securities that may be offered by this prospectus. The prospectus supplement will describe the specific terms of the series of the senior debt securities offered under that prospectus supplement and any general terms outlined in this section that will not apply to those senior debt securities. Because this is only a summary, it does not contain all of the details found in the full text of the senior indenture and the senior debt securities. If you would like additional information, you should read the form of senior indenture and the form of senior debt securities.

We will issue the senior debt securities from time to time in one or more series. Senior debt securities issued under the senior indenture will be issued as part of a series that we have established pursuant to the senior indenture. The form of the senior indenture is filed as an exhibit to the registration statement of which this prospectus is a part, and in this section, we include references in parentheses to specific sections of that form of indenture. The debt securities may be issued either separately, together with, upon conversion of or in exchange for other securities.

#### Ranking

The senior debt securities will be our unsecured and unsubordinated obligations and will rank equally and ratably with our other current and future unsecured and unsubordinated indebtedness. The senior debt securities will be effectively subordinated to all of our secured debt (as to the collateral pledged to secure this debt). As of March 31, 2010, we had \$7.3 million secured debt outstanding. The indenture will not limit the total amount of secured or unsecured debt that we may incur.

#### Terms

The prospectus supplement, including any separate pricing supplement, relating to a series of senior debt securities that we offer using this prospectus will describe the following terms of that series, if applicable:

- the title of the offered senior debt securities;

## Table of Contents

- any limit on the aggregate principal amount of the offered senior debt securities;
- the person or persons to whom interest on the offered senior debt securities will be payable if other than the persons in whose names the senior debt securities are registered;
- the date or dates on which the principal of the offered senior debt securities will be payable;
- the rate or rates, which may be fixed or variable, and/or the method of determination of the rate or rates at which the offered senior debt securities will bear interest, if any;
- the date or dates from which interest, if any, will accrue, the interest payment dates on which interest will be payable and the regular record date for any interest payable on any interest payment date;
- the place or places where
  - the principal of or any premium or interest on the offered senior debt securities will be payable;
  - registration of transfer may be effected;
  - exchanges may be effected; and
  - notices and demands to or upon us may be served;
- the security registrar for the offered senior debt securities and, if such is the case, that the principal of the offered senior debt securities will be payable without presentment or surrender thereof;
- the period or periods within which, or the date or dates on which, the price or prices at which and the terms and conditions upon which any of the offered senior debt securities may be redeemed, in whole or in part, at our option;
- our obligation or obligations, if any, to redeem or purchase any of the offered senior debt securities pursuant to any sinking fund or other mandatory redemption provisions or provisions for redemption at the option of the holder, and the period or periods within which, or the date or dates on which, the price or prices at which and the terms and conditions upon which any of the offered senior debt securities will be redeemed or purchased, in whole or in part, pursuant to that obligation, and applicable exceptions to the requirements of a notice of redemption in the case of mandatory redemption or redemption at the option of the holder;
- the denominations in which the offered senior debt securities will be issuable, if other than denominations of \$1,000 and any integral multiple thereof;
- if other than the currency of the United States, the currency or currencies, including composite currencies, in which payment of the principal of and any premium and interest on the offered senior debt securities will be payable;
- if the principal of or any premium or interest on any of the offered senior debt securities will be payable, at the election of us or the holder, in a coin or currency other than in which the offered senior debt securities are stated to be payable, the period or periods within which and the terms and conditions upon which, the election will be made;
- if the principal of or any premium or interest on the offered senior debt securities will be payable, or will be payable at the election of us or a holder, in securities or other property, the type and amount of securities or other property, or the formula or other method or other means by which the amount will be determined, and the period or periods within which, and the terms and conditions upon which, any such election may be made;
- if the amount of payment of principal of or any premium or interest on the offered senior debt securities may be determined with reference to an index or other fact or event ascertainable outside the indenture, the manner in which the amounts will be determined;
- if other than the principal amount of the offered senior debt securities, the amount which will be payable upon declaration of acceleration of the maturity;

## Table of Contents

- any addition to the events of default applicable to the offered senior debt securities and any addition to our covenants for the benefit of the holders of the offered senior debt securities;
- the terms, if any, pursuant to which the offered senior debt securities may be converted into or exchanged for shares of our capital stock or other securities of any other person;
- the obligations or instruments, if any, which will be considered to be a security that could be used to satisfy and discharge offered senior debt securities denominated in a currency other than U.S. dollars or in a composite currency, pursuant to the procedures discussed in “—Defeasance” below, and any additional or alternative provisions for the reinstatement of our indebtedness in respect of these senior debt securities after its satisfaction and discharge;
- if the offered senior debt securities will be issued in global form, any limitations on the rights of the holder to transfer or exchange the same or obtain the registration of transfer and to obtain certificates in definitive form in lieu of temporary form, and any and all other matters incidental to such senior debt securities;
- if the offered senior debt securities will be issuable as bearer securities;
- any limitations on the rights of the holders of the offered senior debt securities to transfer or exchange the senior debt securities or to obtain the registration of transfer, and if a service charge will be made for the registration of transfer or exchange of the offered senior debt securities, the amount or terms thereof;
- any exceptions to the provisions governing payments due on legal holidays or any variations in the definition of business day with respect to the offered senior debt securities; and
- any other terms of the offered senior debt securities, or any tranche thereof, not inconsistent with the provisions of the indenture. (Section 301)

Although senior debt securities offered by this prospectus will be issued under the senior indenture, there is no requirement that we issue future senior debt securities under the senior indenture. Accordingly, we may use other indentures or documentation containing different provisions in connection with future issuances of our debt.

