



## 14,800,000 Shares of Common Stock Warrants to Purchase 14,800,000 Shares of Common Stock

Enteromedics Inc. is offering 14,800,000 shares of its common stock together with warrants to purchase 14,800,000 shares of common stock. The public offering price of the common stock is \$1.74 per share and of the warrants is \$0.01 per warrant. Each share of common stock is being sold together with one warrant exercisable for one share of common stock at an exercise price of \$2.19 per share (125% of the aggregate offering price for a share of common stock and corresponding warrant). The shares of common stock and warrants are immediately separable after purchase and will be issued separately. The warrants are exercisable beginning 181 days after the closing date of this offering and ending on the fifth anniversary of the date on which the exercise period begins. The warrants do not allow for cashless exercise. For a more detailed description of our common stock and warrants, see the section entitled "Description of the Securities" beginning on page 79 of this prospectus.

Our common stock is listed on the NASDAQ Capital Market under the symbol "ETRM." We do not intend to apply to list the warrants on any securities exchange. The last reported sale price of our common stock on the NASDAQ Capital Market on December 8, 2010 was \$2.21 per share.

**Investing in the common stock and warrants involves risks. See "[Risk Factors](#)" beginning on page 9 of this prospectus.**

	Per Share	Per Warrant	Total
Public offering price	\$1.7400	\$ 0.0100	\$1.7500
Underwriting discounts	\$0.1044	\$ 0.0006	\$0.1050
Proceeds, before expenses, to Enteromedics Inc.	\$1.6356	\$ 0.0094	\$1.6450

The underwriter also may purchase up to an additional 2,220,000 shares of common stock and additional warrants to purchase up to 2,220,000 shares of common stock from us at the public offering price for each security, less the underwriting discount, within 30 days after the date of this prospectus to cover over-allotments. In addition to the underwriting discount, we have agreed to pay up to \$140,000 of the fees and expenses of the underwriter in connection with this offering. As additional compensation, we plan to issue the underwriter warrants to purchase a number of shares of common stock equal to 2.0% of the number of shares of common stock sold in this offering at an exercise price of \$2.19 per share (125% of the aggregate offering price for a share of common stock and corresponding warrant). See "Underwriting."

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The underwriter expects to deliver the securities to purchasers on December 14, 2010.

**Craig-Hallum Capital Group**

December 8, 2010

TABLE OF CONTENTS

<a href="#">PROSPECTUS SUMMARY</a>	1
<a href="#">RISK FACTORS</a>	9
<a href="#">SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</a>	28
<a href="#">USE OF PROCEEDS</a>	29
<a href="#">PRICE RANGE OF OUR COMMON STOCK</a>	30
<a href="#">DIVIDEND POLICY</a>	30
<a href="#">CAPITALIZATION</a>	31
<a href="#">DILUTION</a>	32
<a href="#">BUSINESS</a>	33
<a href="#">MANAGEMENT</a>	55
<a href="#">EXECUTIVE COMPENSATION</a>	59
<a href="#">PRINCIPAL STOCKHOLDERS</a>	74
<a href="#">RELATED PARTY TRANSACTIONS</a>	77
<a href="#">DESCRIPTION OF SECURITIES</a>	78
<a href="#">MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES</a>	85
<a href="#">UNDERWRITING</a>	90
<a href="#">LEGAL MATTERS</a>	92
<a href="#">EXPERTS</a>	92
<a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>	93
<a href="#">INCORPORATION OF DOCUMENTS BY REFERENCE</a>	93

You should rely only on the information contained in this prospectus and any free-writing prospectus that we authorize to be distributed to you. We have not, and the underwriter has not, authorized anyone to provide you with information different from or in addition to that contained in this prospectus or any related free-writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and are seeking offers to buy, the common stock and warrants only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock and warrants. Our business, financial conditions, results of operations and prospects may have changed since that date.

**Registered Trademarks and Trademark Applications:** In the United States we have registered trademarks for VBLOC®, ENTEROMEDICS® and MAESTRO® each registered with the United States Patent and Trademark Office, and have received a Notice of Allowance and fourth extension of time to file a Statement of Use on our application to register the mark EMPOWER™. In addition, the marks VBLOC, MAESTRO and ENTEROMEDICS are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, Saudi Arabia and Switzerland. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are registered in Mexico. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM are the subject of pending trademark applications in the United Arab Emirates. This prospectus contains other trade names and trademarks and service marks of EnteroMedics and of other companies.

We obtained industry and market data used throughout and incorporated by reference into this prospectus through our research, surveys and studies conducted by third parties and industry and general publications. We have not independently verified market and industry data from third-party sources.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained in greater detail elsewhere in this prospectus or incorporated by reference into this prospectus. This summary may not contain all of the information that you should consider before investing in the common stock and warrants. You should carefully read the entire prospectus, including “Risk Factors” beginning on page 9 and the financial statements and related notes and other documents incorporated by reference into this prospectus, before making an investment decision.*

### **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 influences food processing. Our initial product under development, the Maestro System, has been implanted in approximately 400 patients and uses VBLOC therapy to limit the expansion of the stomach and 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.

### **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 to 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**

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)</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	19.4% (2 years) <sup>(2)</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	25.3% (1 year)
ReCharge	US	234	1/5	IDE Approved

- (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. Excess weight loss (EWL) is reported as the percentage of excess weight that is lost by the subject.
- (2) 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.

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:

- Patients that used the device for the prescribed amount of time (99 hours) had clinically meaningful weight-loss;
- Both the treatment and control arm subjects experienced comparable, significant, dose-dependent EWL at 12 months; and
- There was an unanticipated therapeutic effect in which a low-intensity blocking signal introduced VBLOC therapy in human subjects in the control group.

In January 2010, we met with the U.S. Food and Drug Administration (FDA) to discuss the EMPOWER trial results and the regulatory process going forward. Based on this discussion, in March we submitted an Investigational Device Exemption (IDE) for a pivotal trial of our second generation fully implantable Maestro Rechargeable (RC) System. In October 2010, we received an unconditional approval from the FDA for this trial, the ReCharge trial, a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in 234 morbidly obese subjects enrolled at up to 12 U.S. centers. All patients in the study will receive an implanted device and will be randomized in a 2:1 allocation to treatment or control groups. The control group will receive a functional, but non-active device that will deliver no charge to the vagus nerve during the study period. All patients are expected to participate in a weight management program.

## **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).

## **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 key opinion leaders;
- commercialize our products using a distribution network outside the United States;
- commercialize our products using a direct sales and marketing effort within the United States;
- secure appropriate reimbursement for the Maestro System;
- expand and protect our intellectual property position; and
- leverage our VBLOC technology for other disease states.

## **Commercialization**

### ***United States***

If we are able to obtain adequate funding, we will begin enrolling and implanting patients in the ReCharge trial and target an acceleration of the timing of the final implant to take place around the end of 2011 at the

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

#### ***Australia***

We have begun to take the initial steps necessary to commercialize the Maestro RC System in Australia, which includes applying for European CE Mark certification and Australian Therapeutic Goods Administration (TGA) approval. We have applied for European CE Mark certification of the Maestro RC System and hope to receive approval in the first quarter of 2011. Once we receive European CE Mark certification, we intend to use that approval to file an application for approval and listing of the Maestro RC System with the TGA and intend to commercialize the device following receipt of that approval during the second half of 2011.

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

We also are exploring commercialization opportunities in other markets outside of the United States and Australia.

#### **Risks Associated with Our Business**

Our business is subject to numerous risks discussed more fully in the section entitled “*Risk Factors*” immediately following this prospectus summary. 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 other country 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 incorporated by reference into this prospectus and should not be considered a part of this prospectus. As used in this prospectus, references to “we,” “our,” “us” and “EnteroMedics” refer to EnteroMedics Inc. and its subsidiary unless the context requires otherwise.

## THE OFFERING

Securities offered by EnteroMedics	14,800,000 shares of our common stock together with warrants to purchase 14,800,000 shares of our common stock.
Offering price	\$1.74 per share for the common stock and \$0.01 per warrant for the warrants.
Description of the warrants	The warrants are exercisable at an exercise price of \$2.19 per share (125% of the aggregate offering price for a share of common stock and corresponding warrant) beginning 181 days after the closing date of this offering and ending on the fifth anniversary of the date on which the exercise period begins. The warrants do not allow for cashless exercise. See “Description of Securities” for additional information.
Common stock to be outstanding after this offering	25,672,388 shares
Over-allotment option	2,220,000 shares of our common stock together with warrants to purchase 2,220,000 shares of our common stock.
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” for additional information.
Risk factors	You should read the “Risk Factors” beginning on page 9 of this prospectus for a discussion of the factors you should consider carefully before deciding whether to invest in the common stock and warrants offered by this prospectus
Nasdaq Capital Market symbol	ETRM

The number of shares of our common stock that will be outstanding immediately after this offering is based on 10,872,388 shares outstanding as of September 30, 2010. This number assumes the conversion into common stock of all of the outstanding shares of our convertible preferred stock. The number of outstanding shares excludes:

- 4,903,728 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2010, at a weighted average exercise price of \$4.12 per share;
- 911,220 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010, at a weighted average exercise price of \$18.69 per share;
- 174,807 shares of common stock available for future issuance under our 2003 Stock Incentive Plan as of September 30, 2010;
- an increase in the number of shares authorized under our 2003 Stock Incentive Plan by 1,149,817 and the effects of a one-time option exchange program both approved by our stockholders and completed on October 29, 2010;

- 14,800,000 shares of common stock underlying the warrants sold in this offering; and
- 296,000 shares of common stock underlying the warrants issued to the underwriter in connection with this offering.

---

Except where we state otherwise, the information we present in this prospectus reflects:

- a 1-for-6 reverse split of our outstanding common stock that was effected on July 9, 2010;
- the conversion of all of the outstanding shares of our convertible preferred stock into 3,394,309 shares of common stock upon completion of this offering;
- no options, warrants or shares of common stock issued after September 30, 2010, and no outstanding options or warrants that were exercised after September 30, 2010; and
- no exercise by the underwriter of its over-allotment option.



**SUMMARY FINANCIAL DATA**

The following tables summarize our financial data for the periods presented. The summary statement of operations data for each of the years ended December 31, 2009, 2008 and 2007, except for the pro forma net loss per share and pro forma weighted average number of shares data, are derived from our audited financial statements, which are incorporated by reference into this prospectus. The summary statement of operations data for the nine months ended September 30, 2010 and 2009, except for the pro forma net loss per share and pro forma weighted average number of shares data, and summary balance sheet data as of September 30, 2010 have been derived from our unaudited financial statements, which are incorporated by reference into this prospectus. The historical results are not necessarily indicative of the results to be expected for any future periods. You should read this data together with the financial statements and related notes incorporated by reference into this prospectus, as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the other financial information incorporated by reference into this prospectus.

The pro forma balance sheet data give effect to the conversion of all of the outstanding shares of our convertible preferred stock into common stock upon the completion of the offering as well as our sale of common stock and warrants offered by this prospectus at an aggregate offering price of \$1.75 for each share and corresponding warrant sold, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

	Years Ended December 31,			Nine Months Ended September 30,	
	2009	2008	2007	2010	2009
(In thousands, except per share data)					
<b>Statement of operations data:</b>					
Operating expenses:					
Research and development	\$ 15,580	\$ 27,673	\$ 21,053	\$ 7,061	\$ 12,420
Selling, general and administrative	8,632	8,597	6,973	5,496	6,777
Total operating expenses	24,212	36,270	28,026	12,557	19,197
Other income (expense):					
Interest income	79	1,102	1,557	1	79
Interest expense	(4,104)	(2,684)	(1,649)	(975)	(2,470)
Change in value of warrant liability	(3,645)	0	(362)	159	(7,427)
Other, net	(47)	(22)	(95)	(20)	(24)
Net loss	\$ (31,929)	\$ (37,874)	\$ (28,575)	\$ (13,392)	\$ (29,039)
Net loss per share – basic and diluted <sup>(1)</sup>	\$ (6.42)	\$ (13.50)	\$ (70.12)	\$ (1.81)	\$ (6.35)
Shares used to compute basic and diluted net loss per share <sup>(1)</sup>	4,974	2,806	407	7,391	4,574
Pro forma net loss per common share (unaudited) – basic and diluted <sup>(2)</sup>				\$ (1.81)	
Weighted average number of shares used in pro forma per share calculations – basic and diluted <sup>(2)</sup>				7,403	

(1) Please see Note 2 to the notes to our audited financial statements incorporated by reference into this prospectus for an explanation of the method used to calculate basic and diluted net loss per common share. The basic and diluted net loss per share and shares used to compute the basic and diluted net loss per share have been adjusted to reflect a 1-for-6 reverse split that was effected on July 9, 2010.

- (2) Pro forma basic and diluted net loss per common share for the nine months ended September 30, 2010 assumes the conversion of all outstanding shares of convertible preferred stock into shares of common stock on the date of issuance using the as-if converted method.

	As of September 30, 2010	
	Actual	Pro forma
(In thousands)		
<b>Balance sheet data:</b>		
Cash, cash equivalents and short-term investments	\$ 12,554	\$ 36,540
Working capital (current assets less current liabilities)	8,734	32,720
Total assets	14,743	38,729
Long-term debt, net of current portion and discount	4,114	4,114
Convertible preferred stock	34	—
Deficit accumulated during development stage	(146,760)	(146,760)
Total stockholders' equity	5,708	29,694

The following table represents certain unaudited quarterly information for each of the eight quarters in the period ended December 31, 2009 and the three quarters in the interim period ended September 30, 2010. In our opinion, this information has been prepared on the same basis as the audited financial statements incorporated by reference into this prospectus and includes all the adjustments necessary to fairly state the unaudited quarterly results of operations (in thousands, except per share data).

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
<b>2010:</b>				
Net loss	\$(4,748)	\$ (4,259)	\$ (4,385)	N/A
Basic and diluted net loss per share <sup>(1)</sup>	\$ (0.66)	\$ (0.57)	\$ (0.59)	N/A
<b>2009:</b>				
Net loss	\$(6,669)	\$(10,362)	\$(12,008)	\$(2,890)
Basic and diluted net loss per share <sup>(1)</sup>	\$ (1.81)	\$ (2.07)	\$ (2.40)	\$ (0.47)
<b>2008:</b>				
Net loss	\$(8,498)	\$(11,354)	\$(10,200)	\$(7,822)
Basic and diluted net loss per share <sup>(1)</sup>	\$ (3.04)	\$ (4.05)	\$ (3.63)	\$ (2.78)

- (1) The basic and diluted net loss per share amounts have been adjusted to reflect a 1-for-6 reverse split that was effected on July 9, 2010.

## RISK FACTORS

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

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

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

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

***We have incurred losses since inception and we anticipate that we will continue to incur increasing losses for the foreseeable future. If we are unable to raise additional capital, we may be unable to continue as a going concern.***

We have incurred losses in each year since our formation in 2002. As of September 30, 2010, we had experienced net losses during the development stage of \$146.6 million. Our net loss applicable to common stockholders for the nine months ended September 30, 2010 was \$13.4 million and for the fiscal years ended December 31, 2009, 2008 and 2007 was \$31.9 million, \$37.9 million and \$28.6 million, respectively. We have funded our operations to date principally from the sale of our securities and through the issuance of indebtedness. Development of a new medical device, including conducting clinical trials and seeking regulatory approvals, is a long, expensive and uncertain process. If our Maestro System is approved for marketing by the FDA, 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.

Without additional capital, we may run out of cash in the first half of 2011, which has raised a substantial doubt about our ability to continue as a going concern. We have prepared our consolidated financial statements for the nine months ended September 30, 2010 and 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

## [Table of Contents](#)

course of business. The funding of our operations beyond the first half of 2011 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.

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on research and development, including conducting current and future clinical trials for our Maestro System, and initiating the commercialization of our product. Cash used in operations was \$10.1 million for the nine months ended September 30, 2010 and \$24.7 million, \$33.7 million and \$23.4 million for the fiscal years ended December 31, 2009, 2008 and 2007, respectively. Our cash used in operations beyond September 30, 2010 will largely depend on our regulatory path forward. If we obtain adequate funding and launch the approved clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity, ReCharge, we would expect research and development expenditures to increase in support of that study in addition to the continued follow-up on existing trials, such as VBLOC-DM2 ENABLE and EMPOWER. In 2011 and the years following, we expect that our cash used in operations will be significant, and we will need to raise additional capital to continue our research and development programs, commercialize our Maestro System, if approved by the TGA or FDA, and fund our on going operations.

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

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

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

Additional capital may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we

## [Table of Contents](#)

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 and immediately after this offering will be 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 new compliance initiatives.***

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

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

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

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

We do not have the necessary regulatory approvals to market our Maestro System in the United States or in any foreign market other than the European Community for which we received CE Mark approval for our Maestro RF System on March 4, 2009. We plan initially to launch our product, if approved, in countries outside the United States. We are hoping to receive CE Mark approval on our next-generation Maestro RC System in first quarter 2011 and immediately thereafter use that approval to seek approval from the TGA to market the system in Australia by the second half of 2011.

In order to market our Maestro System outside of the United States, we will need to establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries may differ from that required to obtain FDA approval. The regulatory approval process in other countries may also include all of the risks detailed below regarding FDA approval in the United States. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may

## [Table of Contents](#)

negatively impact the regulatory process in others. While we have received the European CE Mark for our Maestro RF System, we cannot assure you when, or if, we will be able to commence sales in the European Economic Area or obtain approval to market our Maestro System in other countries outside the United States.

We cannot market our product in the United States unless it has been approved by the FDA. The FDA approval process involves, among other things, successfully completing clinical trials and obtaining a 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 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.

## Table of Contents

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

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

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

- obtaining adequate funds to support the trial cost;
- reaching agreement on acceptable terms with prospective clinical trial sites;
- manufacturing sufficient quantities of our Maestro System;
- obtaining institutional review board approval to conduct the trial at a prospective site; and
- obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the difficulty in getting patients to endure the implant for the control arm, and the eligibility criteria for the trial.

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

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

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

## [Table of Contents](#)

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

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

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

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

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



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

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

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

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

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

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

We cannot provide any assurance that the data collected from our current and planned clinical trials will be sufficient to demonstrate that our VBLOC therapy is an attractive alternative to other obesity treatment procedures. We rely on experienced and highly trained surgeons to perform the procedures in our clinical trials and both short- and long-term results reported in our clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively impact rates of adoption of our Maestro System

## [Table of Contents](#)

and VBLOC therapy. We believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our Maestro System and VBLOC therapy will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

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

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

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

## Table of Contents

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

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

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,

## [Table of Contents](#)

investigating the safety and efficacy of our therapy requires extensive clinical testing, which is expensive and time-consuming. If we terminate a clinical trial in which we have invested significant resources, our prospects will suffer, as we will have expended resources on a program that will not provide a return on our investment and missed the opportunity to allocate those resources to potentially more productive uses. We will also need to obtain regulatory approval for these new applications, as well as achieve market acceptance and an acceptable level of reimbursement.