We may issue the senior debt securities as original issue discount securities, which will be offered and sold at a substantial discount below their stated principal amount. The prospectus supplement relating to those senior debt securities will describe the federal income tax consequences and other special considerations applicable to them. In addition, if we issue any senior debt securities denominated in foreign currencies or currency units, the prospectus supplement relating to those senior debt securities will also describe any federal income tax consequences and other special considerations applicable to those senior debt securities.

The senior indenture does not contain covenants or other provisions designed to afford holders of senior debt securities protection in the event of a highly-leveraged transaction or a change of control involving us. If this protection is provided for the offered senior debt securities, we will describe the applicable provisions in the prospectus supplement relating to those senior debt securities.

### **Form, Exchange and Transfer**

Unless the applicable prospectus supplement specifies otherwise, we will issue the senior debt securities only in fully registered form without interest coupons and in denominations of \$1,000 and integral multiples of \$1,000. (Sections 201 and 302)

At the option of the holder, subject to the terms of the senior indenture and the limitations applicable to global securities, senior debt securities of any series will be exchangeable for other senior debt securities of the same series, of any authorized denomination and of like tenor and aggregate principal amount. (Section 305)



## [Table of Contents](#)

Subject to the terms of the senior indenture and the limitations applicable to global securities, holders may present senior debt securities for exchange as provided above and for registration of transfer at the office of the security registrar or at the office of any transfer agent designated by us for that purpose. Unless the applicable prospectus supplement indicates otherwise, no service charge will be required for any registration of transfer or exchange of senior debt securities, but we may require payment of a sum sufficient to cover any tax or other governmental charge associated with the transfer or exchange. Senior debt securities presented or surrendered for registration of transfer or exchange must (if so required by us, the senior trustee or the security registrar) be duly endorsed or accompanied by an executed written instrument of transfer in form satisfactory to us, the senior trustee or the security registrar. (Section 305) Any transfer agent (in addition to the security registrar) initially designated by us for the offered senior debt securities will be named in the applicable prospectus supplement. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts. We are required to maintain a transfer agent in each place of payment for the senior debt securities of a particular series. We may maintain an office that performs the functions of the transfer agent. (Section 602) Unless the applicable prospectus supplement specifies otherwise, the senior trustee will act as security registrar and transfer agent with respect to each series of senior debt securities offered by this prospectus.

We will not be required to execute or register the transfer or exchange of senior debt securities, or any tranche thereof, during a period of 15 days preceding the notice to be given identifying the senior debt securities called for redemption, or any senior debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any senior debt securities being redeemed in part. (Section 305)

If a senior debt security is issued as a global security, only the depositary or its nominee as the sole holder of the senior debt security will be entitled to transfer and exchange the senior debt security as described in this prospectus under “—Global Securities.”

### **Payment and Paying Agent**

Unless the applicable prospectus supplement indicates otherwise, we will pay interest on the offered senior debt securities on any interest payment date to the person in whose name the senior debt security is registered at the close of business on the regular record date. (Section 307)

Unless the applicable prospectus supplement indicates otherwise, we will pay the principal of and any premium and interest on the offered senior debt securities at the office of the paying agent or paying agents as we may designate for that purpose from time to time. Unless the applicable prospectus supplement indicates otherwise, the corporate trust office of the senior trustee in New York, New York will be our sole paying agent for payment for each series of senior debt securities. Any other paying agents initially designated by us for the senior debt securities of a particular series will be named in the applicable prospectus supplement. We may at any time designate additional paying agents or rescind the designation of any paying agent or approve a change in the office through which any paying agent acts. We are required to maintain a paying agent in each place of payment for the senior debt securities of a particular series. (Section 602)

Any moneys deposited by us with the senior trustee or any paying agent for the payment of the principal of or any premium or interest on any offered senior debt securities which remain unclaimed at the end of two years after the applicable payment has become due and payable will be paid to us. The holder of that senior debt security, as an unsecured general creditor and not as a holder, thereafter may look only to us for the payment. (Section 603)

### **Redemption**

Any terms for the optional or mandatory redemption of the offered senior debt securities will be set forth in the applicable prospectus supplement. Except as otherwise provided in the applicable prospectus supplement

## [Table of Contents](#)

with respect to senior debt securities that are redeemable at the option of the holder, the offered senior debt securities will be redeemable only upon notice by mail not less than 30 days nor more than 60 days prior to the redemption date. If less than all the senior debt securities of a series are to be redeemed, the particular senior debt securities to be redeemed will be selected by the securities registrar by the method as provided for in the terms of the particular series, or in the absence of any such provision, by such method of random selection as the security registrar deems fair and appropriate. (Sections 403 and 404)

Any notice of redemption at our option may state that the redemption will be conditional upon receipt by the paying agent or agents, on or prior to the redemption date, of money sufficient to pay the principal of and any premium and interest on the offered senior debt securities. If sufficient money has not been so received, the notice will be of no force and effect and we will not be required to redeem the senior debt securities. (Section 404)

### **Consolidation, Merger, Conveyance or Other Transfer**

Under the terms of the senior indenture, we may not consolidate with or merge into any other corporation or convey, transfer or lease our properties and assets substantially as an entirety to any person, unless:

- the corporation formed by the consolidation or into which we are merged or the person which acquires by conveyance or transfer, or which leases, our properties and assets substantially as an entirety is a person organized and existing under the laws of the United States, any state thereof or the District of Columbia and assumes our obligations on the senior debt securities and under the senior indenture;
- immediately after giving effect to the transaction, no Event of Default (as defined below) shall have occurred and be continuing; and
- we have delivered to the senior trustee an officer's certificate and an opinion of counsel as provided in the senior indenture. (Section 1101)

### **Events of Default**

Each of the following will constitute an "Event of Default" under the senior indenture with respect to any series of senior debt securities:

- failure to pay any interest on any senior debt securities of that series within 60 days after the same becomes due and payable;
- failure to pay principal of or premium, if any, on any senior debt securities of that series within three business days after the same becomes due and payable;
- failure to perform or breach of any of our other covenants or warranties in the senior indenture (other than a covenant or warranty in the senior indenture solely for the benefit of a series of senior debt securities other than that series) for 60 days after written notice to us by the senior trustee, or to us and the senior trustee by the holders of at least 33% in principal amount of the outstanding senior debt securities of that series, as provided in the senior indenture;
- the occurrence of events of bankruptcy, insolvency or reorganization relating to us; and
- any other Event of Default specified in the applicable prospectus supplement with respect to senior debt securities of a particular series. (Section 801)

An Event of Default with respect to a series of senior debt securities may not necessarily constitute an Event of Default with respect to senior debt securities of any other series issued under the senior indenture.

If an Event of Default with respect to any series of senior debt securities occurs and is continuing, then either the senior trustee or the holders of not less than 33% in principal amount of the outstanding senior debt

## [Table of Contents](#)

securities of that series may declare the principal amount (or if the senior debt securities of that series are original issue discount securities, such portion of the principal amount thereof as may be specified in the applicable prospectus supplement) of all of the senior debt securities of that series to be due and payable immediately. However, if an Event of Default occurs and is continuing with respect to more than one series of senior debt securities, the senior trustee or the holders of not less than 33% in aggregate principal amount of the outstanding securities of all such series, considered as one class, may make the declaration of acceleration and not the holders of the senior debt securities of any one of such series. (Section 802) There is no automatic acceleration, even in the event of our bankruptcy or insolvency.

Subject to the provisions of the senior indenture relating to the duties of the senior trustee in case an Event of Default shall occur and be continuing, the senior trustee will be under no obligation to exercise any of its rights or powers under the senior indenture at the request or direction of any holder, unless the holder has offered to the senior trustee reasonable security or indemnity. (Section 903) Subject to the provisions of the indemnification of the senior trustee, the holders of a majority in principal amount of the outstanding senior debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the senior trustee, or exercising any trust or power conferred on the senior trustee, with respect to the senior debt securities of that series; provided, however, that if an Event of Default occurs and is continuing with respect to more than one series of senior debt securities, the holders of a majority in aggregate principal amount of the outstanding senior debt securities of all those series, considered as one class, will have this right, and not the holders of any one series of senior debt securities. (Section 812)

No holder of senior debt securities of any series will have any right to institute any proceeding related to the senior indenture, or for the appointment of a receiver or a senior trustee, or for any other remedy thereunder, unless:

- the holder has previously given written notice to the senior trustee of a continuing Event of Default with respect to the senior debt securities of that series;
- the holders of not less than a majority in aggregate principal amount of the outstanding senior debt securities of that series have made written request to the senior trustee, and offered reasonable indemnity to the senior trustee, to institute the proceeding as senior trustee; and
- the senior trustee has failed to institute the proceeding, and has not received from the holders of a majority in aggregate principal amount of the outstanding senior debt securities of that series a direction inconsistent with such request, within 60 days after the notice, request and offer. (Section 807)

Notwithstanding the provisions described in the immediately preceding paragraph or any other provision of the senior indenture, the holder of any senior debt security will have the right, which is absolute and unconditional, to receive payment of the principal and any premium and interest on that senior debt security and to institute suit for enforcement of any payment, and that right will not be impaired without consent of that holder. (Section 808)

We will be required to furnish to the senior trustee annually, not later than October in each year, a statement by an appropriate officer as to the officer's knowledge of our compliance with all conditions and covenants under the senior indenture, such compliance to be determined without regard to any period of grace or requirement of notice under the indenture. (Section 606)

## Right to Cure

At any time after the declaration of acceleration with respect to a series of senior debt securities has been made, but before a judgment or decree for payment of the money due has been obtained, the Event or Events of Default giving rise to the declaration of acceleration will, without further act, be deemed to have been waived, and the declaration and its consequences will, without further act, be deemed to have been rescinded and annulled, if:

- we have paid or deposited with the senior trustee a sum sufficient to pay:
  - all overdue interest, if any, on all senior debt securities of that series;
  - the principal of and premium, if any, on any senior debt securities of that series which have become due, otherwise than by that declaration of acceleration, and interest thereon at the rate or rates prescribed in the senior debt securities;
  - interest upon overdue interest, if any, at the rate or rates prescribed in the senior debt securities, to the extent payment of that interest is lawful; and
  - all amounts due to the senior trustee under the senior indenture; and
- any other Event of Default with respect to the senior debt securities of that series, other than the non-payment of the principal of the senior debt securities of that series which has become due solely by the declaration of acceleration, have been cured or waived as provided in the senior indenture. (Section 802)

## Modification and Waiver

Without the consent of any holder of senior debt securities, we and the senior trustee may enter into one or more supplemental indentures to the senior indenture for any of the following purposes:

- to evidence the assumption by any permitted successor to us of our covenants under the senior indenture and the senior debt securities;
- to add to our covenants or other provisions for the benefit of the holders of all or any series of outstanding senior debt securities or to surrender any right or power conferred upon us by the senior indenture;
- to add any additional Events of Default with respect to all or any series of outstanding senior debt securities;
- to change or eliminate any provision of the senior indenture or to add any new provision to the senior indenture, provided that if the change, elimination or addition will adversely affect the interests of the holders of any series of senior debt securities in any material respect, that change, elimination or addition will become effective with respect to that series only when the consent of the holders of that series so affected has been obtained or when there is no outstanding senior debt security of that series under the senior indenture;
- to provide collateral security for the senior debt securities;
- to establish the form or terms of any series of senior debt securities as permitted by the senior indenture;
- to provide for the authentication and delivery of bearer securities and coupons appertaining to the bearer securities representing interest, if any, on the bearer securities and for the procedures for the registration, exchange and replacement of those bearer securities and for giving of notice to, and the solicitation of the vote or consent of, the holders of those bearer securities and for any and all other matters incidental to the bearer securities;

## Table of Contents

- to evidence and provide for the acceptance of appointment of a separate or successor senior trustee under the senior indenture with respect to senior debt securities of one or more series and to add or to change any of the provisions of the senior indenture as will be necessary to provide for or to facilitate the administration of the senior indenture by more than one senior trustee;
- to provide for the procedures required to permit the utilization of a noncertificated system of registration for any series of senior debt securities;
- to change any place where
  - the principal of and any premium and interest on any senior debt securities will be payable;
  - any senior debt securities may be surrendered for registration of transfer or exchange; or
  - notices and demands to or upon us in respect of the senior debt securities and senior indenture may be served; or
- to cure any ambiguity, to correct or supplement any defective or inconsistent provision or to make or change any other provisions with respect to matters and questions arising under the senior indenture, provided that such action does not adversely affect the interests of the holders of senior debt securities of any series in any material respect. (Section 1201)

The holders of not less than a majority in aggregate principal amount of the outstanding senior debt securities of any series may waive our compliance with some restrictive provisions of the senior indenture. (Section 607) The holders of not less than a majority in principal amount of the outstanding senior debt securities of any series may waive any past default under the senior indenture with respect to that series, except a default:

- in the payment of principal, premium or interest; and
- related to certain covenants and provisions of the senior indenture that cannot be modified or amended without the consent of the holder of each outstanding senior debt security of the series affected. (Section 813)

Without limiting the generality of the foregoing, if the Trust Indenture Act is amended after the date of the senior indenture in such a way as to require changes to the senior indenture or the incorporation of additional provisions or so as to permit changes to, or the elimination of provisions which, at the date of the senior indenture or at any time thereafter, were required by the Trust Indenture Act to be contained in the senior indenture, the senior indenture will be deemed to have been amended so as to conform to such amendment or to effect such changes or elimination. We and the senior trustee may, without the consent of any holders, enter into one or more supplemental indentures to evidence or effect such amendment. (Section 1201)

Except as provided above, the consent of the holders of not less than a majority in aggregate principal amount of the senior debt securities of all series then outstanding, considered as one class, is required for the purpose of adding any provisions to, or changing in any manner, or eliminating any of the provisions of the senior indenture pursuant to one or more supplemental indentures. However, if less than all of the series of outstanding senior debt securities are directly affected by a proposed supplemental indenture, then the consent only of the holders of a majority in aggregate principal amount of outstanding senior debt securities of all series so directly affected, considered as one class, will be required. Further, if the senior debt securities of any series have been issued in more than one tranche and if the proposed supplemental indenture directly affects the rights of the holders of one or more, but less than all, tranches, then the consent only of the holders of a majority in aggregate principal amount of the outstanding senior debt securities of all tranches so directly affected, considered as one class, will be required.

Without the consent of each holder of senior debt securities affected by the modification, no supplemental indenture may:

- change the stated maturity of the principal of or any installment of principal of or interest on, any senior debt security;

## Table of Contents

- reduce the principal amount of the senior debt security;
- reduce the rate of interest on the senior debt security (or the amount of any installment of interest thereon) or change the method of calculating the rate;
- reduce any premium payable upon redemption of the senior debt security;
- reduce the amount of the principal of any original issue discount senior security that would be due and payable upon a declaration of acceleration of maturity;
- change the coin or currency (or other property) in which any senior debt security or any premium or the interest thereon is payable;
- impair the right to institute suit for the enforcement of any payment on or after the stated maturity of any senior debt security (or, in the case of redemption, on or after the redemption date);
- reduce the percentage in principal amount of the outstanding senior debt securities of any series, or any tranche thereof, required for the authorization of any such supplemental indenture, or required for the authorization of any waiver of compliance with any provision of the senior indenture or any default thereunder and its consequences, or reduce the requirements for quorum or voting; or
- modify certain of the provisions of the senior indenture relating to supplemental indentures, waivers of certain covenants and waivers of past defaults with respect to the senior debt securities of any series, or any tranche thereof.