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

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

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

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

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

We do not have a sales organization and have no experience as a company in sales, marketing and distribution of our product. To generate sales we will need to identify and enter into an agreement with a third-party distributor in Australia, our intended first market for product commercial launch. There is no assurance that we can do so on economically acceptable terms or that if we do so, that third party will be successful in selling our product. In the rest of the world and the United States, we will also develop a sales and marketing infrastructure or contract with third parties to perform that function. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. Even if we obtain approval from the FDA to market our Maestro System, we may be unable to develop an effective sales and marketing organization on a timely basis, if at all. If we develop our own sales and marketing capabilities, our sales force will be competing with the experienced and well-funded marketing and sales organizations of our

## [Table of Contents](#)

more established competitors. If we are unable to establish our own sales and marketing capabilities, we will need to contract with third parties to market and sell our product. In this event, our profit margins would likely be lower than if we performed these functions ourselves. In addition, we would necessarily be relying on the skills and efforts of others for the successful marketing of our product. If we are unable to establish and maintain effective sales and marketing capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

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

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

- unfamiliar legal requirements with which we would need to comply;
- fluctuations in currency exchange rates;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;
- increased financial accounting and reporting burdens and complexities; and
- reduced or varied protection for intellectual property rights in some countries.

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

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

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

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

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

## [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 \$5.0 million of product liability insurance, which covers the use of our Maestro System and VBLOC therapy in our clinical trials, which amount we believe is appropriate. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost and on acceptable terms for an adequate coverage amount, or otherwise to protect against potential product liability claims, we could be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our Maestro System and VBLOC therapy in the market.

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

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

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

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare,

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

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

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

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

Our commercial success depends in part on our ability to obtain protection in the United States and other countries for our Maestro System and VBLOC therapy by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. To date, we have 16 issued U.S. patents, 12 of which pertain to treating gastrointestinal disorders, and 18 U.S. patent applications. We have 10 Australian applications, 11 European patent applications, 2 Chinese applications, 2 Indian applications, and 1 Japanese application. We also have 1 granted Australian patent, and two European patent applications we believe will be granted. In addition, we are the exclusive licensee to two U.S. patent applications owned by Mayo Foundation for Medical Education and Research, which are unrelated to our VBLOC therapy. Our pending and future patent

## [Table of Contents](#)

applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. We expect to incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third party's products or patents in litigation or administrative proceedings, including patent interferences or re-examinations. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the loss of the entire patent or the relevant portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our business operations. Even if we were to prevail in any litigation, we cannot assure you that we can obtain an injunction that prevents our competitors from practicing our patented technology. Our competitors may independently develop similar or alternative technologies or products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies.

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

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

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

Many of our competitors who have significant resources and have made substantial investments in competing technologies may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets. Our current or future U.S. or foreign patents may be challenged, circumvented by competitors or others or may be found to be invalid, unenforceable or insufficient. Since patent applications are confidential until patents are issued in the



## [Table of Contents](#)

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 Common Stock**

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

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

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

## [Table of Contents](#)

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

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

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

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

Although our common stock is listed on the NASDAQ Capital Market, our common stock has experienced low trading volume. Reported average daily trading volume in our common stock for the three month period ended September 30, 2010, was approximately 99,800 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 common stock and warrants in this offering, you will experience immediate dilution of \$0.59 per share based on the aggregate offering price of \$1.75 for each share and corresponding warrant because the price that you pay will be substantially greater than the adjusted pro forma net tangible book value per share of common stock that you acquire. See the section entitled "Dilution" in this prospectus for a more detailed description of this dilution.

***The warrants to be sold in this offering will not be transferable and will not be listed on a securities exchange.***

The warrants to be sold in this offering are not transferable and will not be listed on the NASDAQ Capital Market or any other securities exchange. Therefore, you will have to hold the warrants you purchase in this offering until such time, if any, as you wish to exercise the warrants.

## [Table of Contents](#)

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

### ***Our directors and executive officers hold substantial control over us and could limit your ability to influence the outcome of key transactions, including changes of control.***

Our executive officers and directors and entities affiliated with them beneficially own, in the aggregate (including options and warrants exercisable currently or within 60 days of October 31, 2010), approximately 53.4% of our outstanding common stock as of October 31, 2010 on an as converted basis, and approximately 30.1% of our outstanding common stock immediately following the closing of this offering. Our executive officers, directors and affiliated entities, if acting together, would be able to influence significantly all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other significant corporate transactions. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and may affect the market price of our common stock. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

Sales of substantial amounts of our common stock by us or by our stockholders, announcements of the proposed sales of substantial amounts of our common stock or the perception that substantial sales may be made, could cause the market price of our common stock to decline. We may issue additional shares of our common stock in follow-on offerings to raise additional capital or in connection with acquisitions or corporate alliances and we plan to issue additional shares to our employees, directors or consultants in connection with their services to us. All of the currently outstanding shares of our common stock are freely tradable under federal and state securities laws, except for shares held by our directors, officers and certain greater than five percent stockholders, which may be subject to volume limitations, and shares of common stock that will be acquired upon conversion of the preferred stock issued in connection with our recent private placement offering, which will occur upon the closing of this offering. Following the expiration of lock-up agreements entered into for the benefit of the underwriter by certain holders of our common stock, including our directors and executive officers and their affiliated entities 5,449,078 shares of our common stock will become eligible for sale in the public markets from time to time, subject to restrictions under the Securities Act of 1933, as amended (the Securities Act), assuming the parties to the lock-up agreements do not purchase shares in this offering. 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

## [Table of Contents](#)

statement shares held by those holders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

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

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

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

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

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

***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.

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. Forward-looking statements relate to future events or our future financial performance. We generally identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar words, although not all forward-looking statements contain these words. These statements are only predictions. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on our projections of the future that are subject to risks and uncertainties. The outcome of the events described in these forward-looking statements is subject to known and unknown risks, uncertainties and other factors that may cause our, our customers’ or our industry’s actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements, to differ. “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” as well as other sections in this prospectus or incorporated by reference into this prospectus, discuss some of the factors that could contribute to these differences.

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events.

This prospectus also contains market data related to our business and industry. These market data include projections that are based on a number of assumptions. While we believe these assumptions to be reasonable and sound as of the date of this prospectus, if these assumptions turn out to be incorrect, actual results may differ from the projections based on these assumptions. As a result, our markets may not grow at the rates projected by these data, or at all. The failure of these markets to grow at these projected rates may have a material adverse effect on our business, results of operations, financial condition and the market price of our common stock.

## USE OF PROCEEDS

We estimate that the net proceeds from our sale of 14,800,000 shares of common stock together with warrants to purchase 14,800,000 shares of common stock in this offering will be approximately \$24.0 million, or approximately \$27.6 million if the underwriter exercises its over-allotment option in full, 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.

## PRICE RANGE OF OUR COMMON STOCK

Our common stock has been traded on the NASDAQ Stock Market under the symbol “ETRM” since our initial public offering (IPO) on November 15, 2007. Prior to that date, there was no public market for our common stock. Our common stock was traded on the NASDAQ Global Market from its initial listing at the time of our IPO until January 21, 2010. Subsequently, in anticipation of not curing our deficiencies with the continued listing requirements of the NASDAQ Global Market, we requested and were approved to transfer to the NASDAQ Capital Market, effective January 22, 2010.

The following table sets forth on a per share basis the high and low sale prices of our common stock on the NASDAQ Stock Market during the periods indicated. These prices have been adjusted to reflect the 1-for-6 reverse split of our common stock that was effected on July 9, 2010.

	<u>High</u>	<u>Low</u>
<b>Fiscal Year 2010</b>		
First Quarter	\$ 8.64	\$ 3.06
Second Quarter	\$ 4.86	\$ 1.62
Third Quarter	\$ 2.94	\$ 1.52
Fourth Quarter (through December 8, 2010)	\$ 2.71	\$ 1.63
<b>Fiscal Year 2009</b>		
First Quarter	\$32.28	\$ 6.60
Second Quarter	\$26.22	\$ 7.50
Third Quarter	\$33.48	\$16.08
Fourth Quarter	\$29.40	\$ 2.40
<b>Fiscal Year 2008</b>		
First Quarter	\$61.56	\$20.70
Second Quarter	\$34.50	\$22.50
Third Quarter	\$31.44	\$18.12
Fourth Quarter	\$19.44	\$ 4.98

As of November 5, 2010, there were approximately 64 stockholders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock. We currently intend to retain any future earnings to finance the growth and development of our business. Therefore, we do not anticipate declaring or paying any cash dividends in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. Our credit agreement also restricts our ability to pay dividends.



## CAPITALIZATION

The following table describes our capitalization and cash and cash equivalents as of September 30, 2010 on an actual basis and on a pro forma basis to reflect:

- the conversion of all of the outstanding shares of our convertible preferred stock into 3,394,309 shares of common stock upon completion of this offering; and
- our sale of 14,800,000 shares of common stock together with warrants to purchase 14,800,000 shares of common stock in this offering at an aggregate offering price of \$1.75 for each share and corresponding warrant sold in this offering, after deducting underwriting discounts and commissions and estimated offering expenses.

You should read this capitalization table together with the financial statements and related notes that are incorporated by reference into this prospectus, as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the other financial information incorporated by reference into this prospectus.

	As of September 30, 2010	
	Actual	Pro forma
	(In thousands, except share and per share data)	
Cash and cash equivalents	\$ 12,554	\$ 36,540
Notes payable	\$ 6,327	\$ 6,327
Stockholders’ equity:		
Series A non-voting convertible preferred stock, \$0.01 par value: 3,600,000 shares authorized, actual; 3,394,309 shares issued and outstanding, actual; 3,600,000 shares authorized, pro forma; and no shares issued and outstanding, pro forma	34	—
Common stock, \$0.01 par value: 85,000,000 authorized, actual; 7,478,079 shares issued and outstanding, actual; 85,000,000 shares authorized, pro forma; and 25,672,388 shares issued and outstanding, pro forma	75	257
Additional paid-in capital	152,359	176,197
Deficit accumulated during development stage	(146,760)	(146,760)
Total stockholders’ equity	\$ 5,708	\$ 29,694
Total capitalization	\$ 12,035	\$ 36,021

The preceding table excludes 4,903,728 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2010 on an as converted basis and at a weighted average exercise price of \$4.12 per share, 911,220 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010 at a weighted average exercise price of \$18.69 per share, 174,807 shares of common stock available for future issuance upon completion of this offering under our 2003 Stock Incentive Plan. The preceding table also excludes an increase in the number of shares authorized under our 2003 Stock Incentive Plan by 1,149,817 and the effects of a one-time option exchange program both approved by our stockholders and completed on October 29, 2010. The preceding table also excludes 14,800,000 shares of common stock underlying the warrants sold in this offering and 296,000 shares of common stock underlying the warrants to be issued to the underwriter in connection with this offering.

## DILUTION

A purchaser of our common stock and warrants in this offering will be diluted to the extent of the difference between the price per share of our common stock and warrants in this offering and the net tangible book value per share of our common stock after this offering. As of September 30, 2010, our historical net tangible book value was \$5.7 million, or \$0.76 per share of common stock, based on 7,478,079 shares of our common stock outstanding at September 30, 2010. 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 September 30, 2010.

After giving effect to our sale of 14,800,000 shares of common stock together with warrants to purchase 14,800,000 shares of common stock at an aggregate offering price of \$1.75 for each share and corresponding warrant and after deducting underwriting discounts and commissions and estimated offering expenses, our pro forma as adjusted net tangible book value as of September 30, 2010 would have been \$29.7 million, or \$1.16 per share. This amount represents an immediate increase in net tangible book value to our existing stockholders of \$0.64 per share and an immediate dilution to new investors of \$0.59 per share. The following table illustrates this per share dilution:

Aggregate offering price per share and warrant	\$1.75
Historical net tangible book value per share at September 30, 2010	\$ 0.76
Pro forma decrease in net tangible book value per share attributable to conversion of convertible preferred stock	(0.24)
Pro forma net tangible book value per share before this offering	<u>0.52</u>
Pro forma increase per share attributable to investors in this offering	<u>\$ 0.64</u>
Pro forma net tangible book value per share, as adjusted to give effect to this offering	<u>\$1.16</u>
Pro forma dilution to investors in this offering	<u>\$0.59</u>

The above discussion and table are based on 7,478,079 shares of common stock and 3,394,309 shares of convertible preferred stock outstanding as of September 30, 2010, respectively, and excludes:

- 4,903,728 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2010, at a weighted average exercise price of \$4.12 per share;
- 911,220 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2010, at a weighted average exercise price of \$18.69 per share;
- 174,807 shares of common stock available for future issuance under our 2003 Stock Incentive Plan as of September 30, 2010;
- an increase in the number of shares authorized under our 2003 Stock Incentive Plan by 1,149,817 and the effects of a one-time option exchange program both approved by our stockholders and completed on October 29, 2010;
- 14,800,000 shares of common stock underlying the warrants sold in this offering; and
- 296,000 shares of common stock underlying the warrants to be issued to the underwriter in connection with 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.

## BUSINESS

### Overview

We are a clinical 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, 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. 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 in that the weight loss for the treatment arm was not statistically different from the control arm in which therapy was turned off. 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:

- 1) Patients that used the device for the prescribed amount of time (9 hours) had clinically meaningful weight-loss;
- 2) Both the treatment and control arm subjects experienced comparable, significant, dose-dependent EWL at 12 months; and
- 3) There was an unanticipated therapeutic effect in which a low-intensity blocking signal introduced VBLOC therapy in human subjects in the control group.

In January 2010, we met with the U.S. Food and Drug Administration (FDA) to discuss the EMPOWER trial results and the regulatory process going forward. Based on this discussion, in March we submitted an IDE for a pivotal trial of our second generation fully implantable Maestro Rechargeable (RC) System. In October 2010, we received an unconditional approval from the FDA for this trial, the ReCharge trial, a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in 234 morbidly obese subjects enrolled at up to 12 U.S. centers. The control group will receive a functional, but non-active device without implanted leads that will deliver no charge to the vagus nerve during the study period. We plan to initiate this trial in the second half of 2011 and assuming that we successfully enroll and implant the trial and achieve favorable results, we plan to use data from that trial to support a premarket approval (PMA) application for the Maestro RC System. 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.

## [Table of Contents](#)

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

We obtained European CE Mark approval for our Maestro RF System on March 4, 2009 and are currently pursuing CE Mark certification for our Maestro RC System. We plan to commercialize the Maestro RC System in Australia and intend to file an application for approval and listing with the Australian Therapeutic Goods Administration (TGA) upon receiving CE Mark certification for the Maestro RC System. We also are exploring commercialization opportunities in other markets outside of the United States and Australia. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which falls into Class III), the method involved a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. We used KEMA in the Netherlands as the Notified Body for our CE marking approval process.

### **The Obesity Epidemic**

Obesity has been identified by the U.S. Surgeon General as the fastest growing cause of disease and death in the United States. In 1980, approximately 15% of the adult population in the United States was obese according to National Health and Nutrition Examination Survey. By 2005, the incidence of obesity had more than doubled to 33%. 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. 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.

The CDC has identified obesity as a leading public health threat in the United States and has estimated that there are approximately 112,000 obesity-related deaths each year in the United States. WHO has estimated that about 2.5 million deaths worldwide are attributed to people being overweight or 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. According to the North American Association for the Study of Obesity and the CDC, obesity is associated with many significant weight-related co-morbidities including Type 2 diabetes, high blood-pressure, sleep apnea, certain cancers, high cholesterol, coronary artery disease, osteoarthritis and stroke. In addition, a number of disorders involving the central nervous system may also be complicated by obesity, such as anxiety, bipolar disorder, agoraphobia, depression and insomnia. 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.

In Australia, 62% of all adults in Australia 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).

We believe that the obesity epidemic will continue to grow worldwide given dietary trends in developed nations that favor highly processed sugars, larger meals and fattier foods, as well as increasingly sedentary

## [Table of Contents](#)

lifestyles. Despite the growing obesity rate, increasing public interest in the obesity epidemic and significant medical repercussions and economic costs associated with obesity, there continues to be a significant unmet need for more effective treatments. We believe existing options for the treatment of obesity have seen limited adoption to date due to a range of efficacy and potential side effects including morbidity. The principal treatment alternatives available today for obesity include:

**Behavioral modification.** Behavioral modification, which includes diet and exercise, is an important component in the treatment of obesity; however, most obese patients find it difficult to achieve and maintain significant weight loss with a regimen of diet and exercise alone.

**Pharmaceutical therapy.** Pharmaceutical therapies often represent a first option in the treatment of obese patients within lower BMI ranges but carry significant safety risks and may present troublesome side effects.

**Bariatric surgery.** In more severe cases of obesity, patients may pursue more aggressive surgical treatment options such as gastric bypass, sleeve gastrectomy and gastric banding. These procedures promote weight loss by surgically restricting the stomach's capacity and outlet size. While largely effective, they may present substantial side effects and carry short- and long-term safety risks that have limited their adoption.

Given the limitations of behavioral modification, pharmaceutical therapy and bariatric surgical approaches, we believe there is a substantial need for a safer and more effective solution that:

- preserves normal anatomy;
- is “non-punitive” in that it supports continued ingestion and digestion of foods and micronutrients such as vitamins and minerals found in a typical, healthy diet while allowing the user to modify his or her eating behavior appropriately without inducing punitive physical restrictions that physically force a limitation of food intake;
- enables non-invasive adjustability while reducing the need for frequent clinic visits;
- minimizes unpleasant side-effects such as persistent vomiting;
- minimizes the risks of re-operations, malnutrition and mortality; and
- reduces the natural hunger drive of patients.

### **EnteroMedics' Solution**

The vagus nerve controls much of the activity of the stomach, intestine and pancreas and plays a significant role in food processing. 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 to 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;

## [Table of Contents](#)

- offers a favorable safety profile; and
- targets multiple factors that contribute to hunger and obesity.

### ***The Vagus Nerve and the Digestive System***

Beginning in the brain, the vagus nerve travels down alongside the esophagus to the stomach and other gastrointestinal organs and is primarily responsible for autonomic regulation involved in heart, lung and gastrointestinal function. The vagus nerve controls much of the activity of the stomach, intestine and pancreas and plays a role in food processing, including:

- expansion of the stomach as food enters;
- contractions of the stomach to break food into smaller particles;
- release of gastric acid required for food processing;
- emptying of the stomach contents into the small intestine;
- secretion of digestive pancreatic enzymes that enable absorption of calories; and
- controlling sensations of hunger, satisfaction and fullness.