A supplemental indenture which changes or eliminates any covenant or other provision of the senior indenture which has expressly been included solely for the benefit of one or more particular series of senior debt securities or one or more tranches thereof, or modifies the rights of the holders of senior debt securities of that series or tranche with respect to such covenant or other provision, will be deemed not to affect the rights under the senior indenture of the holders of the senior debt securities of any other series or tranche. (Section 1202)

The senior indenture provides that in determining whether the holders of the requisite principal amount of the outstanding senior debt securities have given any request, demand, authorization, direction, notice, consent or waiver under the senior indenture as of any date, or whether or not a quorum is present at a meeting of holders:

- senior debt securities owned by us or any other obligor upon the senior debt securities or any affiliate of ours or of such other obligor (unless we, the affiliate or the obligor own all securities outstanding under the senior indenture, or all outstanding senior debt securities of each such series and each such tranche, as the case may be, determined without regard to this clause) will be disregarded and deemed not to be outstanding;
- the principal amount of an original issue discount security that will be deemed to be outstanding for such purposes will be the amount of the principal thereof that would be due and payable as of the date of such determination upon a declaration of acceleration of the maturity thereof, as provided in the senior indenture; and
- the principal amount of a senior debt security denominated in one or more foreign currencies or a composite currency that will be deemed to be outstanding will be the U.S. dollar equivalent, determined as of such date in the manner prescribed for such senior debt security, of the principal amount of the senior debt security (or, in the case of a senior debt security described in second bullet above, of the amount described in that clause). (Section 101)

If we solicit from holders any request, demand, authorization, direction, notice, consent, election, waiver or other action, we may, at our option, by company order, fix in advance a record date for the determination of holders entitled to give such request, demand, authorization, direction, notice, consent, election, waiver or other action. If a record date is fixed, such request, demand, authorization, direction, notice, consent, election, waiver or other action may be given before or after that record date, but only the holders of record at the close of business on the record date will be deemed to be holders for the purposes of determining whether holders of the

## [Table of Contents](#)

requisite proportion of the outstanding senior debt securities have authorized or agreed or consented to such request, demand, authorization, direction, notice, consent, election, waiver or other action, and for that purpose the outstanding senior debt securities will be computed as of the record date. Any request, demand, authorization, direction, notice, consent, election, waiver or other action of a holder will bind every future holder of the same senior debt security and the holder of every senior debt security issued upon the registration of transfer thereof or in exchange therefor or in lieu thereof in respect of anything done, omitted or suffered to be done by the senior trustee or us in reliance thereon, whether or not notation of that action is made upon the senior debt security. (Section 104)

### **Defeasance**

Unless the applicable prospectus supplement otherwise indicates, any senior debt securities, or any portion of the principal amount thereof, will be deemed to have been paid for purposes of the senior indenture, and, at our election, our entire indebtedness in respect of the senior debt securities will be deemed to have been satisfied and discharged, if there has been irrevocably deposited with the senior trustee or any paying agent (other than us), in trust:

(a) money in an amount which will be sufficient, or

(b) eligible obligations (as described below), which do not contain provisions permitting the redemption or other prepaying at the option of the issuer thereof, the principal of and the interest on which when due, without any regard to reinvestment thereof, will provide monies which, together with money, if any, deposited with or held by the senior trustee or the paying agent, will be sufficient, or

(c) a combination of (a) and (b) which will be sufficient, to pay when due the principal of and any premium and interest due and to become due on the senior debt securities or portions thereof. (Section 701)

For this purpose, unless the applicable prospectus supplement otherwise indicates, eligible obligations include direct obligations of, or obligations unconditionally guaranteed by, the United States, entitled to the benefit of the full faith and credit thereof, and certificates, depositary receipts or other instruments which evidence a direct ownership interest in such obligations or in any specific interest or principal payments due in respect thereof. (Section 101)

### **Resignation of Senior Trustee**

The senior trustee may resign at any time by giving written notice to us or may be removed at any time by act of the holders of a majority in principal amount of the outstanding senior debt securities of a series. No resignation or removal of the senior trustee and no appointment of a successor senior trustee will become effective until the acceptance of appointment by a successor senior trustee in accordance with the requirements of the senior indenture. So long as no Event of Default or event which, after notice or lapse of time, or both, would become an Event of Default has occurred and is continuing and except with respect to a senior trustee appointed by act of the holders of a majority in principal amount of the outstanding senior debt securities, if we have delivered to the senior trustee a board resolution appointing a successor senior trustee and the successor has accepted the appointment in accordance with the terms of the senior indenture, the senior trustee will be deemed to have resigned and the successor will be deemed to have been appointed as senior trustee in accordance with the senior indenture. (Section 910)

### **Notices**

Notices to holders of senior debt securities will be given by mail to the addresses of the holders as they appear in the security register. (Section 106)

## [Table of Contents](#)

### **Title**

We, the senior trustee and any agent of ours or the senior trustee may treat the person in whose name a senior debt security is registered as the absolute owner (whether or not the senior debt security may be overdue) for the purpose of making payment and for all other purposes. (Section 308)