### ***VBLOC Therapy***

Several studies of the vagus nerve and its effect on the digestive system have focused on the effects of surgical vagotomy, the permanent severing of the vagus nerve at the level of the junction between the esophagus and the stomach. Given the role of the vagus nerve in regulating the release of gastric acid, early researchers originally used vagotomy as a treatment for peptic ulcers. They discovered that their patients often experienced weight loss or, at a minimum, failure to gain weight following vagotomy. However, weight loss after vagotomy alone has been disappointing, particularly over the long-term and likely dissipates as the body compensates for the anatomical disruption by partial restoration of nervous system function.

VBLOC therapy is designed to block the gastrointestinal effects of the vagus nerve by using high-frequency, low-energy electrical impulses to intermittently interrupt naturally occurring neural impulses on the vagus nerve between the brain and the digestive system. Our therapy is designed to control hunger sensations between meals, limit the expansion of the stomach and to 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. By intermittently blocking the vagus nerve and allowing it to return to full function between therapeutic episodes, we believe we have limited the body's natural tendency to circumvent the therapy, which can result in long-term weight loss.

We have designed our Maestro System to address a significant market opportunity that we believe exists for a 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 could lead to the adoption of VBLOC as the therapy of choice for obesity:

- ***Preserves Normal Anatomy.*** The Maestro neuroblocking pulse generator is designed to deliver therapy that blocks the neural signals that influence a patient's hunger and sense of fullness without altering digestive system anatomy. Accordingly, patients should experience fewer and less severe side effects compared to treatments that incorporate anatomical alterations.
- ***Allows Continued Ingestion and Digestion of Foods Found in a Typical, Healthy Diet.*** Because our therapy leaves the digestive anatomy unaltered, we believe that patients will be able to maintain a more consistent nutritional balance compared to existing surgical approaches, thus allowing them to effect positive changes in their eating behavior in a non-forced and potentially more consistent way.

## [Table of Contents](#)

- **May be Implanted on an Outpatient Basis and Adjusted Non-Invasively.** The Maestro System is designed to be laparoscopically implanted in approximately one hour, allowing patients to leave the hospital or clinic on the same day. The implantable system is designed to be turned off and left in place for patients who reach their target weight. When desired, the follow-up physician can simply and non-invasively turn the therapy back on. Alternatively, the implantable system can be removed in a laparoscopic procedure.
- **Offers Favorable Safety Profile.** We have designed our EMPOWER clinical trial to demonstrate the safety of the Maestro System. In our clinical trials to date, including the EMPOWER trial, we have not observed any mortality or any medically serious device related adverse events that have required surgical attention in the patients we have implanted with the Maestro System. We have also not observed any long-term problematic clinical side effects in any patients, including in those patients who have been using the Maestro System for more than one year.
- **Targets Multiple Factors that Contribute to Hunger and Obesity.** We designed VBLOC therapy to target the multiple digestive functions of the vagus nerve and to affect the perception of hunger and fullness, which together contribute to obesity.

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

### **Our Strategy**

Our goal is to establish VBLOC therapy, delivered via our Maestro System pulse generator, 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.** We received an IDE from the FDA for use of the Maestro System in the United States in our EMPOWER trial, and announced on October 2, 2009 that based on an initial analysis, the study did not meet its primary and secondary efficacy endpoints. 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, to help ensure patient safety delivered low-level safety and diagnostic check electrical signals to the system which were intended to be inactive, apparently provided a low-intensity blocking signal that introduced VBLOC therapy in human subjects. After meeting with the FDA in January 2010 to discuss the EMPOWER trial results and the regulatory process going forward, we submitted an IDE application for a clinical trial using the second generation Maestro Rechargeable(RC) System in the treatment of morbid obesity. In October 2010, we received an unconditional approval to proceed with the trial of our Maestro RC System, called the ReCharge trial. Assuming that we successfully enroll and implant the trial and achieve favorable results, we plan to use data from that trial to pursue a PMA from the FDA to allow us to commence sales in the United States. We have also received the European CE Mark for our Maestro RF System to enable the eventual commercialization of our systems in the European Economic Area. We are currently pursuing CE Mark certification for our Maestro RC System. We plan to commercialize the Maestro RC System in Australia and intend to file an application for approval and listing with the Australian Therapeutic Goods Administration (TGA) upon receiving CE Mark certification for the Maestro RC System. We also are exploring commercialization opportunities in other markets outside of the United States and Australia. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which falls into Class III),

## [Table of Contents](#)

the method involved a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. We used KEMA in the Netherlands as the Notified Body for our CE marking approval process.

***Drive the Adoption and Endorsement of VBLOC Therapy Through Obesity Therapy Experts.*** Our clinical development strategy is to collaborate closely with regulatory bodies, obesity therapy experts and scientific experts. We have established credible and open relationships with obesity therapy experts and scientific experts and we believe these obesity therapy experts and scientific experts will be important in promoting patient awareness and gaining widespread adoption if the Maestro System is approved and commercialized.

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

***Commercialize Our Products using a Direct Sales and Marketing Effort within the United States.*** We plan to build a sales force to call directly on key opinion leaders and bariatric surgeons, primarily within bariatric Centers of Excellence. We believe this currently represents approximately 378 facilities within the United States, which we believe will enable us to target them effectively with a small sales force. We expect that our direct sales force will promote the Maestro System to physicians and patients who have concerns with current bariatric surgical procedures. We also plan to call on physicians, weight-management specialists and nurses who influence patient adoption.

***Identify Appropriate Coding, Obtain Coverage and Payment for the Maestro System.*** While payors are not our direct customers, their coverage and reimbursement policies influence patient and physician selection of obesity treatment. We plan to employ a focused campaign to obtain payor support for VBLOC therapy. We plan to seek specific and appropriate coding, coverage and payment for our Maestro System from the Australia Medical Services Advisory Committee (MSAC) and the U.S. Centers for Medicare and Medicaid Services (CMS) and from private insurers.

***Expand and Protect Our Intellectual Property Position.*** We believe that our issued patents and our patent applications encompass a broad platform of neuromodulation therapies, including vagal blocking and combination therapy focused on obesity and other gastrointestinal disorders. We intend to continue to pursue further intellectual property protection through U.S. and foreign patent applications.

***Leverage our VBLOC Technology for Other Disease States.*** We intend to continue to conduct research and development for other potential applications for our VBLOC therapy and believe we have a broad technology platform that will support the development of additional clinical applications and therapies for other gastrointestinal disorders in addition to obesity.

### **The Maestro System, Implantation Procedure and Usage**

***The Maestro System.*** Our Maestro System pulse generator 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. We are developing the Maestro System in two different energy configurations, the Maestro RF System and the Maestro RC System. The Maestro RF System is the device currently being used in our EMPOWER trial, which we announced on October 2, 2009 did not meet its primary and secondary efficacy endpoints.





The major components of the Maestro System include:

- **Neuroregulator.** The neuroregulator, sometimes referred to as a neuroblocking pulse generator, is an implanted device that controls the delivery of VBLOC therapy to the vagus nerve. It is surgically implanted just below, and parallel to, the skin, typically on the side of the body over the ribs. The neuroregulator emits short, charge-balanced electrical pulses at a high pulse rate that travel down the leads to the electrodes and intermittently block natural nerve signals on the vagus nerve.
- **Lead system.** Our neuroblocking leads are powered by the neuroregulator and deliver electrical pulses to the vagus nerve via the electrodes. The leads and electrodes are similar to those used in traditional cardiac rhythm management and some neurostimulation products, are intended to be implanted and may be removed laparoscopically.
- **Controller/Mobile charger.** Our controller regulates the rate and intensity of the electrical pulses delivered by the neuroregulator and maintains a log of device and treatment changes. In the Maestro RF System, the controller is an external unit. In the Maestro RC System, the external controller is replaced by an external mobile charger and the control logic is contained within the implanted neuroregulator.
- **Transmit coil.** The transmit coil is positioned over the implanted neuroregulator and delivers radiofrequency battery charging daily energy for a few minutes and therapy programming information across the skin into the device. The coil is held in position over the neuroregulator for these short periods time with an adjustable elastic belt.
- **Clinician programmer.** The clinician programmer connects to the controller to enable clinicians to customize therapy settings as necessary and download reports stored in system components. The reports include patient use and system performance information used to manage therapy. The clinician programmer incorporates our proprietary software and is operated with a commercially available laptop computer.

Our Maestro System is designed to be implanted by a bariatric surgeon in approximately one hour during an outpatient procedure that is typically performed using a short-acting general anesthetic. The physician activates the Maestro System after a short healing period following implantation. VBLOC therapy is then delivered intermittently (approximately five minutes “on” and five minutes “off” in an alternating pattern) each day during the patient’s waking hours through the neuroregulator.

## [Table of Contents](#)

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

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

*Implantation Procedure.* The Maestro System is designed to be implanted by a bariatric surgeon in approximately one hour during an outpatient procedure that will be typically performed using a short-acting general anesthetic. During the procedure, the surgeon laparoscopically implants the electrodes in contact with the vagal nerve trunks and then connects the lead wires to the neuroregulator. After the electrodes have been attached adjacent to the vagal trunks and connected to the neuroregulator, the surgeon confirms final system operation by sending electrical pulses to the leads by the neuroregulator. Once system operation has been confirmed, the surgeon implants the neuroregulator under the skin and closes all incisions. We believe that patients who are implanted with the Maestro System will be able to return home from the hospital or clinic on the same day. The implantation procedure and usage of the Maestro System carry some risks, such as the risks generally associated with laparoscopic procedure as well as the possibility of device malfunction. In addition, in rare circumstances during implantation, the vagus nerve or esophagus may be damaged causing problems such as difficulty in swallowing, vomiting, heartburn, belching, abdominal fullness or discomfort, diarrhea, or decreased appetite. We expect that any of these problems would be temporary without lasting effects, although there is the risk of permanent injury to the vagus nerve. Some post-operative effects that may occur after implantation of our Maestro System include movement of the leads or neuroregulator from their original positions, erosion or wire breakage and potential allergic reaction with internal or external device contacts.

*Usage of the Maestro System.* The physician activates the Maestro System shortly after implantation. VBLOC therapy is then delivered intermittently each day during the patient's waking hours through the neuroregulator. The scheduled delivery of the intermittent electrical pulses blocking the vagus nerve is customized for each patient by the physician using the clinician programmer and when necessary, therapy can also be easily and non-invasively modified by the physician. The physician determines the duration of the therapy in consultation with the patient based on the patient's weight loss and overall treatment objectives. Patients using the Maestro RF System can elect to suspend or circumvent therapy at any time by simply not carrying the controller. Without the controller, the RF neuroregulator receives no power and cannot provide therapy. Patients using the Maestro RC System are more limited in their ability to suspend or circumvent therapy because the control logic is embedded in the implanted neuroregulator.

The physician is able to download reports to monitor patient use and system performance information. This information is particularly useful to physicians to ensure that patients are properly using the system. Although usage of our Maestro System generally proceeds without complications, as part of the therapy or intentional weight loss, subjects in our clinical trials have observed side-effects such as heartburn, bloating, diarrhea, sweating, nausea, constipation, greasy bowel movements, tiredness and excessive feelings of fullness, especially after meals. In addition, patient noncompliance with wearing the external components of the Maestro RF System may render VBLOC therapy less effective in achieving long-term weight loss.

## **Clinical Development**

We are developing our Maestro System to deliver VBLOC therapy for the long-term treatment of obesity. Based on our preclinical and clinical findings, we believe that our Maestro System has the potential to offer a compelling combination of efficacy and safety. We are continuing to evaluate the Maestro System in human clinical studies conducted in the United States and internationally. We announced on October 2, 2009 that based on an initial analysis, our EMPOWER trial 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. After meeting with the FDA in January 2010 to discuss the EMPOWER trial results and the regulatory process going forward, we recently submitted an IDE application for a clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity. In October 2010, we received an unconditional approval from the FDA for this trial, the ReCharge trial.

### ***Preclinical Experience***

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

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

### ***Clinical Experience***

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

We have not observed any mortality or any medically serious device related adverse events in any of our completed or ongoing studies. Reported events include those associated with laparoscopic surgery or any implantable electronic device. The effects of VBLOC therapy include changes in appetite, and, in some subjects, effects that may be expected with decreased intra-abdominal vagus nerve activity, such as temporary abdominal discomfort and short episodes of belching, bloating, cramping or nausea.

Findings from our clinical feasibility trials have resulted in more than 20 publications peer-reviewed and accepted for presentation between 2006 and 2010 at the following meetings: Digestive Disease Week, American Society for Metabolic and Bariatric Surgery, International Federation for Surgery of Obesity, Obesity Surgery Society of Australia & New Zealand and Obesity Society (formerly the North American Association for the Study of Obesity).

## [Table of Contents](#)

We used our clinical studies data in a submission to our Notified Body and obtained European CE Mark approval for our Maestro RF System on March 4, 2009. We are currently pursuing CE Mark certification for our Maestro RC System.

Below is a summary of our planned and ongoing clinical studies.

### ***VBLOC-RF2 Trial***

Enrollment of 38 subjects in the VBLOC-RF2 trial began in November 2006 and is designed to evaluate the safety and efficacy of the Maestro RF2 System in treating patients with obesity over a period of 60 months. The trial is an international, open-label, prospective, multi-center study. We are implementing weight management programs and plan to evaluate the efficacy of VBLOC therapy by measuring average percentage EWL at one month, three, six and 12 months and possibly longer. We are using results from this trial to further optimize selection of VBLOC therapy parameters. Preliminary data indicate that the RF2 system improvements have resulted in improved therapy delivery and improved weight loss. To date, no deaths or medically serious device related adverse events have been reported during the VBLOC-RF2 trial. As of October 20, 2010, the most recent follow-up of nine RF2 patients, among the earliest patients implanted in the VBLOC-RF2 trial, showed an EWL of 23.0% at 24 months of VBLOC therapy in 18 RF2 patients. At that time, the most recent results for the prior follow-up periods demonstrated an EWL of 28.3% in 18 RF2 patients at 18 months and an EWL of 22.6% in 26 RF2 patients at 12 months of VBLOC therapy.

### ***VBLOC-RC Trial***

We initiated the VBLOC-RC trial in November 2007. The trial is an international feasibility study designed to demonstrate that the clinical performance of the Maestro RC System in five subjects is similar to that of the RF2 system. It is also intended to demonstrate that the subject can effectively recharge the implanted RC device and the physician and staff can perform device programming and operation. We are implementing weight management programs such as diet, behavior modification or exercise programs and plan to evaluate system performance and efficacy by measuring average percentage EWL at one, three and six months. To date, no deaths or medically serious device related adverse events have been reported during the VBLOC-RC trial.

### ***VBLOC-DM2 ENABLE Trial***

Enrollment of the VBLOC-DM2 ENABLE trial began in the second quarter of 2008 and is designed to evaluate the effects of VBLOC therapy on glucose regulation and blood pressure using the Maestro RC System in approximately 30 subjects. The trial is an international, open-label, prospective, multi-center study. We plan to evaluate the efficacy of VBLOC therapy by measuring average percentage EWL, HbA1c (blood sugar) and FPG (fasting plasma glucose) and blood pressure at one week, one month, three, six and 12 months and possibly longer. The Maestro RC System is powered by an internal battery recharged via an external mobile charger and transmit coil worn by the patient for a short time each week. To date, no deaths or medically serious device related adverse events have been reported during the VBLOC-DM2 ENABLE trial and the safety profile is similar to that seen in the other VBLOC trials. As of October 20, 2010 the most recent follow-up of patients shows an average device usage of approximately 14 hours per day and the below data.

- H<sub>b</sub>A<sub>1c</sub> change (Company updated data):

Visit (post-device activation)	H <sub>b</sub> A <sub>1c</sub> change	Percent H <sub>b</sub> A <sub>1c</sub>	N	p
Week 1 (Baseline 7.8%)	-0.3	7.5	28	0.002
Week 4 (Baseline 7.8%)	-0.7	7.1	28	<.001
Week 12 (Baseline 7.7%)	-0.9	6.8	26	<.001
6 Months (Baseline 7.8%)	-0.9	6.8	25	<.001
12 Months (Baseline 7.6%)	-1.0	6.6	25	<.001

- Percent excess weight loss (EWL) (BMI Method from implant, Company updated data):

Visit (post-device activation)	EWL	N	P
Week 1	-8.9	28	<.001
Week 4	-13.7	28	<.001
Week 12	-20.8	26	<.001
6 Months	-24.4	25	<.001
12 Months	-25.3	25	<.001

- Change in diastolic blood pressure in hypertensive patients (baseline 87.2 mmHg, average) in mmHg:

Visit (post-device activation)	DBP change	N	p
Week 1	-10.1	12	<.001
Week 4	-10.2	12	0.005
Week 12	-8.9	11	<.001
6 Months	-13.8	10	<.001
12 Months	-10.2	11	0.009

- Change in mean arterial pressure in hypertensive patients (baseline 99.5 mmHg, average) in mmHg:

Visit (post-device activation)	MAP change	N	p
Week 1	-6.8	15	0.04
Week 4	-8.6	15	0.02
Week 12	-8.9	14	<.001
6 Months	-12.5	13	<.001
12 Months	-7.8	14	0.03

#### **EMPOWER Trial**

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 in that the weight loss for the treatment arm was not statistically different from the control arm in which therapy was turned off. 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 including a maximum of 300 subjects at up to 15 U.S. and international sites. We completed enrollment and implantation of 294 subjects in the EMPOWER trial in 2008.

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 with overall study results showing that for all patients (n=253), 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. The review further suggests that:

- 1) Patients that used the device for the prescribed amount of time (≥9 hours) had clinically meaningful weight-loss;

## Table of Contents

- 2) Both the treatment and control arm subjects experienced comparable, significant, dose-dependent EWL at 12 months; and
- 3) There was an unanticipated therapeutic effect in which a low-intensity blocking signal introduced VBLOC therapy in human subjects in the control group.

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.

It is our belief after continuing to analyze the EMPOWER trial data that there is a direct correlation between weight loss and hours of daily device usage. On January 14, 2010 we announced the below observations and additional data from our ongoing detailed review of the EMPOWER trial.

*Weight loss corresponded directly to hours of use for patients in the treatment arm. At 12 months, results were as follows:*

	<u>&lt;6 Hours /Day</u>	<u>Greater- than or Equal to 6 and &lt;9 Hours/Day</u>	<u>Greater- than or Equal to 9 and &lt;12 Hours/Day</u>	<u>Greater- than or Equal to 12 Hours/Day</u>
Percent EWL (BMI Method)	4.7%	12.9%	21.5%	29.5%

*Weight loss corresponded directly to hours of use when both the treatment and control arms are combined. At 12 months, results were as follows:*

<u>12 Months from Implant (BMI Method)</u>	<u>Greater-than or Equal to 9 Hours/Day (n=128)</u>	<u>&lt;9 Hours/Day (n=125)</u>	<u>p</u>
Subjects Achieving Greater-than or Equal to 25% EWL	39.1%	12.0%	<0.0001
Average Daily Use in Subjects	11.2 hrs	7.7 hrs	<0.0001

As of October 20, 2010 the 24 month EMPOWER EWL was as follows:

Visit	EWL (mean)	N
6 Months	-17.9%	271
12 Months	-16.3%	265
18 Months	-17.3%	187
24 Months	-19.4%	159

*Interim analysis. N at 18 and 24 months are patients who have reached those time points.*

At 24 months, 71 patients using the device for <sup>39</sup> hours daily have an average EWL of 22.7%.

The purpose of the EMPOWER trial was to measure the safety and efficacy of our Maestro System in obese subjects after 12 months of VBLOC therapy. After all subjects completed 12 months of follow up, the trial was unblinded and all subjects, including those in the control group, had the option to receive ongoing VBLOC therapy. Subjects will continue to be followed out to 60 months as part of the trial and we will continue to monitor average percentage EWL and safety during this extended period.

### **ReCharge Trial (Maestro RC System)**

In January 2010, we met with the FDA to discuss the EMPOWER trial results and the regulatory process going forward. Based on this discussion, we submitted an IDE application for a clinical trial using the next-generation Maestro RC System in the treatment of morbid obesity and in October 2010 we received an unconditional

## [Table of Contents](#)

approval to proceed with this trial, the Recharge Trial. The trial will be a randomized, double-blind, parallel-group, multicenter clinical trial of its Maestro RC System in 234 morbidly obese subjects enrolled at up to 12 U.S. centers. Obesity is a criteria for participation in the trial, and obese patients are known to have higher rates of disease and health problems than patients with a BMI of 25 or lower. Health conditions unrelated to VBLOC therapy may complicate or confound the assessment of the Maestro System's safety and effectiveness. All subjects in the study would receive an implanted device and would be randomized in a 2:1 allocation to treatment or control groups. The control group will receive a functional, but non-active device that will deliver no charge to the vagus nerve during the study period. All subjects are expected to participate in a weight management program. 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, which we expect to submit no earlier than the fourth quarter of 2012. If the FDA grants us approval, we anticipate we will be able to commercialize the Maestro System in the United States in late 2013 at the earliest.

### **Research and Development**

We have an experienced research and development team, including clinical, regulatory affairs and quality, comprised of scientists, electrical engineers, software engineers and mechanical engineers with significant clinical knowledge and expertise. Our research and development efforts are focused in the following major areas:

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

We have spent a significant portion of our capital resources on research and development. Our research and development expenses were \$7.1 million for the nine months ended September 30, 2010, \$15.6 million in 2009, \$27.7 million in 2008 and \$21.1 million in 2007. Our research and development expenditures for the remainder of 2010 and beyond will largely depend on our regulatory path forward. With the approval of the ReCharge trial IDE application we expect research and development expenditures to increase in support of this new clinical trial in addition to the continued follow-up on existing trials, such as VBLOC-DM2 ENABLE, EMPOWER and RF2.

### ***Other Diseases and Disorders***

We believe that our VBLOC therapy may have the potential, if validated through appropriate clinical studies, to treat a number of additional gastrointestinal disorders or co-morbidities frequently associated with obesity, including the following:

- ***Type 2 Diabetes.*** Metabolic syndrome refers to a group of risk factors for cardiovascular disease and Type 2 diabetes mellitus and affects an estimated 50 million people in the United States. We believe that VBLOC therapy has significant potential in treating metabolic syndrome. We have launched an international feasibility trial, VBLOC-DM2 ENABLE, to further explore the efficacy of VBLOC therapy in this patient population and have reported preliminary findings in the "Clinical Development" section above.
- ***Hypertension.*** Blood pressure normally rises and falls throughout the day. When it consistently stays too high for too long, it is called hypertension. It is estimated that one out of three American adults has high blood pressure or hypertension. We believe that VBLOC therapy may improve mean systolic and diastolic blood pressure in hypertensive patients. We have included an evaluation of the blood pressure effects of VBLOC therapy in our international feasibility trial, VBLOC-DM2 ENABLE, to further explore the efficacy of VBLOC therapy in this patient population and have reported preliminary findings in the "Clinical Development" section above.
- ***Pancreatitis.*** Primary and recurrent cases of acute pancreatitis are estimated to number from 150,000 to 200,000 annually, resulting in approximately 80,000 hospital admissions each year in the United

## [Table of Contents](#)

States. In animal and human studies, we have shown that VBLOC therapy suppresses pancreatic exocrine secretion, suggesting its potential efficacy in treating pancreatitis.

- **Other Gastrointestinal Disorders.** We believe that VBLOC therapy may have potential in a number of other gastrointestinal disorders, including irritable bowel syndrome and inflammatory bowel disease.

None of these conditions are included in our current IDE and supplemental PMA approval will be required to market the Maestro System for these indications in the United States.

### ***Mayo Clinic Relationship***

Our research and development team works with clinicians from Mayo Clinic Rochester, Minnesota pursuant to exclusive know-how, license, and consulting agreements. Mayo clinicians with multiple specialties such as bariatric surgery, gastroenterology and laparoscopic surgery consult with our research and development team on an exclusive basis to advise us as we develop our devices for vagal blocking therapy to treat obesity. Specifically, Mayo clinicians, along with other of our consultants, have offered their expertise to advise us with regard to our clinical trials and surgical techniques for our implantation procedure and participate on our medical advisory board and therapeutic algorithm panel. The agreements with Mayo Clinic also include a similar collaboration for the development of products to address a wide variety of disorders susceptible to treatment by electrically blocking neural impulses on the vagus nerve. We retain the exclusive rights to obesity-related device inventions developed through this collaboration. We have also licensed-in two obesity-related patent applications from Mayo Clinic. These patent applications cover a number of medical device concepts for treating obesity, all of which are unrelated to our VBLOC technology. The five-year agreement entered into with the Mayo Clinic in 2005 was extended for two additional years effective February 3, 2010.

### ***Australian Institute of Weight Control (AIWC)***

We have entered into a collaboration agreement with the AIWC, an Australian network of surgical clinics specializing in laparoscopic weight loss surgery and clinical research for the morbidly obese. It consists of three partner clinics in Perth, Adelaide and Sydney, with expansion plans for two or more other centers in Australia. The AIWC is a group globally recognized in bariatric procedures, including the Maestro System. The AIWC works with public and private organizations to develop treatment platforms for the seriously obese, striving for continual clinical improvement through leadership research and training programs. The AIWC performed more than 1,250 bariatric procedures in 2009 and have a base of over 7,000 patients. The bariatric surgeons of the AIWC were among the first in the world to implant the Maestro System and have participated in all of our clinical studies to date. The AIWC will be the first group of surgeons to implant the Maestro system if Australian regulatory approval is obtained. The AIWC will work with us to develop a surgical implantation training program, distribution and research plans. The AIWC will support our efforts to gain TGA approval and regulatory approval in other territories and support our and distributors' efforts in gaining reimbursement for the private sector through the MSAC as it relates to the Maestro System in Australia.

### ***Medical Advisors***

In addition to our collaboration with Mayo Clinic, we also have medical advisors who provide strategic guidance to our development programs, consult with us on clinical investigational plans and individual study protocols, and advise on clinical investigational site selection. Members of our medical advisory group also:

- serve on our Data Safety Monitoring Board and Clinical Events Committee;
- meet with governmental regulatory authorities;
- provide consultation on professional meeting presentations and journal manuscript submissions; and
- develop and participate in clinical site training programs, including study surgical technique training and study subject follow-up training.



## **Sales and Marketing**

### ***United States***

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

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

Initially, we anticipate that our sales representatives will exclusively target selected bariatric surgery Centers of Excellence and nationally recognized bariatric surgery centers. To be approved as a bariatric surgery Center of Excellence, a surgery center needs to perform a minimum of 125 bariatric surgical procedures per year. As of December 31, 2009, there were approximately 378 bariatric surgery Centers of Excellence approved by the Surgical Review Corporation and 75 Level I Centers of Excellence approved by the American College of Surgeons. In addition we expect to market our products to a small number of nationally-recognized hospitals that do not intend to pursue the Center of Excellence certification.

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

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

### ***Outside of the United States***

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

We have begun to take the initial steps necessary to commercialize the Maestro RC System in Australia. We have also entered into a cooperation agreement with the AIWC by which the AIWC has agreed to work with us toward regulatory approval in Australia and to collaborate on subsequent marketing and distribution efforts in Australia. We are also exploring commercialization opportunities in other markets outside of the United States and Australia.

## **Competition**

We compete primarily in the market for obesity treatment with surgical obesity procedures and various devices used to implement neurostimulation and gastric stimulation systems. We also compete with pharmaceutical therapies. The market for obesity treatments is intensely competitive, subject to rapid technological change and significantly affected by new product development. Although we expect to compete in the market for gastric stimulation systems and other neurotechnology devices that treat obesity, there are currently no FDA-approved neuromodulation or neuroblocking therapies for the treatment of obesity. We believe we are the first and only company currently pursuing neuroblocking therapy for the treatment of obesity.

## Table of Contents

We also compete against the manufacturers of pharmaceuticals that are directed at treating obesity. We are aware of two drugs that are approved for long-term treatment of obesity in the United States: Sibutramine, marketed by Abbott Labs as Meridia which has recently been withdrawn from the market worldwide by the manufacturer based on safety concerns, and Orlistat, marketed by Roche as Xenical and GlaxoSmithKline as Alli. In addition, numerous pharmaceutical companies are working on additional drug therapies that may prove effective in addressing obesity.

We compete with several private early-stage companies developing neurostimulation devices for application to the gastric region and related nerves for the treatment of obesity. These companies may prove to be significant competitors, particularly through collaborative arrangements with large and established companies. They also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

In addition, there are many larger potential competitors experimenting in the field of neurostimulation to treat various diseases and disorders. For example, Medtronic, which develops deep brain stimulators and spinal cord stimulators, acquired TransNeuronix, which sought to treat obesity by stimulating the smooth muscle of the stomach wall and nearby tissue. St. Jude Medical, through its acquisition of Advanced Neuromodulation Systems, is developing spinal cord stimulators. Cyberonics is developing vagus nerve stimulators to modulate epileptic seizures and other neurological disorders. Boston Scientific, through its Advanced Bionics division, is developing neurostimulation devices such as spinal cord stimulators and cochlear implants. Ethicon-Endo Surgery acquired Cyberonics' patents and patent applications pertaining to vagus nerve stimulation for the treatment of obesity and two related co-morbidities, diabetes and hypertension, in overweight patients.

In addition to competition from developers of neurostimulation and gastric modulation systems, we expect our Maestro System will also compete with surgical obesity procedures, including gastric bypass, gastric banding, vertical-banded gastroplasty and biliopancreatic diversion. The leader in the field of gastric banding is Allergan, whose Lap-Band received FDA approval for marketing in 2001. Allergan also recently acquired EndoArt, a European band company that has developed the EasyBand, which uses RF telemetry to adjust the gastric band. Additionally, we are aware that Johnson & Johnson received approval on September 28, 2007 of their gastric band product known as the Realize Adjustable Gastric Band.

We believe that the principal competitive factors in our market include:

- acceptance by healthcare professionals, patients and payors;
- published rates of safety and efficacy;
- reliability and high quality performance;
- effectiveness at controlling co-morbidities such as diabetes and hypertension;
- invasiveness and the inherent reversibility of the procedure or device;
- cost and average selling price of products and relative rates of reimbursement;
- effective marketing, education, sales and distribution;
- regulatory and reimbursement expertise;
- technological leadership and superiority; and
- speed of product innovation and time to market.

Many of our competitors are either publicly-traded or are divisions of publicly-traded companies, and they enjoy several competitive advantages over us, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;

## [Table of Contents](#)

- established distribution networks;
- greater experience in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals, obtaining reimbursement and marketing approved products; and
- greater financial and human resources.

As a result, we cannot assure you that we will be able to compete effectively against these companies or their products.

### **Third-party Coverage and Reimbursement**

We plan to set a market price for the Maestro System in the United States that is comparable to other high-end, active implantable devices such as implantable cardioverter defibrillators (ICDs), neurostimulation devices for chronic pain, and cochlear implant systems. We expect that the procedure will be performed in the outpatient setting.

We believe that establishing appropriate third-party coverage for the therapy should be achievable as important structural elements are already in place. Physician claims for payment use Current Procedural Terminology, Fourth Edition (CPT) billing codes to describe procedures and services performed. Currently, there are established CPT codes for the implantation of cranial nerve pulse generators and related leads, and we expect providers may seek payment for our therapy based on these codes. With respect to possible usage of our product in the hospital inpatient setting, hospital inpatient billing is referenced by International Classifications of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure codes. There is an existing ICD-9-CM diagnosis code for morbid obesity and our studies are intended to provide the necessary outcomes data to link appropriate billing codes with the ICD-9 diagnosis code for morbid obesity. By October 2013, health plans and providers must replace the ICD-9-CM system and begin using the newer ICD-10-CM system for billing hospital inpatient procedures. The ICD-10-CM system should not impact coverage decisions, but could impact reimbursement for various procedures. Our clinical trial data substantiating VBLOC therapy will also be used to seek coverage of VBLOC therapy for patients with morbid obesity and appropriate reimbursement for surgeons and hospitals under the codes already in place.

CMS, the federal agency that administers the Medicare program, has issued a national coverage determination for several specific types of bariatric surgery, which we view as positive, potential precedent and guidance to factors that CMS might use in deciding to cover our therapy. The policy indicates that Medicare will cover these bariatric surgical procedures when they are performed in an approved Bariatric Center of Excellence by a bariatric surgeon who also meets established requirements. Subjects with a BMI greater than or equal to 35, at least one obesity-related disease or disorder and who were previously unsuccessful with medical treatment for obesity are considered eligible. However, the policy reiterates that treatments for obesity alone are not covered, because such treatments are not considered reasonable and necessary. Although Medicare policies are often emulated or adopted by other third-party payors, other governmental and private insurance coverage currently varies by carrier and geographic location. We intend to actively work with major insurance carriers as well as CMS to obtain coverage for procedures using our product.

Other manufacturers of neurostimulator devices for a variety of indications have been successful in securing third-party coverage and reimbursement for use of their devices after early commercialization. We will actively pursue all similar opportunities to secure appropriate payment for our device.

### **Intellectual Property**

Our success will depend in part on our ability to obtain and defend patent protection for our products and processes, to preserve our trade secrets and to operate without infringing or violating the proprietary rights of third parties. To date, we have 16 issued U.S. patents, 12 of which pertain to treating gastrointestinal disorders and we believe provide us with broad intellectual property protection covering electrically-induced vagal

## [Table of Contents](#)

blocking and for treating obesity. Assuming timely payment of maintenance fees as they become due, the earliest these patents will expire is in 2023. We also have 18 U.S. patent applications, 10 Australian applications, 11 European applications, 2 Chinese applications, 2 Indian applications, and 1 Japanese application. EnteroMedics also has granted 1 Australian patent, and two European patents we believe will be granted. These applications primarily pertain to our vagal blocking technology and its application to obesity as well as other gastrointestinal disorders. In addition to our patents and applications, we have a license agreement with Mayo Foundation for Medical Education and Research for two pending U.S. patent applications on medical device obesity treatments, which are unrelated to our VBLOC therapy.

We also register the trademarks and trade names through which we conduct our business. To date, in the United States we have registered trademarks for VBLOC®, ENTEROMEDICS® and MAESTRO® each registered with the United States Patent and Trademark Office, and have received a Notice of Allowance and fourth extension of time to file a Statement of Use on our application to register the mark EMPOWER™. In addition, the marks VBLOC, MAESTRO and ENTEROMEDICS are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, Saudi Arabia and Switzerland. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are registered in Mexico. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM are the subject of pending trademark applications in the United Arab Emirates.

In addition to our patents, we rely on confidentiality and proprietary information agreements to protect our trade secrets and proprietary knowledge. These confidentiality and proprietary information agreements generally provide that all confidential information developed or made known to individuals by us during the course of their relationship with us is to be kept confidential and not disclosed to third parties, except in specific circumstances. The agreements also provide for ownership of inventions conceived during the course of such agreements. If our proprietary information is shared or our confidentiality agreements are breached, we may not have adequate remedies, or our trade secrets may otherwise become known to or independently developed by competitors.

### **Manufacturers and Suppliers**

We have designed and developed all of the elements of our Maestro System, except for the clinician programmer hardware, which uses a commercially available laptop computer. To date, all of the materials and components of the system used in our clinical trials are procured from qualified suppliers and contract manufacturers in accordance with our proprietary specifications. We use third parties to manufacture our Maestro System to minimize our capital investment, help control costs and take advantage of the expertise these third parties have in the large-scale production of medical devices. We do not currently plan to manufacture our Maestro System ourselves. All of our key manufacturers and suppliers have experience working with commercial implantable device systems, are ISO certified and are regularly audited by us. Our key manufacturers and suppliers have a demonstrated record of compliance with international regulatory requirements.

In the event that the Maestro System receives FDA or TGA approval, we expect to increase our production volume by a significant amount. Given that we rely primarily on third-party manufacturers and suppliers for the production of our products, our ability to increase production will depend upon the experience, certification levels and large scale production capabilities of our suppliers and manufacturers. Qualified suppliers and contract manufacturers have been and will continue to be selected to supply products on a commercial scale according to our proprietary specifications. We also intend to increase our inventory levels to support commercial forecasts as we expand our implanting centers. Our FDA approval process requires us to name and obtain approval for the suppliers of key components of our Maestro System.

Many of our parts are custom designed and in certain instances, are obtained through long-term supply arrangements that are exclusive. Due to these factors, we may not be able to quickly qualify and establish additional or replacement suppliers for the components of our Maestro System. A delay in the approval process with the FDA for our Maestro System as a result of the need to qualify or obtain alternate vendors for any of our components would delay our ability to sell and market the Maestro System and could have a material adverse effect on our business.