### **Governing Law**

The senior indenture and the senior debt securities will be governed by, and construed in accordance with, the laws of the State of New York, except to the extent the law of any other jurisdiction is mandatorily applicable. (Section 112)

### **Limitation on Suits**

The senior indenture limits a holder's right to institute any proceeding with respect to the senior indenture, the appointment of a receiver or trustee, or for any other remedy under the senior indenture. (Section 807)

### **Maintenance of Properties**

A provision in the senior indenture provides that we will cause (or, with respect to property owned in common with others, make reasonable effort to cause) all our properties used or useful in the conduct of our business to be maintained and kept in good condition, repair and working order and will cause (or, with respect to property owned in common with others, make reasonable effort to cause) to be made all necessary repairs, renewals, replacements, betterments and improvements, all as, in our judgment, may be necessary so that the business carried on in connection therewith may be properly conducted. However, nothing in this provision will prevent us from discontinuing, or causing the discontinuance of the operation and maintenance of any of our properties if the discontinuance is, in our judgment, desirable in the conduct of our business. (Section 605)

### **Global Securities**

The senior debt securities of a series may be issued in whole or in part in the form of one or more global securities that will be deposited with, or on behalf of, a depository identified in the applicable prospectus supplement. The specific terms of the depository arrangements with respect to a series of senior debt securities will be described in the applicable prospectus supplement. See “—Global Securities.”

## **Description of Subordinated Debt Securities**

### **General**

This section describes the general terms and provisions of the subordinated debt securities that may be offered by this prospectus. The prospectus supplement will describe the specific terms of the series of the subordinated debt securities offered under that prospectus supplement and any general terms outlined in this section that will not apply to those subordinated debt securities. The provisions of the subordinated indenture are substantially identical in substance to the provisions of the senior indenture, except for the subordination provisions described below, for which there are no counterparts in the senior indenture. See “Description of Debt Securities—Description of Senior Debt Securities.” Because this is only a summary, it does not contain all of the details found in the full text of the subordinated indenture and the subordinated debt securities. If you would like additional information you should read the form of subordinated indenture and the form of subordinated debt securities, which have been or will be filed as exhibits to the registration statement of which this prospectus is a part. In this section, we include references in parentheses to specific sections of that form of indenture.



## Subordination

Subordinated debt securities will be subordinate and subject in right of payment, in the manner and to the extent set forth in the subordinated indenture, to the prior payment in full of all Senior Debt. (Section 1501)

If we make a distribution to our creditors as a result of:

- a liquidation;
- a dissolution;
- winding up;
- a reorganization;
- an assignment for the benefit of creditors;
- marshaling of assets and liabilities; or
- any bankruptcy, insolvency or similar proceeding involving us;

then, the holders of Senior Debt will first be entitled to receive payment in full in cash of all obligations due on or to become due on or in respect of all Senior Debt, before the holders of subordinated debt securities are entitled to receive any payment or distribution (“Securities Payments”).

Until the Senior Debt is paid in full, any Securities Payment to which the holders of subordinated debt securities would be entitled will be paid or delivered by us or any other person making the payment or distribution, directly to the holders of Senior Debt for application to all of the Senior Debt then due. (Section 1502)

We may not make any payments on the account of the subordinated debt securities, or on account of the purchase or redemption or other acquisition of the subordinated debt securities, if there has occurred and is continuing a default in the payment of the principal of (or premium, if any) or interest on any Senior Debt. (Section 1503)

In the event that the subordinated trustee receives any Securities Payment prohibited by the subordination provisions of the subordinated indenture, the payment will be held by the subordinated trustee in trust for the benefit of, and will immediately be paid over upon written request to, the holders of Senior Debt or their representative or representatives, or the trustee or trustees under any applicable indenture for application to the payment of Senior Debt. (Section 1504) The subordination will not prevent the occurrence of any event of default in respect of the subordinated debt securities.

For purposes of the foregoing, “Securities Payments” will be deemed not to include:

- a payment or distribution of our stock or securities provided for by a plan of reorganization or readjustment authorized by an order or decree of a court of competent jurisdiction in a reorganization proceeding under any applicable bankruptcy law or of any other corporation provided for by such plan of reorganization or readjustment which stock or securities are subordinated in right of payment to all then outstanding Senior Debt to the same extent as, or to a greater extent than, the subordinated debt securities are so subordinated as provided in the subordinated indenture; or
- payments of assets from any defeasance trust which have been on deposit for 90 consecutive days without the occurrence of blockage of payment on any series of subordinated debt securities as described above. (Section 1502)

By reason of the subordination of the subordinated debt securities, in the event of our insolvency, holders of Senior Debt may receive more, ratably, and holders of the subordinated debt securities having a claim pursuant to such securities may receive less, ratably, than our other creditors. There may also be interruption of scheduled interest and principal payments resulting from events of default on Senior Debt.

## [Table of Contents](#)

### **Certain Definitions**

Set forth below are certain defined terms used in the subordinated indenture. Please refer to the subordinated indenture for a full definition of all such terms.

“Junior Subordinated Debt” means any indebtedness for money that we have borrowed, created or evidenced by an instrument which expressly provides that the indebtedness for money borrowed is subordinated in right of payment to the subordinated debt securities.

“Senior Debt” means all indebtedness for money that we have borrowed, except

- indebtedness for money borrowed under the subordinated debt securities and junior subordinated debt securities; and
- indebtedness for money borrowed (including, without limitation, any Junior Subordinated Debt) created or evidenced by an instrument which expressly provides that the indebtedness for money borrowed is subordinated in right of payment to any other indebtedness for money borrowed by us.

Notwithstanding anything to the contrary in the foregoing, Senior Debt shall not include:

- any indebtedness for money borrowed incurred for the purchase of goods or materials or for services obtained in the ordinary course of business (other than with the proceeds of revolving credit borrowings permitted by the subordinated indenture). (Section 101)

### **Global Securities**

We may issue a series of debt securities offered by this prospectus, in whole or in part, in the form of one or more global securities, which will have an aggregate principal amount equal to that of the debt securities represented thereby.

Unless it is exchanged in whole or in part for the individual debt securities it represents, a global security may be transferred only as a whole:

- by the applicable depository to a nominee of the depository;
- by any nominee to the depository itself or another nominee; or
- by the depository or any nominee to a successor depository or any nominee of the successor.

We will describe the specific terms of the depository arrangement related to a series of debt securities in the applicable prospectus supplement. We anticipate that the following provisions will generally apply to depository arrangements for our debt securities.

Each global security will be registered in the name of a depository or its nominee identified in the applicable prospectus supplement and will be deposited with the depository or its nominee or a custodian. The global security will bear a legend regarding the restrictions on exchanges and registration of transfer referred to below and any other matters as may be provided in the indenture.

As long as the depository, or its nominee, is the registered holder of the global security, the depository or nominee, as the case may be, will be considered the sole owner and holder of the debt securities represented by the global security for all purposes under the applicable indenture. Except in limited circumstances, owners of beneficial interests in a global security:

- will not be entitled to have the global security or any of the underlying debt securities registered in their names;

## Table of Contents

- will not receive or be entitled to receive physical delivery of any of the underlying debt securities in definitive form; and
- will not be considered to be the owners or holders under the indenture relating to those debt securities.

All payments of principal of and any premium and interest on a global security will be made to the depositary or its nominee, as the case may be, as the registered owner of the global security representing these debt securities. The laws of some states require that some purchasers of securities take physical delivery of securities in definitive form. These limits and laws may impair the ability to transfer beneficial interests in a global security.

Ownership of beneficial interests in a global security will be limited to institutions that have accounts with the depositary or its nominee, which institutions we refer to as the participants, and to persons that may hold beneficial interests through participants. In connection with the issuance of any global security, the depositary will credit, on its book-entry registration and transfer system, the respective principal amounts of debt securities represented by the global security to the accounts of its participants. Ownership of beneficial interests in a global security will be shown only on, and the transfer of those ownership interests will be effective only through, records maintained by the depositary and its participants. Payments, transfers, exchanges and other matters relating to beneficial interests in a global security may be subject to various policies and procedures adopted by the depositary from time to time. Neither we, the applicable trustee, nor any of our or the applicable trustee's agents will have any responsibility or liability for any aspect of the depositary's or any participant's records relating to, or for payments made on account of, beneficial interests in a global security, or for maintaining, supervising or reviewing any records relating to beneficial interests.

## DESCRIPTION OF SECURITIES WARRANTS

The following summary of the general terms and provisions of the securities warrants represented by warrant agreements and warrant certificates that we may offer using this prospectus is only a summary and does not purport to be complete. You must look at the applicable forms of warrant agreement and warrant certificate for a full understanding of the specific terms of any securities warrant. The forms of the warrant agreement and the warrant certificate will be filed or incorporated by reference as exhibits to the registration statement to which this prospectus is a part. See “Where You Can Find More Information” for information on how to obtain copies.

A prospectus supplement will describe the specific terms of the securities warrants offered under that prospectus supplement, including any of the terms in this section that will not apply to those securities warrants, and any special considerations, including tax considerations, applicable to investing in those securities warrants.

### General

We may issue securities warrants alone or together with other securities offered by the applicable prospectus supplement. The securities warrants may be issued independently or together with any securities and may be attached to or separate from the securities. Each series of securities warrants will be issued under a separate warrant agreement between us and a bank or trust company, as warrant agent, as described in the applicable prospectus supplement. The warrant agent will act solely as our agent in connection with the securities warrants and will not act as an agent or trustee for any holders or beneficial owners of the securities warrants.

The prospectus supplement relating to any securities warrants we offer will describe the specific terms relating to the offering. These terms may include some or all of the following:

- the offering price;
- the currencies in which the securities warrants will be offered;
- the designation, total principal amount, currencies, denominations and terms of the series of debt securities that may be purchased upon exercise of the securities warrants;
- the principal amount of the series of debt securities that may be purchased if a holder exercises the securities warrants and the price at which and currencies in which the principal amount may be purchased upon exercise;
- the total number of shares that may be purchased if all of the holders exercise the securities warrants and, in the case of securities warrants for the purchase of shares of preferred stock, the designation, total number and terms of the series of preferred stock that can be purchased upon exercise of the securities warrants;
- the number of shares of preferred stock or common stock that may be purchased if a holder exercises any one securities warrant and the price at which and currencies in which the shares of preferred stock or common stock may be purchased upon exercise;
- the designation and terms of any series of securities with which the securities warrants are being offered, and the number of securities warrants offered with each security;
- the date on and after which the holder of the securities warrants can transfer them separately from the related series of securities;
- the date on which the right to exercise the securities warrants begins and expires;
- the triggering event and the terms upon which the exercise price and the number of underlying securities that the securities warrants are exercisable into may be adjusted;
- whether the securities warrants will be issued in registered or bearer form;

## Table of Contents

- the identity of any warrant agent with respect to the securities warrants and the terms of the warrant agency agreement with that warrant agent;
- a discussion of material U.S. federal income tax consequences; and
- any other terms of the securities warrants.