## [Table of Contents](#)

We believe that our current manufacturing and supply arrangements will be adequate to continue our ongoing and planned clinical trials. In order to produce the Maestro System in the quantities we anticipate to meet future market demand, we will need our manufacturers and suppliers to increase, or scale up, manufacturing production and supply arrangements by a significant factor over the current level of production. There are technical challenges to scaling up manufacturing capacity and developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and suppliers and hiring and retaining additional management and technical personnel who have the necessary experience. If our manufacturers or suppliers are unable to do so, we may not be able to meet the requirements for the launch of the product or to meet future demand, if at all. We may also represent only a small portion of our suppliers' or manufacturers' business and if they become capacity constrained they may choose to allocate their available resources to other customers that represent a larger portion of their business. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of the Maestro 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.

### **Government Regulations**

#### *United States*

Our Maestro System is regulated by the FDA as a medical device under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the regulations promulgated under the FFDCA. Pursuant to the FFDCA, the FDA regulates the research, design, testing, manufacture, safety, labeling, storage, record keeping, advertising, sales and distribution, post-market adverse event reporting, production and advertising and promotion of medical devices in the United States. Noncompliance with applicable requirements can result in warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket approval for devices and criminal prosecution.

Medical devices are classified into one of three classes, Class I, II or III, on the basis of the amount of risk and the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I, low risk, devices are subject to general controls (e.g., labeling and adherence to good manufacturing practices (GMPs)). Class II, intermediate risk, devices are subject to general controls and to special controls (e.g., performance standards, and premarket notification). Generally, Class III devices are those which must receive premarket approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices), and require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class II devices. In both the United States and certain international markets, there have been a number of legislative and regulatory initiatives and changes, such as the Modernization Act, which could and have altered the healthcare system in ways that could impact our ability to sell our medical devices profitably. Recent, widely-publicized events concerning the safety of certain drug, food and medical device products have raised concerns among members of Congress, medical professionals, and the public regarding the FDA's handling of these events and its perceived lack of oversight over regulated products. The increased attention to safety and oversight issues could result in a more cautious approach by the FDA to device clearances and approvals, as well as post-market compliance, which could prevent, delay clearance or approval of our new products or product modifications, or require us to expend additional resources on post-market studies and controls.

The FFDCA provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FFDCA, where the manufacturer submits to the FDA a premarket notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the 510(k) procedure, the manufacturer must file a premarket approval (PMA)

## [Table of Contents](#)

application with the FDA. This procedure requires more extensive pre-filing clinical and preclinical testing than the 510(k) procedure and involves a significantly longer FDA review process.

### ***Premarket Approval***

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

If the FDA determines that a PMA is complete, the FDA accepts the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted PMA application, although the review and response activities generally occur over a significantly longer period of time, typically one year, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of our, and our manufacturers', facilities to evaluate compliance with the quality system regulation. Under the Medical Device User Fee and Modernization Act of 2002, the fee to submit a PMA can be up to \$259,600 per PMA, however, we have qualified for a small business exemption. If the FDA's evaluation of the PMA is favorable, the PMA is approved, and the device may be marketed in the United States. The FDA may approve the PMA with post-approval conditions intended to ensure the safety and effectiveness of the device. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of a PMA, new PMAs or supplemental PMAs are required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a PMA except that the supplement is limited to information needed to support any changes from the device covered by the original PMA.

### ***Clinical Trials***

A clinical trial is almost always required to support a PMA. Clinical trials for a "significant risk" device such as ours require submission of an application for an IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the IDE application is allowed to proceed by the FDA and the institutional review boards overseeing the clinical trial at the various investigational sites.

Clinical trials require extensive recordkeeping and detailed reporting requirements. Our clinical trials must be conducted under the oversight of an institutional review board at the relevant clinical trial site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice (GCP) requirements. We, the trial data safety monitoring board, the FDA or the institutional review board at each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

### ***Pervasive and Continuing FDA Regulation***

Both before and after FDA approval, numerous regulatory requirements apply. These include:

- quality system regulation, which requires manufacturers to follow design, testing, control, documentation, complaint handling and other quality assurance procedures during the design and manufacturing processes;
- regulations which govern product labels and labeling, prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- notices of correction or removal and recall regulations.

Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA-regulated products have resulted in enforcement actions brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act, competitors and others can initiate litigation relating to advertising claims.

Compliance with regulatory requirements is enforced through periodic, unannounced facility inspections by the FDA. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters or untitled letters;
- fines, injunction and civil penalties;
- recall or seizure of our products;
- customer notification, or orders for repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production or clinical trials;
- refusing our request for premarket approval of new products;
- withdrawing premarket approvals that are already granted; and
- criminal prosecution.

### ***International***

#### ***Australia***

The Company’s Maestro System is regulated as a medical device under the *Therapeutic Goods Act* (TG Act), which regulates the research, design, testing, manufacture, safety, labeling, storage, record keeping, advertising, sales and distribution, post-market adverse event reporting, production and advertising and promotion of medical devices in Australia. The TG Act requires medical devices to be included on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia. The TGA’s requirements in relation to the inclusion process depend on the classification of devices based on risk level and other factors. In this case, the device will require a full conformity assessment prior to inclusion on the ARTG to satisfy the TGA that the device and its manufacturer comply with the “Essential Principles” under the TG Act relating to the safety and performance characteristics of medical devices. Accordingly, among other things, the TGA will need to review data demonstrating the safety and efficacy of the device including data obtained through clinical trials. TGA regulations continue to apply to a device after inclusion on the ARTG. For example the sponsor will be required to report certain adverse events to the TGA, and if a recall is required, it will need to comply with TGA

## [Table of Contents](#)

requirements. Even after the device is included, the TGA will conduct audits from time to time in relation to the product to ensure ongoing compliance. In addition, advertising material to consumers relating to the device is regulated by the TG Act. Advertising material in general is also subject to trade practices legislation, the regulatory agency for which is the Australian Competition and Consumer Commission.

### ***Other Countries***

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. The primary regulatory environment in Europe is that of the European Economic Community (EEC), which consists of 25 countries encompassing nearly all the major countries in Europe. Other countries that are not part of the EEC, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the EEC with respect to medical devices. The EEC has adopted Directive 90/385/EEC for active implantable medical devices and numerous standards that govern and harmonize the national laws and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices that are marketed in member states. Medical devices that comply with the requirements of the national law of the member state in which they are first marketed will be entitled to bear CE marking, indicating that the device conforms to applicable regulatory requirements, and, accordingly, can be commercially marketed within EEC states and other countries that recognize this mark for regulatory purposes.

We obtained European CE Mark approval for our Maestro RF System on March 4, 2009 and our current pursuing CE Mark certification for our Maestro RC System. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which falls into Class III), the method involved a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a product complies with applicable regulatory requirements. The manufacturer's assessment included a clinical evaluation of the conformity of the device with applicable regulatory requirements. We use KEMA in the Netherlands as the Notified Body for our CE marking approval process.

### **Employees**

As of September 30, 2010, we had a total of 29 employees. All of these employees are located in the United States.

From time to time we also employ independent contractors, consultants and temporary employees to support our operations. None of our employees are subject to collective bargaining agreements. We have never experienced a work stoppage and believe that our relations with our employees are good.

### **Properties**

We lease approximately 28,388 square feet of lab and office space in St. Paul, Minnesota. The lease agreement began October 1, 2008 and ends September 30, 2015.

### **Legal Proceedings**

We are not currently a party to any litigation and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our business, operating results or financial condition. The medical device industry in which we operate is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices and products liability. As a result, we may be involved in various legal proceedings from time to time.



## MANAGEMENT

### Executive Officers and Directors

The following table sets forth information regarding our executive officers and directors, including their ages, as of October 31, 2010:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Mark B. Knudson, Ph.D.	62	President, Chief Executive Officer, Chairman and Director
Greg S. Lea	58	Senior Vice President and Chief Financial Officer
Adrianus (Jos) Donders	57	Senior Vice President of Operations
Daniel L. Cohen	52	Senior Vice President of Government Relations and Health Policy
Katherine S. Tweden	50	Vice President of Research and Clinical
Luke Evin, Ph.D. <sup>(2)(3)</sup>	47	Director
Catherine Friedman <sup>(1)</sup>	50	Director
Carl Goldfischer, M.D. <sup>(3)</sup>	52	Director
Bobby I. Griffin <sup>(2)</sup>	73	Director
Donald C. Harrison, M.D. <sup>(1)</sup>	76	Director
Paul H. Klingenstein <sup>(1)(3)</sup>	54	Director
Nicholas L. Teti, Jr	58	Director
Jon T. Tremmel <sup>(2)</sup>	64	Director

(1) Member of audit committee.

(2) Member of compensation committee.

(3) Member of nominating and governance committee.

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

*Greg S. Lea* has served as our Senior Vice President and Chief Financial Officer since May 21, 2007. Prior to joining us, Mr. Lea served as Chief Financial Officer of Pemstar Inc. from July 2002 through January 2007 when it was acquired by Benchmark Electronics, Inc. Mr. Lea also served as a director of Pemstar from April 2001 through January 2007 and held the position of Corporate Controller from April 2002 through July 2002. From 1993 to April 2002, Mr. Lea served as a corporate Vice President for Jostens Corporation, a commemorative and affiliation products manufacturer, serving most recently as corporate Vice President-Business Ventures. Prior to that, Mr. Lea held several financial management and administrative positions at IBM Corporation from 1974 to 1993 and was President and a director of the Ability Building Center, Inc. from 1981 to 1993. Mr. Lea holds a B.S. in Accounting/Business Management from Minnesota State University, Mankato.

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

## [Table of Contents](#)

*Daniel L. Cohen* has served as our Senior Vice President of Government Relations and Health Policy since September 2009. From March to September 2009, Mr. Cohen worked as a consultant for the company, assisting us with reimbursement policies. From 2006 to 2009, Mr. Cohen served as Senior Vice President for Government Relations and Public Policy for US Oncology and, from 2003 to 2006, he served as Vice President Global, Corporate and Government Affairs for Inamed Corporation. Mr. Cohen also served as a consultant for Inamed Corporation from 2001 to 2003 and for Inamed, a division of Allergan, Inc., from 2006 to 2008, providing strategic advice with respect to medical device-related regulatory issues. Mr. Cohen holds a Master of Arts in Liberal Studies/International Affairs from Georgetown University and a Bachelor of Science Degree from Willamette University.

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

*Luke Evnin, Ph.D.*, has served as one of our directors since inception in 2002. Dr. Evnin has served as a Managing Director at MPM Capital since he co-founded MPM's asset management business in 1997. Prior to joining MPM, Dr. Evnin was at Accel Partners for over seven years including four as a General Partner. He was involved in biopharmaceutical, medical device and healthcare service companies for Accel's funds III, IV and V. Dr. Evnin has served as director of other public companies, including Epix Medical, Inc., Metabasis Therapeutics, Inc., Oscient Pharmaceuticals Corp., Restore Medical, Inc. (acquired by Medtronic, Inc.), Sonic Innovations, Inc. and Signal Pharmaceuticals, Inc. (acquired by Celgene Corporation) and is currently or has been a director of several private healthcare companies in both the medical device and biopharmaceutical sectors.

Areas of Relevant Experience: Dr. Evnin's experience managing venture investment funds, including co-founding a fund that was one of the initial investors in EnteroMedics, as well as his experience working with companies in the medical device and biopharmaceutical industries, makes him well-suited to serve as a member of the Board of Directors.

*Catherine Friedman*, has served as one of our directors since May 2007. Ms. Friedman currently is an independent financial consultant serving public and private companies in the lifesciences. Prior to that, Ms. Friedman held numerous positions over a 23 year investment banking career with Morgan Stanley. Ms. Friedman held the position of Managing Director at Morgan Stanley from 1997 to 2006 and Head of West Coast Healthcare and Co-Head of the Biotechnology Practice at Morgan Stanley from 1993 to 2006. Ms. Friedman joined the Board of XenoPort Inc., a publicly-held biopharmaceutical company, in September 2007 and also serves on its audit committee.

Areas of Relevant Experience: Ms. Friedman's lengthy career in investment banking in the healthcare and biotechnology industry, as well as her accounting and financial reporting expertise, makes her well-suited to serve as a member of the Board of Directors.

*Carl Goldfischer, M.D.*, has served as one of our directors since July 2004. Dr. Goldfischer is currently an Investment Partner and Managing Director of Bay City Capital, serving as a member of the Board of Directors and executive committee, and has been with the firm since December 2000. His background includes extensive public and private investment and transaction work, as well as clinical trial development knowledge. Prior to joining Bay City Capital, Dr. Goldfischer was, until mid-2000, Chief Financial Officer of ImClone Systems Incorporated, a publicly-held biotechnology company focused on developing therapeutic oncology products, where he oversaw financial operations and strategic planning. Previously, he was a Research Analyst with the

## [Table of Contents](#)

Reliance Insurance Company, helping to establish its portfolio and presence in the health care investment community. Dr. Goldfischer is a member of the Board of Directors of Poniard Pharmaceuticals, Inc., a publicly-held biopharmaceutical company focused on commercializing innovative oncology products, and MAP Pharmaceuticals, Inc., a publicly-held company focused on developing proprietary drug candidates for delivery via the respiratory tract, and also serves on the boards and audit committees of several private companies.

Areas of Relevant Experience: Dr. Goldfischer's experience managing a venture investment fund that was an early investor in EnteroMedics, as well as his accounting and financial reporting background, makes him well-suited to serve as a member of the Board of Directors.

*Bobby I. Griffin*, has served as one of our directors since September 2006. In 1998, Mr. Griffin retired from a 25 year career with Medtronic, Inc., where he held various positions, including Executive Vice President from 1985 to 1998 and President of Medtronic's Pacemaker Business from 1991 to 1998. Since his retirement, Mr. Griffin has been a private investor, managing his own fund of companies as well as serving on the advisory boards of Affinity Capital Management Fund III and IV and Sapien Capital Management Fund, in which he also invests. In addition, Mr. Griffin has served on the Board of Directors of several public companies, including MTS Systems Corporation and Urologix, Inc., and is currently a director of several private companies.

Areas of Relevant Experience: Mr. Griffin's lengthy career and senior leadership positions at a leading global implantable medical device company, as well as his experience with managing venture investments, makes him well-suited to serve as a member of the Board of Directors.

*Donald C. Harrison, M.D.*, has served as one of our directors since September 2003. Dr. Harrison is currently Managing Partner of Charter Life Sciences, a venture capital firm, where he has served since 2003. From 1967 to 1986, he was Chief of Cardiology at Stanford University and from 1981 to 1986 was Co-Director of the Falk Cardiovascular Research Center. From 1986 to 2003, Dr. Harrison was Chief Executive Officer of the University of Cincinnati Medical Center. He is a member of the Board of Kendle International Inc., a publicly-held global clinical research organization, and AtriCure, Inc., a publicly-held company that develops innovative products for tissue ablation during surgical procedures, and also serves on the audit committees of both of these companies. He is also a member of the board of several private companies.

Areas of Relevant Experience: Dr. Harrison's lengthy career as a cardiac surgeon, including his leadership positions at prestigious medical centers, as well as his venture investment and accounting and financial reporting background, makes him well-suited to serve as a member of the Board of Directors.

*Paul H. Klingenstein*, has served as one of our directors since July 2006. Mr. Klingenstein has served as Managing Partner of Aberdare Ventures since he founded it in 1999. Formerly, he served as a General Partner of Accel Partners, as a consultant to the Rockefeller Foundation, and as an employee of E.M. Warburg, Pincus & Co. In addition, Mr. Klingenstein has served on the Board of Directors of several public companies, including Aviron, Isis Pharmaceuticals, Inc., Pharmion Corporation and Xomed Surgical Products, Inc., and currently serves on the boards and audit committees of several private companies.

Areas of Relevant Experience: Mr. Klingenstein's experience managing venture investment funds, including founding a fund that was an early investor in EnteroMedics, as well as his accounting and financial reporting background, makes him well-suited to serve as a member of the Board of Directors.

*Nicholas L. Teti, Jr.*, has served as one of our directors since May 2007. Mr. Teti currently serves as Chairman of the Board, President and Chief Executive Officer of Suneva Medical, Inc., a privately-held aesthetic medical device company. He also serves as an independent consultant to public and private health care companies. Since April 2009, Mr. Teti has also served in a consultancy capacity to the Chief Executive Officer of EnteroMedics. From June 2009 to the present, Mr. Teti has served on the Cowen Royalty Partners Strategic Advisory Board. Since February 2009 he has served on the Board of CAVU, a "start-up" obesity research

## [Table of Contents](#)

company. From January 2008 to March 2009, Mr. Teti was Chief Executive Officer of Den-Mat, a dental aesthetics company focused on developing non-invasive techniques. Since June 2006, Mr. Teti also served as Chairman of the Board of Isolagen, Inc., a biotechnology company which develops emergent, novel skin and tissue rejuvenation technologies. From June 2006 to January 2008, he also was Chief Executive Officer of Isolagen. From 2001 to 2006, Mr. Teti was President and Chief Executive Officer of Inamed Corporation, a healthcare products manufacturer focused on marketing breast implants, dermal fillers to correct facial wrinkles, and devices to treat severe and morbid obesity, including the LAP-BAND Adjustable Gastric Banding System. Mr. Teti served on the board of Inamed during 2001 and was Chairman of the Board from 2002 to 2006. Prior to that, Mr. Teti spent 25 years at DuPont and DuPont Merck where he held a number of senior management positions including President and Chief Executive Officer of DuPont Pharmaceuticals.

Areas of Relevant Experience: Mr. Teti's executive leadership experience in the medical device field, specifically with the research, marketing and commercialization of medical devices that treat morbid obesity, makes him well-suited to serve as a member of the Board of Directors.

*Jon T. Tremmel*, has served as one of our directors since January 2009. Mr. Tremmel has been retired and acting as an independent consultant since 2007. Over the course of his career at Medtronic, Inc., Mr. Tremmel served in a variety of senior management positions, including President of the Neurological Division from 2003 to 2007, President of the Physio Control Division, President of the Tachyarrhythmia Management Division and President of the Interventional Vascular Division. Mr. Tremmel currently serves on the board of Cyberonics, Inc., a publicly-held company that designs, develops and markets implantable medical devices for the treatment of epilepsy and other debilitating neurological disorders, and a number of corporate and civic organizations.

Areas of Relevant Experience: Mr. Tremmel's lengthy career and leadership positions at a leading global implantable medical device company, makes him well-suited to serve as a member of the Board of Directors.

## EXECUTIVE COMPENSATION

### *Compensation Discussion and Analysis*

This Compensation Discussion and Analysis describes the compensation policies and programs for our named executive officers, who consist of our Chief Executive Officer, our Chief Financial Officer, and our three next most highly paid executive officers as determined under the rules of the SEC.