A holder of securities warrants may:

- exchange them for new securities warrants of different denominations;
- present them for registration of transfer, if they are in registered form; and
- exercise them at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement.

Until the securities warrants are exercised, holders of the warrants will not have any of the rights of holders of the underlying securities.

### **Exercise of Securities Warrants**

Each holder of a securities warrant is entitled to purchase the number of shares of common stock or preferred stock or the principal amount of debt securities, as the case may be, at the exercise price described in the applicable prospectus supplement. After the close of business on the day when the right to exercise terminates (or a later date if we extend the time for exercise), unexercised securities warrants will become void.

Holders of securities warrants may exercise them by

- delivering to the warrant agent the payment required to purchase the underlying securities, as stated in the applicable prospectus supplement;
- properly completing and signing the reverse side of their warrant certificate(s), if any, or other exercise documentation; and
- delivering their warrant certificate(s), if any, or other exercise documentation to the warrant agent within the time specified by the applicable prospectus supplement.

If you comply with the procedures described above, your securities warrants will be considered to have been exercised when warrant agent receives payment of the exercise price. As soon as practicable after you have completed these procedures, we will issue and deliver to you the shares of common stock, preferred stock or debt securities, as the case may be, that you purchased upon exercise. If you exercise fewer than all of the securities warrants represented by a warrant certificate, we will issue to you a new warrant certificate for the unexercised amount of securities warrants.

### **Amendments and Supplements to Warrant Agreements**

We may amend or supplement a warrant agreement or warrant certificates without the consent of the holders of the securities warrants if the changes are not inconsistent with the provisions of the securities warrants and do not adversely affect the interests of the holders.

## DESCRIPTION OF UNITS

We may, from time to time, issue units comprised of one or more of the other securities described in this prospectus in any combination. A prospectus supplement will describe the specific terms of the units offered under that prospectus supplement, and any special considerations, including tax considerations, applicable to investing in those units. You must look at the applicable prospectus supplement and any applicable unit agreement for a full understanding of the specific terms of any units. The form of unit agreement will be filed or incorporated by reference as an exhibit to the registration statement to which this prospectus is a part. See “Where You Can Find More Information” for information on how to obtain copies.

## PLAN OF DISTRIBUTION

We may sell the securities or the selling stockholders named herein may sell their common stock from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities or the selling stockholders may sell their 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 may distribute the securities or the selling stockholders may distribute their 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 respective securities being offered by this prospectus. We or the selling stockholders may also designate agents to solicit offers to purchase the respective securities from time to time. We will name in a prospectus supplement any agent involved in the offer or sale of our securities.

If we or the selling stockholders utilize a dealer in the sale of the respective securities being offered by this prospectus, we or the selling stockholders will sell the respective securities to the dealer, as principal. The dealer may then resell the securities 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 respective securities 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 securities to the public. In connection with the sale of the securities, we or the purchasers of securities 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 securities 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 respective securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the securities 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

## Table of Contents

them on resale of the securities 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.

The securities may or may not be listed on a national securities exchange. To facilitate the offering of securities, 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 securities, which involve the sale by persons participating in the offering of more securities 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 securities by bidding for or purchasing securities in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if securities 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 securities 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 respective securities 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 securities 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 securities covered by this prospectus and the applicable prospectus supplement, including short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of stock. 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. In addition, we may otherwise loan or pledge securities to a financial institution or other third party that in turn may sell the securities short using this prospectus. Such financial institution or other third party may transfer its economic short position to investors in our securities or in connection with a concurrent offering of other securities.

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

### **LEGAL MATTERS**

Dorsey & Whitney LLP will issue a legal opinion as to the validity of the securities 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, 2009, adoption of new authoritative accounting guidance regarding the financial reporting for outstanding equity-linked financial instruments and an explanatory paragraph regarding going concern uncertainty), and have been so incorporated in reliance upon that report of such firm given upon their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

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

We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities offered by this prospectus. When used in this prospectus, the term "registration statement" includes amendments to the registration statement as well as the exhibits, schedules, financial statements and notes filed as part of the registration statement. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement. This prospectus omits information contained in the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and the 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, 2009;
- Current Reports on Form 8-K filed on January 15, 2010, January 20, 2010, January 21, 2010, February 10, 2010, February 12, 2010, February 23, 2010, March 15, 2010 and March 17, 2010; and
- the description of our common stock 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





**8,800,000 Shares of Common Stock  
Warrants to Purchase 1,760,000 Shares of Common Stock**

---

**Craig-Hallum Capital Group**

---

**September 23, 2011**