#### **Compensation Determination Process**

Commencing April 27, 2007, our Board of Directors appointed independent directors to the Compensation Committee, formally adopted a charter outlining the responsibilities of the committee and granted the committee the authority to oversee our compensation programs. The Compensation Committee reviews and approves the compensation programs and all forms of compensation for our Chief Executive Officer and recommends for approval by our Board of Directors the compensation programs and all forms of compensation for our other executive officers. The Chief Executive Officer's compensation package is set by the Compensation Committee in its sole discretion. Although our Chief Executive Officer does not make a recommendation as to his own compensation, he may respond to the Compensation Committee's proposal for his compensation, which the Compensation Committee may, but is not required to, consider. The Chief Executive Officer is also permitted to make compensation recommendations for the other executive officers, which the Compensation Committee may, but is not required to, consider. In addition, the Chief Executive Officer may participate as an observer at the Compensation Committee's meetings when the committee invites him to attend its meetings. Other than these rights granted to the Chief Executive Officer, management does not participate in the determination of the amount or form of executive compensation.

Commencing in 2007, the Compensation Committee adopted a practice of reviewing each element of total compensation on an annual basis in the first half of the year in connection with the review of our annual performance. In 2008, the Compensation Committee asked our Chief Financial Officer to analyze the base salaries, percentage equity ownership and percentage cash incentives paid to our executive officers at the level of vice president and above against the compensation awarded to such officers at comparable companies. The comparable companies (CNS, Inc., Conor Medsystems, Inc., Hansen Medical, Inc., Helicos Biosciences Corporation, Insulet Corporation, Northstar Neuroscience, Inc., Restore Medical, Inc., Urologix, Inc. and Xtent, Inc.) were selected by our Chief Financial Officer and consisted of medical device companies that were publicly-traded, comparably-sized and located in the same geographical area. In addition the peer group of selected companies was compared to three national third-party surveys: (1) Top Five Data Services, 2006 MEDIC Executive Compensation Survey; (2) Compstudy, a joint E&Y / Harvard study; and (3) The Management Association of Illinois' 2007 National Executive Compensation Survey. The Chief Financial Officer presented the results of this analysis and his findings with respect to the competitiveness of the elements of our compensation program to the Compensation Committee. The Compensation Committee primarily uses the comparative analysis as a starting point in its annual review of executive compensation to benchmark each executive's current compensation package against compensation packages offered to similar executive officers by the peer group companies. In general, the Compensation Committee tries to keep each executive's base salary and total compensation at the midpoint of the range of base salaries and total compensation paid to similar executive officers at the peer group companies and may make recommendations to adjust an executive's compensation accordingly. The goal of this review is to try to maintain base salaries and total compensation packages that are market competitive, so the Company can attract and retain executive talent. However, the Compensation Committee may deviate from this benchmark as it considers other factors such as each executive's individual performance and responsibilities, the Company's overall strategy and performance and the pool of resources available for compensation adjustments each year. These factors, especially the Company's desire to reward individual efforts and performance, weigh much more heavily in the Compensation Committee's final recommendations with respect to compensation adjustments and were the primary drivers behind the base salary increases that were recommended and approved for Mr. Lea and Dr. Tweden in 2010. Since the Company's intent with respect to stock-based compensation relates more to aligning executives' interests with those of the

## [Table of Contents](#)

Company and encouraging their efforts for the long-term growth and success of the Company, the peer group analysis generally plays a role as a reference point in the Compensation Committee's decisions to make additional awards of stock options to the executives. More importantly, the Compensation Committee considers individual performance and experience, contributions and achievements, stock option grants previously awarded to each executive and the Compensation Committee's view of the appropriate levels of equity compensation for individuals with certain responsibilities, professional expertise and experience.

In 2009, the Compensation Committee did not ask for an updated detailed compensation review nor did it recommend to the Board of Directors any adjustments to our executive officers' base salaries or the Management Incentive Plan as they determined that the compensation packages were appropriate and reflective of the economic situation. However, on three separate occasions during 2009, the Compensation Committee and Board of Directors approved the granting of stock options to our executive officers as a means of continuing to provide long-term incentives to motivate and retain our executive officers. In 2010, the Compensation Committee asked to look at current compensation packages being paid to our executive officers compared to the analysis prepared in 2008. After reviewing the analysis prepared by our Chief Financial Officer, the Compensation Committee approved base salary increases of 6.0% and 4.5% to Mr. Lea and Dr. Tweden, respectively. There were no additional changes recommended or approved to the compensation packages of our executive officers.

The Compensation Committee has the authority to use outside compensation consultants to assist it in analyzing our compensation programs and determining appropriate levels of compensation and benefits or to retain outside counsel and other advisors to assist it in the performance of its functions. The decision to retain consultants and, if so, which consultants to retain, is made solely by the Compensation Committee. The Compensation Committee has not used the services of a compensation consultant to date; however, it will continue to consider the need to retain a compensation consultant in connection with each annual review of compensation.

### **Compensation Philosophy and Components**

We are committed to attracting, hiring and retaining an experienced management team. Our fundamental executive compensation philosophy is to provide executive officers with compensation we believe to be comparable with similarly situated executives in other companies of similar size and stage of development operating in the medical device industry, taking into account our relative performance and our own strategic goals. Our objective is to have each executive officer's total compensation be contingent upon both our overall company performance and each executive officer's individual performance. To achieve this objective, our Compensation Committee has maintained and expects to continue to implement and maintain compensation programs that tie a portion of the executives' overall compensation to key strategic, financial and operational goals, such as clinical trial progress, continued research and development, continued establishment of intellectual property and implementation of appropriate financing strategies, while also recognizing not only individual executive responsibilities and breadth of experience but also competitive market compensation paid by other companies for similar positions. Accordingly, the compensation package for each executive officer is comprised of three elements: (i) a base salary that reflects individual responsibilities and experience and is intended to be competitive in the context of base salaries paid by comparable companies for similar positions; (ii) cash incentive payments under our Management Incentive Plan that are contingent upon our achievement of specific pre-determined performance objectives as communicated to the executives following their determination by the Compensation Committee and the Board of Directors on an annual basis, thereby making such objectives vary from year to year; and (iii) stock-based incentive awards, which reward long-term performance and align the mutuality of interests between our executive officers and our stockholders.

### ***Base Salary***

Base salaries are designed to provide recurring compensation for the fulfillment of the duties and responsibilities associated with job roles, and are paid in cash on a semi-monthly basis. The base salaries for our executive officers are structured to be market-competitive and to attract and retain these key employees. An

## Table of Contents

executive's base salary is also determined by reviewing the executive's other compensation to ensure that the executive's total compensation is in line with our overall compensation philosophy. In 2009, the Compensation Committee reviewed each individual's experience, each individual's performance during the prior year and the base salaries paid to our executive officers at the level of vice president and above in 2008. Based on this review and after considering the current economic environment, the Compensation Committee did not recommend adjustments to any of the named executive officers for 2009. Mr. Cohen commenced employment on September 21, 2009 and the Compensation Committee approved a base salary commensurate with his experience, market conditions and other senior level officers of the Company. On February 18, 2010 the Compensation Committee reviewed each individual's experience, each individual's performance during the prior year and the base salaries paid to our executive officers at the level of vice president and above in 2009 against the base salaries paid to such officers at comparable companies selected as part of a survey prepared by our Chief Financial Officer in 2008 at the request of the committee. Based on this review, the Compensation Committee approved increases of 6.0% and 4.5% to Mr. Lea and Dr. Tweden, respectively, effective March 1, 2010. The committee did not recommend any other adjustments to executive officers' base salaries for 2010.

We have also entered into executive employment agreements and amendments to the agreements with Drs. Knudson and Tweden and Messrs. Lea and Donders that establish certain guaranteed minimum base salary and incentive compensation thresholds and provide other benefits described in more detail below under the heading "Executive Employment Agreements and Severance Benefits." The base salaries recommended by the Compensation Committee and approved by the Board for Drs. Knudson and Tweden and Messrs. Lea and Donders have been consistent with these agreements since they were executed.

The Compensation Committee may adjust base salaries as warranted throughout the year for promotions or other changes in the scope or breadth of an executive's role or responsibilities. In 2009, no such adjustments were made.

### *Annual Cash Incentives*

Our Management Incentive Plan is designed to provide executive officers with annual incentive compensation based on the achievement of certain pre-established performance objectives. By utilizing a combination of objective and subjective performance factors critical to our success, this program incentivizes our executive officers to achieve results that benefit them and the company.

At the beginning of each year, the Compensation Committee recommends and the Board of Directors approves new "Base Plan" and "Incremental Plan" corporate objectives for the Management Incentive Plan. The objectives are established and measured on an annual basis to better align personal objectives with the direction and objectives of the company. When these objectives are established and approved, each objective, and, if applicable, the subparts to each objective, is weighted and assigned a percentage value relative to the "Base Plan" or "Incremental Plan" corporate objectives taken as a whole. At that time, the Compensation Committee also establishes the maximum bonus amount for each of our executive officers, based on a set percentage of each executive officer's base salary, that the "Base Plan" and "Incremental Plan" corporate objectives are worth (see table below). The Compensation Committee may modify or re-weight the objectives during the course of the fiscal year, if necessary, to reflect changes in our business plan. To date, the Compensation Committee has not made any mid-year modifications to the objectives.

## [Table of Contents](#)

Under the terms of the Management Incentive Plan, if participants achieve the designated “Base Plan” objectives, they are entitled to receive a bonus equal to a “Base Plan” percentage of their base salary for the year. In addition, to the “Base Plan” bonus amount, participants are also eligible to receive an additional bonus equal to the designated “Incremental Plan” percentage of their base salary if certain additional “Incremental Plan” objectives are achieved. The bonus percentages that may be paid to the named executive officers under the 2009 “Base Plan” and “Incremental Plan” are set forth in the table below:

<b>Title</b>	<b>“Base Plan” (bonus as percentage of salary)</b>	<b>“Incremental Plan” (bonus as percentage of salary)</b>	<b>Maximum Bonus (as a percentage of salary)</b>
President and CEO	40%	10%	50%
Chief Financial Officer	32%	8%	40%
Senior Vice President	32%	8%	40%
Vice President	24%	6%	30%

The Compensation Committee’s decision to include “Base Plan” and “Incremental Plan” bonuses and performance objectives in conjunction with bonus award percentages that may be earned by the named executive officers was based on its determination that such an incentive plan is necessary to strategically align the company’s compensation with that of similarly positioned publicly-traded medical device companies and to increase the company’s ability to attract and retain talented executive management. Additionally, the “Incremental Plan” objectives were designed as an extension of certain “Base Plan” objectives in order to provide additional incentive for achievement.

The Management Incentive Plan includes corporate and individual performance goals for all participants, except the Chief Executive Officer, whose bonus is based entirely on corporate objectives. The weighting of the corporate to individual performance goals for the named executive officers under the Management Incentive Plan is set forth in the table below:

<b>Title</b>	<b>Corporate Objective Weighting</b>	<b>Individual Objective Weighting</b>
President and CEO	100%	0%
Chief Financial Officer	90%	10%
Senior Vice President	80%	20%
Vice President	75%	25%

These percentages were weighted based upon the Compensation Committee’s determination that the achievement of the company’s strategic corporate goals was a more meaningful measure of performance for senior executive officers than the achievement of individual goals and that such weighting yielded an incentive that was most beneficial to the company’s overall performance.

At the beginning of each year, the Compensation Committee, with input from the Chief Executive Officer, reviews the performance objectives that were established for the prior year’s Management Incentive Plan and assesses whether the objectives were fully achieved, not achieved or partially achieved. If an objective was fully achieved, 100% credit is given for the objective. If an objective was not achieved, 0% credit is given for the objective. If an objective was partially achieved, the Compensation Committee, with input from the Chief Executive Officer, will review the objective and the Company’s performance to determine whether any partial credit is appropriate. In some cases, for example where an objective has subparts and one or more of the subparts was achieved, even though the main objective was not achieved, partial credit may be given for the subparts that were achieved. Since each of the objectives was assigned a weighting when it was established, the Compensation Committee adds the percentages for the objectives that were achieved to determine the total percentage of the “Base Plan” and “Incremental Plan” corporate objectives that were achieved for the year. Then, if there were any executive officers who did not serve as executive officers for the full year and had an agreement with the Company to receive a pro-rated amount of the Management Incentive Plan, like Mr. Cohen did in 2009, the



## [Table of Contents](#)

Compensation Committee will calculate the pro-rated percentage of the bonus award that such executive officer is entitled to receive. Finally, the Compensation Committee calculates the bonus award amount for each executive officer by first multiplying (i) the total percentage amount that the “Base Plan” corporate objective was achieved by the maximum “Base Plan” bonus amount for that officer, (ii) the total percentage amount that the “Incremental Plan” corporate objective was achieved by the maximum “Incremental Plan” bonus amount for that officer and (iii) for all of the executive officers except the Chief Executive Officer, the total percentage amount that the individual objective was achieved by the maximum individual bonus amount for that officer and then adding the amounts together. Based on these calculations, the Compensation Committee recommends the bonus award amounts to be paid to each of the executive officers and the Board of Directors reviews and approves the payment of the awards.

At its February 4, 2009 meeting, the Compensation Committee established the “Base Plan,” “Incremental Plan” and individual performance objectives for the 2009 bonus awards under the Management Incentive Plan. The 2009 “Base Plan” corporate objectives consisted of: (1) the achievement of certain results for the company’s U.S. pivotal trial of the Maestro System, the EMPOWER trial, including the submission of the company’s premarket approval (PMA) application for the Maestro System in fiscal 2009, (2) publication of certain sub-study results relating to type 2 diabetes and hypertension in the company’s VBLOC-RF2 feasibility study in 2009, (3) establishment of certain sales and marketing objectives, (4) the achievement of the fiscal 2009 capital plan, and (5) the achievement of certain approvals necessary for future clinical trials. The 2009 “Incremental Plan” corporate objectives consisted of: (1) the achievement of objectives for the release of certain EMPOWER clinical trial data, (2) the achievement of the secondary endpoint for excess weight loss measured from implant in the EMPOWER trial, and (3) submission of certain PMA modules at plan submission dates.

At its November 9, 2009 meeting, the Compensation Committee reviewed the achievement of the corporate and individual objectives in awarding bonuses under the Management Incentive Plan, and concluded that 25% of the 2009 “Base Plan” corporate performance objectives and 33.3% of the 2009 “Incremental Plan” corporate objectives had been met for all of the named executive officers. Additionally, our Chief Executive Officer, as authorized by the Compensation Committee, concluded that on average 50% of the individual performance objectives for the Chief Financial Officer, Senior Vice President and Vice President were achieved. The Compensation Committee also factored into this assessment the fact that Mr. Cohen’s bonus was to be prorated 53.55% based on his time served as a consultant and employee of the company. Based on these assessments, the Compensation Committee recommended and the Board of Directors approved 2009 bonus awards of \$44,933, \$32,471, \$22,984, \$18,416 and \$28,560 for Dr. Knudson, Mr. Lea, Mr. Donders, Mr. Cohen and Dr. Tweden, respectively. These bonus awards were paid to the named executive officers in November 2009.

In the first quarter of 2010, the individual performance objectives under the Management Incentive Plan were set separately and specifically for each participating executive officer by the Chief Executive Officer. With respect to the corporate performance component, on February 4, 2010, the Compensation Committee established objectives for both the “Base Plan” and the “Incremental Plan.” The “Base Plan” corporate performance objectives established by the Compensation Committee for fiscal year 2010 consist of: (1) the achievement of certain milestones in 2010 with respect to the company’s proposed U.S. pivotal trial of the Maestro System using the RC2 device, including submission of the IDE application for the trial, approval of the IDE application by the U.S. Food and Drug Administration (FDA) and initiation of implants for the trial, (2) publication in 2010 of 12-month data for sub-study results relating to type 2 diabetes and hypertension in the company’s VBLOC-RC2 feasibility study, (3) the development of a strategic financing plan for the company, and (4) the achievement of the fiscal 2010 capital plan. The “Incremental Plan” corporate performance objectives for fiscal year 2009 consist of: (1) obtaining the capital necessary to finance the company into 2011, (2) receipt of IDE approval from the FDA for the U.S. pivotal trial of the Maestro System, and (3) initiation of implants for this trial assuming receipt of FDA’s approval of the IDE. The “Incremental Plan” objectives are designed as an extension of certain “Base Plan” objectives in order to provide additional incentive for achievement. In the event that some, but not all, of the “Base Plan” or “Incremental Plan” corporate goals are achieved, the Compensation Committee, in its discretion, may determine to award partial or full payment of annual cash incentive compensation.

### *Long-Term Incentives*

Our 2003 Stock Incentive Plan allows us the opportunity to grant stock options, restricted stock and other equity-based awards. Currently, long-term incentives are awarded to our executive officers through the grant of stock options. Our stock option grants are designed to align the long-term interests of each executive officer with those of our stockholders by providing executive officers with an incentive to manage our business from the perspective of an owner with an equity stake in the business. The Compensation Committee and the Board of Directors have used stock options, rather than other forms of long-term incentives, because they create value for executive officers only if stockholder value is increased through an increased share price. In general, we view stock option grants as incentives for future performance and not as compensation for past accomplishments. We also believe that equity awards reward continued employment by an executive officer, with an associated benefit to us of employee continuity and retention. Since our initial public offering and the commencement of the trading of our common stock on the NASDAQ Stock Market on November 15, 2007, the exercise price of stock options awarded by the Compensation Committee has been and will continue to be the closing sales price of our common stock on the date of grant.

Executive officers are granted stock options at the time they commence their employment with us. New hire grants occur at regularly scheduled Board meetings. Executive officers are also eligible for annual grants thereafter, which are expected to occur at the first regularly scheduled Board meeting of each fiscal year. Stock options granted to our executive officers at the time of hire generally vest twenty-five percent on the first anniversary of the date of hire and then 1/36<sup>th</sup> per month for 36 months thereafter and expire ten years after the date of grant subject to earlier termination in the event of a termination of employment. The vesting of additional stock options issued to our executive officers is at the discretion of our Compensation Committee and the Board of Directors and may be in accordance with this schedule or may be monthly over different periods of time or may have a component of immediate vesting or may be tied to specified performance milestones. Stock option grants are made with an exercise price equal to the fair market value of our common stock on the date of grant. Prior to May 1, 2006, the grant date was the same as an employee's hire date, the date an agreement was entered into with a consultant or the date the Board of Directors approved the option grant. Since May 1, 2006, the stock option grant date has consistently been the day the Compensation Committee or the Board of Directors approves the option grant.

The Compensation Committee and the Board of Directors do not award stock options according to a prescribed formula or target, although they review equity data from comparable companies to inform their decisions. In determining the number of stock options granted to executive officers, individual responsibilities and experience, as well as contributions and achievements are considered, and, in appropriate circumstances, the Compensation Committee considers the recommendations of the Chief Executive Officer. The objectives utilized to assess individual contributions and achievements vary depending on the individual executive, but relate generally to strategic factors such as clinical trial progress and enrollment, research and development, continued establishment of intellectual property and implementation of appropriate financing strategies. While the Chief Executive Officer may provide recommendations to the Compensation Committee regarding the number of stock option grants awarded to other executive officers from time to time, he does not make a recommendation as to his stock options. Although our Chief Executive Officer may respond to the Compensation Committee's proposal regarding whether and the amount of stock options he should be granted, to date he has not done so and has accepted the initial proposal of the Compensation Committee. Beginning in 2007, a review of each component of the executive's compensation is conducted when determining annual equity awards to ensure that an executive's total compensation is in line with our overall compensation philosophy.

On February 4, 2009, the Compensation Committee approved stock option grants of 45,454, 16,601, 11,160 and 2,200 shares for Dr. Knudson, Mr. Lea, Mr. Donders and Dr. Tweden, respectively that vest 1/48<sup>th</sup> per month for 48 months. On June 22, 2009, the Compensation Committee approved stock option grants of 60,566, 17,516, 7,016 and 24,499 shares for Dr. Knudson, Mr. Lea, Mr. Donders and Dr. Tweden, respectively that vest 1/48<sup>th</sup> per month for 48 months. On November 9, 2009, the Compensation Committee approved stock option

## Table of Contents

grants of 20,833, 16,666, 11,666, 16,666 and 16,666 shares for Dr. Knudson, Mr. Lea, Mr. Donders, Mr. Cohen and Dr. Tweden, respectively, to be granted on November 18, 2009 with a vesting schedule such that 25% vested immediately and 75% will vest on November 15, 2010. All of these amounts were determined by the Compensation Committee without a recommendation by management, including the Chief Executive Officer, and were based on the Compensation Committee's subjective determination that additional stock option grants to such individuals were appropriate. The relative size of the grants reflected the Compensation Committee's subjective assessment of the relative contributions of such individuals, taking into consideration the option grants previously made to such individuals and the consensus of the Compensation Committee regarding the appropriate levels of equity incentives for individuals with such responsibilities, professional expertise and experience. The additional stock option grants in 2009 were in response to current economic conditions and the Compensation Committee's desire to motivate and retain key executive officers after not providing adjustments to base salaries in 2009. On May 28, 2009 and September 21, 2009 the Board of Directors approved stock option grants of 4,166 and 41,666 shares, respectively, for Mr. Cohen. The 4,166 shares were granted pursuant to a consulting agreement entered into on March 1, 2009 and amended on June 1, 2009 and the 41,666 shares were granted on the commencement of his employment with EnteroMedics on September 21, 2009.

### ***Other Compensation***

We provide our executive officers with benefits, including health insurance, life and disability insurance and dental insurance, that we believe are reasonable, competitive and consistent with our overall executive compensation program in order to attract and retain talented executives. Specifically, we fund the executive's Flex Spending Accounts and we pay 100% of the health and dental insurance premium costs for the families of our executive officers. The Compensation Committee periodically reviews the levels of benefits provided to executive officers.

We provide a 401(k) retirement savings plan in which all full-time employees, including the executive officers, may participate. Eligible employees may elect to reduce their current compensation by an amount no greater than the statutorily prescribed annual limit and may have that amount contributed to the 401(k) plan. Participation of the executive officers is on the same terms as any other participant in the plan. Matching contributions may be made by us to the 401(k) plan at the discretion of our Board of Directors. To date, we have not made any matching contributions to the 401(k) plan.

### **Executive Employment Agreements and Severance Benefits**

We have entered into executive employment agreements with Drs. Knudson and Tweden and Messrs. Lea and Donders. These agreements establish a specified minimum base compensation and a maximum percentage of annual incentive compensation that may be earned as a bonus by each of these executive officers in a given year. On April 3, 2008, in connection with the approval of the bonus award percentages for 2008 under the Management Incentive Plan, the company formally waived the maximum annual incentive compensation percentages set forth in these agreements in order to permit the maximum potential cash bonus awards under the Management Incentive Plan. On May 4, 2009, we entered into an amended and restated executive employment agreement with Dr. Knudson, which amended the prior executive employment agreement entered into on June 22, 2005. These agreements also provide for the payment of severance benefits upon certain termination events with Drs. Knudson and Tweden and Messrs. Lea and Donders and for the right to certain benefits upon a change in control of EnteroMedics. The purpose of these agreements is to attract and retain high caliber executive officers, recognizing that termination and change in control protections are commonly provided at comparable companies with which we compete for executive talent. In addition, the Compensation Committee believes change in control protections enhance the impartiality and objectivity of the executive officers in the event of a change in control transaction and better ensure that stockholder interests are protected. A more complete description of the executive employment agreements, as amended, is found in the sections entitled "Employment Agreements" and "Potential Payments Upon Termination or Change in Control."

**Compliance with Internal Revenue Code Section 162(m)**

As a result of Section 162(m) of the Internal Revenue Code of 1986, as amended (the Code), we are not allowed a federal income tax deduction for compensation paid to certain executive officers to the extent that compensation exceeds \$1.0 million per officer in any one year. This limitation applies to all compensation paid to the covered executive officers which is not considered to be performance-based. Compensation which qualifies as performance-based compensation does not have to be taken into account for purposes of this limitation.

Section 162(m) of the Code did not affect the deductibility of compensation paid to our executive officers in 2007, 2008 and 2009 and it is anticipated it will not affect the deductibility of such compensation expected to be paid in the foreseeable future. The Compensation Committee will continue to monitor this matter and may propose additional changes to the executive compensation program if warranted.

**Summary Compensation Table**

The following table sets forth information regarding compensation earned by our named executive officers during our fiscal years ended December 31, 2009, 2008 and 2007.

**Summary Compensation Table**

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)<sup>(1)</sup></u>	<u>Option Awards (\$)<sup>(2)</sup></u>	<u>Non- equity Incentive Plan Compensation (\$)<sup>(3)</sup></u>	<u>All Other Compensation (\$)<sup>(4)</sup></u>	<u>Total (\$)</u>
Mark B. Knudson, Ph.D. <i>President and Chief Executive Officer</i>	2009	\$337,000	\$—	\$1,366,881	\$ 44,933	\$ 4,466	\$1,753,280
	2008	335,065	—	2,261,145	155,445	5,341	2,756,996
	2007	308,025	—	790,715	74,880	4,737	1,178,357
Greg S. Lea <sup>(5)</sup> <i>Senior Vice President and Chief Financial Officer</i>	2009	248,500	—	443,677	32,471	4,466	729,114
	2008	248,357	—	341,622	91,699	4,602	686,280
	2007	151,398	—	695,984	30,205	2,441	880,028
Adrianus (Jos) Donders <i>Senior Vice President of Operations</i>	2009	253,500	—	214,709	22,984	5,638	496,831
	2008	252,890	—	570,892	93,544	5,216	922,542
	2007	241,292	—	171,897	48,880	5,481	467,550
Daniel L. Cohen <sup>(6)</sup> <i>Senior Vice President of Government Relations and Health Policy</i>	2009	69,723	—	1,104,987	18,416	88,825	1,281,951
Katherine S. Tweden, Ph.D. <i>Vice President of Research and Clinical</i>	2009	240,000	—	496,959	28,560	6,263	771,782
	2008	221,273	—	112,984	61,601	5,471	401,329
	2007	205,392	—	34,382	34,320	5,205	279,299

(1) Under current reporting rules, only discretionary or guaranteed bonuses are disclosed in this column.

(2) The amount in this column represents the grant date fair value based on the Black-Scholes model of option valuation, as prescribed by GAAP. The assumptions used to arrive at the Black-Scholes value are disclosed in Note 11 to our consolidated financial statements for the fiscal year ended December 31, 2009 included in our Annual Report on Form 10-K, incorporated by reference into this prospectus, excluding the impact of forfeitures. Mr. Cohen's amount also includes the grant date fair value of \$52,391 for 4,166 stock options granted pursuant to the terms of his consulting agreement effective June 1, 2009.

(3) Represents bonuses earned under our Management Incentive Plan. All of our executive officers participate in the Management Incentive Plan. The details of the Management Incentive Plan are discussed further above under the heading "Compensation Discussion and Analysis."

[Table of Contents](#)

- (4) The amounts in this column include company contributions to each executive officer's Flex Spending Account (FSA) and premiums paid by the company for health care and dental coverage for the dependents of each of our executive officers. With respect to the FSA spending contribution, the maximum contribution amount is included regardless of actual amounts used by the executives. With respect to the dependent health care and dental coverage, the amounts only include the 20% additional coverage paid by the company for executive officers as the company covers 80% of this expense for all employees. In addition, Mr. Cohen's amount includes a total of \$87,290 in consulting and expense payments made in 2009 pursuant to a consulting agreement entered into on March 1, 2009 and amended on June 1, 2009. The consulting agreement with Mr. Cohen was terminated on September 21, 2009 upon the commencement of Mr. Cohen's employment with EnteroMedics.
- (5) Mr. Lea joined the company on May 21, 2007.
- (6) Mr. Cohen joined the company on September 21, 2009.

**Grants of Plan-Based Awards**

The table below sets forth information regarding all plan-based awards granted to our named executive officers during fiscal year 2009. The equity awards described in this table have not been adjusted to reflect the option exchange offer that we completed on October 29, 2010.

**Grants of Plan-Based Awards**

Name	Grant Date	Estimated future payouts under non-equity incentive plan awards <sup>(1)</sup>			All other option awards: number of securities underlying options (#)	Exercise or base price of option awards (\$/Sh)	Grant date fair value of option awards (\$) <sup>(2)</sup>
		Threshold (\$)	Target (\$)	Maximum (\$)			
Mark B. Knudson, Ph.D.	2/4/09	\$ —	\$ 134,800	\$ 168,500	45,454	\$ 6.60	\$ 225,081
	6/22/09	—	—	—	60,566	22.20	1,080,627
	11/18/09	—	—	—	20,833	3.78	61,173
Greg S. Lea	2/4/09	—	79,520	99,400	16,601	6.60	82,207
	6/22/09	—	—	—	17,516	22.20	312,531
	11/18/09	—	—	—	16,666	3.78	48,938
Adrianus (Jos) Donders	2/4/09	—	81,120	101,400	11,160	6.60	55,261
	6/22/09	—	—	—	7,016	22.20	125,191
	11/18/09	—	—	—	11,666	3.78	34,257
Daniel L. Cohen <sup>(3)</sup>	5/28/09	—	—	—	4,166	13.80	52,391
	9/21/09	—	42,498	53,122	41,666	30.36	1,003,658
	11/18/09	—	—	—	16,666	3.78	48,938
Katherine S. Tweden, Ph.D.	2/4/09	—	57,600	72,000	2,200	6.60	10,894
	6/22/09	—	—	—	24,499	22.20	437,128
	11/18/09	—	—	—	16,666	3.78	48,938

- (1) Represents bonuses earned under our Management Incentive Plan. The target bonus for each executive officer is a percentage of the respective base salary for the executive officer. Under the Management Incentive Plan for 2009, Dr. Knudson could have earned a bonus up to 50% of his base salary with a target of 40% of his base salary. Messrs. Lea and Donders could have earned a bonus up to 40% of their respective base salary with a target of 32% of their respective base salaries. Dr. Tweden could have earned a bonus up to 30% of her base salary with a target of 24% of her base salary. Under the Management Incentive Plan, there are no guaranteed minimum payouts. In other words, the minimum level of payout or the threshold level is zero. While the Management Incentive Plan allows for payouts at less than the target level, all such

## Table of Contents

payments are made at the sole discretion of the Compensation Committee and the Board of Directors. The bonus awards are reviewed by the Compensation Committee and, upon the recommendation of the Compensation Committee, approved by the Board of Directors. The actual awards earned by the named executive officers in fiscal 2009 are reported in the Non-Equity Incentive Plan Compensation column in the Summary Compensation Table and are discussed further above under the heading "Compensation Discussion and Analysis."

- (2) The amounts shown represent the grant date fair value based on the Black-Scholes model of option valuation, as prescribed by GAAP. The assumptions used to arrive at the Black-Scholes value are disclosed in Note 11 to our consolidated financial statements for the fiscal year ended December 31, 2009 included in our Annual Report on Form 10-K, incorporated by reference into this prospectus, excluding the impact of forfeitures.
- (3) Mr. Cohen entered into a consulting agreement with the company effective March 1, 2009 that was subsequently amended effective June 1, 2009. Pursuant to such consulting agreement, Mr. Cohen was granted 4,166 options on May 28, 2009. Mr. Cohen joined the company as an employee on September 21, 2009 and at such time became eligible to earn a bonus under our Management Incentive Plan. Mr. Cohen could have earned a bonus up to 40% of his respective base salary with a target of 32% of his respective base salary. The bonus Mr. Cohen could have earned was to be prorated 53.55% for 2009 based on both his time served as a consultant and as an employee.

### **Employment Agreements**

#### **Executive Employment Agreement with Mark B. Knudson**

On May 4, 2009, we entered into an amended and restated executive employment agreement with Dr. Knudson, our President and Chief Executive Officer, which amended the prior executive employment agreement entered into on June 22, 2005. The agreement has an initial term of two years and automatically renews for successive one year terms unless either party delivers written notice 90 days prior to the expiration of the current term or unless it is earlier terminated as described below. Pursuant to the agreement, Dr. Knudson is entitled to a base salary of not less than \$300,000, or a higher annual rate if approved by the Board of Directors, and to cash and equity awards pursuant to our incentive compensation plan, contingent on Dr. Knudson meeting certain annual objectives agreed to by him and the Compensation Committee. The agreement establishes that the target amount of Dr. Knudson's annual incentive compensation may not be less than 30% of his base salary for that year. Dr. Knudson's executive employment agreement also provides for the receipt of certain benefits upon the occurrence of particular termination events or a change in control. See the section entitled "Potential Payments Upon Termination or Change in Control" for a more detailed discussion of these benefits. In addition, Dr. Knudson's agreement includes a non-disclosure and assignment provision and non-competition, non-solicitation and no recruitment commitments each lasting for a period of one year following termination.

#### **Executive Employment Agreements with Greg S. Lea, Adrianus (Jos) Donders and Katherine Tweden**

In 2007 and 2008, we also entered into executive employment agreements with Mr. Lea, our Senior Vice President and Chief Financial Officer, Mr. Donders, our Senior Vice President of Operations and Dr. Tweden, our Vice President of Research and Clinical. These agreements have an initial term of one year and automatically renew for successive one year terms unless either party delivers written notice 90 days prior to the expiration of the current term or unless it is earlier terminated as described below. Pursuant to these agreements, these executive officers are entitled to a base salary, as set forth in the table below, or a higher annual rate if approved by the Board of Directors, and to cash and equity awards pursuant to our incentive compensation plan, contingent on the executive officers meeting certain annual objectives agreed to by them and the Chief Executive Officer. The agreements for Messrs. Lea and Donders establish that the target amount of these executives' annual incentive compensation may not exceed 25% of their respective base salary for that year. On April 3, 2008, in connection with the approval of the bonus award percentages for 2008 under the Management Incentive Plan, the company formally waived the maximum annual incentive compensation percentages set forth in these

## [Table of Contents](#)

agreements in order to permit the maximum potential cash bonus awards under the Management Incentive Plan. The agreement for Dr. Tweden establishes that the target amount of her annual incentive compensation may not be less than 24% of her base salary for that year.

Greg S. Lea	\$245,000
Adrianus (Jos) Donders	235,000
Katherine S. Tweden, Ph.D.	218,000

These agreements also provide for the receipt of certain benefits upon the occurrence of particular termination events or a change in control. See the section entitled "Potential Payments Upon Termination or Change in Control" for a more detailed discussion of these benefits. In addition, these agreements include non-disclosure and assignment provisions and non-competition, non-solicitation and no recruitment commitments each lasting for a period of one year following termination.

### **Outstanding Equity Awards at Fiscal Year-End**

The following table summarizes the outstanding equity award holdings held by our named executive officers at December 31, 2009. The equity awards described in this table have not been adjusted to reflect the option exchange offer that we completed on October 29, 2010.

#### **Outstanding Equity Awards at Fiscal Year-End**

Name	Option awards		Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Exercisable Options (#)	Number of Securities Underlying Unexercisable Options (#)		
Mark B. Knudson, Ph.D.	11,575	— <sup>(1)</sup>	\$ 2.76	8/16/14
	7,915	— <sup>(2)</sup>	2.76	4/27/15
	6,212	564 <sup>(3)</sup>	2.76	4/20/16
	29,838	12,286 <sup>(3)</sup>	31.14	2/6/17
	16,264	33,415 <sup>(4)</sup>	49.62	2/6/18
	9,469	35,985 <sup>(5)</sup>	6.60	2/4/19
	8,832	51,734 <sup>(6)</sup>	22.20	6/22/19
	5,208	15,625 <sup>(7)</sup>	3.78	11/18/19
Greg S. Lea	16,407	6,486 <sup>(11)</sup>	50.78	5/21/17
	2,457	5,047 <sup>(4)</sup>	49.64	2/6/18
	3,458	13,143 <sup>(5)</sup>	6.60	2/4/19
	2,554	14,962 <sup>(6)</sup>	22.20	6/22/19
	4,166	12,500 <sup>(7)</sup>	3.78	11/18/19
Adrianus (Jos) Donders	14,652	— <sup>(8)</sup>	2.76	4/11/15
	3,663	— <sup>(2)</sup>	2.76	4/27/15
	5,288	481 <sup>(3)</sup>	2.76	4/20/16
	6,486	2,671 <sup>(3)</sup>	31.14	2/6/17
	1,831	— <sup>(9)</sup>	49.63	2/6/18
	3,720	7,642 <sup>(4)</sup>	49.63	2/6/18
	2,325	8,835 <sup>(5)</sup>	6.60	2/4/19
	1,023	5,993 <sup>(6)</sup>	22.20	6/22/19
	2,916	8,750 <sup>(7)</sup>	3.78	11/18/19
Daniel L. Cohen	810	3,356 <sup>(12)</sup>	13.80	5/28/19
	—	41,666 <sup>(3)</sup>	30.36	9/21/19
	4,166	12,500 <sup>(7)</sup>	3.78	11/18/19

## [Table of Contents](#)

Name	Option awards		Option Exercise Price (\$)	Option Expiration Date
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable		
Katherine S. Tweden, Ph.D.	10,192	— <sup>(10)</sup>	2.76	8/16/14
	183	— <sup>(2)</sup>	2.76	4/27/15
	2,434	221 <sup>(3)</sup>	2.76	4/20/16
	1,297	534 <sup>(3)</sup>	31.15	2/6/17
	812	1,669 <sup>(4)</sup>	49.65	2/6/18
	458	1,742 <sup>(5)</sup>	6.60	2/4/19
	3,572	20,927 <sup>(6)</sup>	22.20	6/22/19
	4,166	12,500 <sup>(7)</sup>	3.78	11/18/19

- (1) Stock options vest 5,494 shares immediately upon the date of grant, which was August 16, 2004, and then 25% on the first anniversary of the date of grant and 1/36<sup>th</sup> per month for 36 months thereafter.
- (2) Stock options vest 100% upon the achievement of a milestone, which was defined for purposes of these grants as the implant of the Maestro RF System in 12 patients. These grants did not provide for any time restrictions with respect to the milestone, except the ten-year term of the option. The milestone was achieved in March 2006.
- (3) Stock options vest 25% on the first anniversary of the date of grant and 1/36<sup>th</sup> per month for 36 months thereafter.
- (4) 50% of the stock options vest 1/48<sup>th</sup> per month for 48 months and the remaining 50% of the stock options vest equally and individually upon the achievement of five milestones: (1) full enrollment of EMPOWER RF2 and RC in 2008; (2) PMA submission in 2009; (3) achieving the primary endpoint for EMPOWER in 2009; (4) achieving the secondary endpoint for EMPOWER in 2009; and (5) FDA acceptance of the EMPOWER PMA. In November 2009 the Compensation Committee determined that 75% of milestone (1) was achieved and milestones (2), (3) and (4) were not achieved. As a result a portion of these grants were cancelled in 2009. The achievement of milestone (5) is not restricted by time, except the ten-year term of the option, and is still pending.
- (5) Stock options vest 1/48<sup>th</sup> per month for 48 months from the date of grant.
- (6) Stock options vest 1/48<sup>th</sup> per month for 48 months beginning June 30, 2009.
- (7) Stock options vest 25% immediately upon the date of grant and the remaining 75% vest on November 15, 2010.
- (8) Stock options vest 25% on the first anniversary of the date of grant and 1/36<sup>th</sup> per month for 36 months thereafter. Since these grants were made prior to May 1, 2006, the date of grant for these options is the hire date, rather than the Board approval date. See the "Compensation Discussion and Analysis" for further detail. Mr. Donders' hire date related to this option grant is April 11, 2005.
- (9) Stock options vest 100% immediately upon the date of grant.
- (10) Stock options vest 3,406 shares immediately upon the date of grant, which was August 16, 2004, and then 25% on the first anniversary of the date of grant and 1/36<sup>th</sup> per month for 36 months thereafter.
- (11) Stock options vest 4,578 shares immediately upon the date of grant, which was May 21, 2007, and then 25% on the first anniversary of the date of grant and 1/36<sup>th</sup> per month for 36 months thereafter.
- (12) Stock options vest 1/36<sup>th</sup> per month for 36 months from the date of grant.

### ***Option Exercises and Stock Vested***

There were no option exercises or restricted stock awards that vested during our fiscal year ended December 31, 2009.



## [Table of Contents](#)

### ***Pension Benefits***

None of our named executive officers participate in or have account balances in qualified or non-qualified defined benefit plans sponsored by us.

### ***Non-Qualified Deferred Compensation***

We currently do not have any non-qualified defined contribution plans or other deferred compensation plans.

### ***Potential Payments and Benefits Upon Termination or Change in Control***

We are a party to Executive Employment Agreements with Mark B. Knudson, Greg S. Lea, Adrianus (Jos) Donders and Katherine S. Tweden that provide for the receipt of certain payments and benefits upon particular termination events or change in control.

These agreements may be terminated prior to the expiration of the term by mutual written agreement of the parties, in the event of death or disability, by us for cause (*i.e.*, for uncured willful breach of duties or this agreement, conviction of any felony or crime involving fraud, dishonesty or moral turpitude or participation in any fraud against or affecting us or any of our subsidiaries, affiliates, suppliers, clients, agents or employees or an act of personal dishonesty intended to result in personal enrichment at our expense or any other act we determine constitutes gross or willful misconduct) or by these executives for good reason (*i.e.*, a significant change and substantial reduction in their responsibilities or a relocation to more than 25 miles from our current facility). In addition, either party may terminate the executive's employment at any time for any reason or no reason, including after a change in control, with 30 days written notice. For purposes of these agreements, a change in control includes: (1) a change in beneficial ownership of our securities after the date of the agreement resulting in a new beneficial owner holding 50% or more of the combined voting power of our securities; (2) a majority of the Board ceases to be composed of continuing directors (as defined in the agreement); (3) any consolidation or merger involving the company where the company is not the surviving corporation or the shares of the company's capital stock are converted into cash, securities or other property, except if the company is the surviving corporation and its stockholders immediately prior to the transaction maintain a proportionate ownership in the company's stock following the transaction; (4) any sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of the company; (5) any liquidation or dissolution of the company; or (6) a majority of the continuing directors determine, in their sole and absolute discretion, that there has been a change in control.

#### **Payments Made Upon Termination at End of Term.**

In the event that Dr. Knudson is terminated at the end of the term of his agreement (as defined in the agreement), he is entitled to (1) receive base salary at the rate then currently in effect for a period of 12 months following the termination date, (2) exercise all vested options as of the termination date for a period of five years following his termination, and (3) receive continued health benefits for a period of 18 months following the termination date.

#### **Payments Made Upon Termination Due to Death or Disability.**

In the event that Dr. Knudson's employment is terminated due to death or disability (as defined in the agreement), he, or in the event of his death, his then spouse, is entitled to 18 months of continued health benefits. In the event that Messrs. Lea or Donders' or Dr. Tweden's employment is terminated due to death or disability, each of them, or in the event of their death, their then spouses, are entitled to six months of continued health benefits.

**Payments Made Upon Termination Without Cause or Resignation for Good Reason.**

In the event that Dr. Knudson resigns for good reason or his employment is terminated without cause prior to the end of the term of his agreement, he is entitled to (1) receive base salary at the rate then currently in effect for a period of 18 months following the termination date, (2) exercise all vested options as of the termination date for a period of five years following his termination, and (3) receive continued health benefits for a period of 18 months following the termination date. In the event that Messrs. Lea or Donders or Dr. Tweden resigns for good reason or is terminated without cause prior to the end of the term of their agreements, they are entitled to (1) receive base salary at the rate then currently in effect for a period of six months following the termination date, (2) exercise all vested options and those that would have vested within one year of the termination date for a period of five years following their termination, and (3) receive continued health benefits for a period of six months following the termination date. Drs. Knudson and Tweden and Messrs. Lea and Donders' severance pay is subject to signing, and not rescinding, a general release of all claims against the company.

**Benefits Upon Change in Control.**

In the event of a change in control, Dr. Knudson's agreement provides that 100% of the remaining unvested portion of his stock options will automatically vest and be exercisable for a period of five years following the change in control regardless of whether Dr. Knudson's employment is terminated in connection therewith. In addition, should Dr. Knudson resign for good reason or his employment be terminated without cause in connection with or within the first two years after a change in control, (1) he is entitled to receive base salary at the rate then currently in effect for a period of 18 months following the termination date and (2) the vesting schedule of any options issued to Dr. Knudson after the change of control will accelerate such that 100% of any unvested shares under the options shall immediately vest and be exercisable for a period of five years following the termination of employment. For Messrs. Lea and Donders and Dr. Tweden, in the event of a change in control in which the employment of these executive officers is not terminated, their agreements provide that 50% of the remaining unvested portion of their stock options will automatically vest and be exercisable for a period of five years following termination of employment. In the event of a change in control in which the employment of these executive officers is terminated, 100% of the remaining unvested portion of their options will immediately vest and be exercisable for a period of five years following termination of employment. However, with respect to any of these provisions, if these executive officers receive a cash payment for their options in connection with the change in control equal to the difference between the per share amount paid to the common stockholders in the transaction and the exercise price of the option, their options will be cancelled in exchange for the cash payment.

**Potential Payments Upon Termination or Change in Control**

The table below shows our reasonable estimates of potential payments and benefits payable to the named executive officers upon termination without cause, resignation for good reason and change in control of EnteroMedics, with or without termination, based on the closing price of our common stock on the NASDAQ Global Market of \$3.36, on December 31, 2009. The amounts shown assume that termination or change in control was effective as of December 31, 2009, the last business day of the fiscal year, and are estimates of the amounts that would be paid to the executive officer in addition to the base salary and bonus earned by the executives during 2009. Benefits payable to all employees, such as accrued vacation and life insurance premiums are excluded. The actual amounts to be paid can only be determined at the actual time of an executive officer's termination.

<u>Name<sup>(1)</sup></u>	<u>Type of Payment</u>	<u>Payments Upon Change in Control With Termination (\$)<sup>(2)</sup></u>	<u>Payments Upon Change in Control Without Termination (\$)<sup>(2)</sup></u>	<u>Payments Upon Termination Without Cause or Resignation for Good Reason (\$)</u>
Mark B. Knudson, Ph.D.	Severance Pay	\$ —	\$ —	\$ 505,500
	Value of Stock Options Accelerated <sup>(3)</sup>	339	339	—
	Health Care Benefits <sup>(4)</sup>	—	—	18,561
	<b>Total</b>	<u>\$ 339</u>	<u>\$ 339</u>	<u>\$ 524,061</u>
	Greg S. Lea	Severance Pay	\$ —	\$ —
Greg S. Lea	Value of Stock Options Accelerated <sup>(3)</sup>	—	—	—
	Health Care Benefits <sup>(4)</sup>	—	—	6,187
	<b>Total</b>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 130,437</u>
	Adrianus (Jos) Donders	Severance Pay	\$ —	\$ —
Adrianus (Jos) Donders	Value of Stock Options Accelerated <sup>(3)</sup>	289	144	289
	Health Care Benefits <sup>(4)</sup>	—	—	9,118
	<b>Total</b>	<u>\$ 289</u>	<u>\$ 144</u>	<u>\$ 136,157</u>
	Katherine S. Tweden, Ph.D.	Severance Pay	\$ —	\$ —
Katherine S. Tweden, Ph.D.	Value of Stock Options Accelerated <sup>(3)</sup>	133	66	133
	Health Care Benefits <sup>(4)</sup>	—	—	9,118
	<b>Total</b>	<u>\$ 133</u>	<u>\$ 66</u>	<u>\$ 129,251</u>

- (1) Daniel L. Cohen does not have an employment agreement with the company and is not entitled to any additional benefits in the event of termination or change of control.
- (2) Assumes that options were not cashed out in connection with change in control. Additional amounts may be payable if the termination is without cause or is a resignation for good reason, as specified in the third column.
- (3) Value computed based on the difference between \$3.36, the closing price of our common stock on the NASDAQ Global Market on December 31, 2009, and the exercise price for each option accelerated. No value is included in the table where the option price is greater than the closing price of our common on the NASDAQ Global Market of \$3.36 on December 31, 2009.
- (4) Amount represents the estimated full premiums to be paid by the company for health and dental coverage for the executive officer and his family for the duration of the severance period, as applicable, based on current premiums paid.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth information with respect to the beneficial ownership of our common stock as of October 31, 2010 for:

- each beneficial owner of more than 5% of our outstanding common stock;
- each of our Named Executive Officers and directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include shares of common stock issuable upon the exercise of stock options, warrants or other convertible securities that are immediately exercisable or exercisable within 60 days after October 31, 2010. Except as otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

Percentage ownership calculations for beneficial ownership prior to this offering are based on 10,872,388 shares outstanding, on an as-converted basis, as of October 31, 2010. Except as otherwise indicated in the table below, addresses of named beneficial owners are in care of EnteroMedics Inc., 2800 Patton Road, St. Paul, Minnesota 55113.

<u>Name and Address of Beneficial Owner</u>	<u>Amount and Nature of Beneficial Ownership</u>	<u>Percentage Owned Before the Offering</u>	<u>Percentage Owned After the Offering<sup>(9)</sup></u>
<b>5% Stockholders:</b>			
Bay City Capital <sup>(1)(2)(3)(7)</sup> 750 Battery St., Ste. 400 San Francisco, CA 94111	2,501,906	22.7%	16.3%
MPM Capital <sup>(2)(4)(7)</sup> 601 Gateway Blvd., Ste. 360 S. San Francisco, CA 94080	1,822,009	16.5%	7.1%
Aberdare Ventures <sup>(2)(5)(7)</sup> One Embarcadero Ctr., Ste. 400 San Francisco, CA 94111	1,039,860	9.5%	4.0%
T. Rowe Price <sup>(2)(6)</sup> 100 E. Pratt Street Baltimore, MD 21202	722,829	6.5%	9.4%
<b>Executive Officers and Directors:</b>			
Mark B. Knudson, Ph.D. <sup>(1)(2)</sup>	149,800	1.4%	*
Greg S. Lea <sup>(1)(2)</sup>	41,255	*	*
Adrianus (Jos) Donders <sup>(1)</sup>	47,889	*	*
Katherine S. Tweden <sup>(1)</sup>	40,587	*	*
Daniel L. Cohen <sup>(1)</sup>	31,610	*	*
Luke Evnin, Ph.D. <sup>(1)(2)(4)(7)</sup>	1,827,650	16.6%	7.1%
Catherine Friedman <sup>(1)</sup>	11,299	*	*
Carl Goldfischer, M.D. <sup>(1)(2)(3)(7)</sup>	2,507,547	22.8%	16.3%
Bobby I. Griffin <sup>(1)(2)</sup>	105,255	1.0%	*
Donald C. Harrison <sup>(1)(2)(7)</sup>	346,025	3.2%	1.3%
Paul H. Klingenstein <sup>(1)(2)(5)(7)</sup>	1,071,708	9.8%	4.2%
Nicholas L. Teti, Jr. <sup>(1)(7)</sup>	37,626	*	*
Jon T. Tremmel <sup>(1)</sup>	7,186	*	*
<b>All executive officers and directors as a group (13 persons)<sup>(8)</sup></b>	<b>6,225,437</b>	<b>53.4%</b>	<b>30.1%</b>

## Table of Contents

- \* Represents beneficial ownership of less than 1%.
- (1) Includes the following shares subject to options exercisable currently or within 60 days of October 31, 2010: Dr. Knudson, 106,965 shares; Mr. Lea, 36,631 shares; Mr. Donders, 47,889 shares; Dr. Tweden, 39,534 shares; Mr. Cohen 31,610 shares; Dr. Evnin, 5,641 shares; Ms. Friedman, 9,299 shares; Dr. Goldfischer, 5,641 shares; Mr. Griffin, 33,113 shares; Dr. Harrison, 5,641 shares; Mr. Klingenstein, 5,641 shares; Mr. Teti, 26,786 shares; and Mr. Tremmel, 4,773 shares. Dr. Goldfischer has assigned the shares underlying his options to Bay City Capital Fund IV upon the exercise of these options.
  - (2) Includes warrants exercisable currently or within 60 days of October 31, 2010 as follows: Bay City Capital (see footnote (3)), 137,456 shares; MPM Capital (see footnote (4)), 152,255 shares; Aberdare Ventures (see footnote (5)), 103,092 shares; T. Rowe Price (see footnote (6)), 210,007 shares; Dr. Knudson, 5,667 shares; Mr. Lea, 1,374 shares; Dr. Evnin, 152,255 shares; Dr. Goldfischer, 137,456 shares; Mr. Griffin, 17,182 shares; Dr. Harrison, 169 shares; and Mr. Klingenstein, 103,092 shares.
  - (3) Consists of information supplied to us or filed with the SEC by Bay City Capital LLC (BCC) on behalf of Bay City Capital Fund IV, L.P. (Fund IV), Bay City Capital Fund IV Co-Investment Fund, L.P. (Co-Investment IV) and Bay City Capital Management IV LLC (Management IV), each of which has shared voting power and shared dispositive power of 2,501,906 shares, which includes 1,626,016 shares of Series A non-voting convertible preferred stock. 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 5,641 shares.
  - (4) Consists of information supplied to us or filed with the SEC by MPM BioVentures III, L.P. (BV III), MPM BioVentures III-QP, L.P. (BV III QP), MPM BioVentures III Parallel Fund L.P. (BV III PF), MPM Bio Ventures III GmbH & Co. Beteiligungs KG (BV III KG), MPM Asset Management Investors 2002 BV III LLC (AM LLC), MPM BioVentures III GP, L.P. (BV III GP), MPM BioVentures III LLC (BV III LLC), and Luke Evnin, Ansbert Gadicke, Nicholas Galakatos, Michael Steinmetz, Kurt Wheeler, Nicholas Simon III, and Dennis Henner. BV III has the sole power to vote and sole power to dispose of 101,749 shares, which includes 39,423 shares of Series A non-voting convertible preferred stock, BV III QP has the sole power to vote and sole power to dispose of 1,516,696 shares, which includes 586,338 shares of Series A non-voting convertible preferred stock, BV III PF has the sole power to vote and sole power to dispose of 45,719 shares, which includes 17,714 shares of Series A non-voting convertible preferred stock, BV III KG has the sole power to vote and sole power to dispose of 127,881 shares, which includes 49,548 shares of Series A non-voting convertible preferred stock, and AM LLC has the sole power to vote and sole power to dispose of 29,964 shares, which includes 11,584 shares of Series A non-voting convertible preferred stock. BV III GP and BV III LLC each have shared power to vote and shared power to dispose of 1,792,045 shares. 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. Dr. Evnin and Messrs. Gadicke, Galakatos, Steinmetz, Wheeler, Simon and Henner each have shared power to vote and shared power to dispose of 1,822,009 shares. Dr. Evnin and Messrs. Gadicke, Galakatos, Steinmetz, Wheeler, Simon and Henner are each a member of BV III LLC and a manager of AM LLC, and each disclaims beneficial ownership of all such shares except to the extent of his proportionate pecuniary interests therein. Dr. Evnin is a member of our Board of Directors and has sole voting and dispositive power of 5,641 shares.
  - (5) Consists of information supplied to us or filed with the SEC by Aberdare Ventures II, L.P. (Aberdare II), Aberdare Ventures II (Bermuda), L.P. (Aberdare Bermuda), Aberdare II Annex Fund, L.P. (Aberdare II Annex), Aberdare GP II, L.L.C. (Aberdare GP II) and Paul H. Klingenstein. Mr. Klingenstein serves as Manager of Aberdare GP II, which serves as the general partner of Aberdare II, which holds 238,566 shares, Aberdare II Bermuda, which holds 4,951 shares, and Aberdare II Annex, which holds 796,343 shares, which includes 406,504 shares of Series A non-voting convertible preferred stock, and has voting and investment control of 1,039,860 shares owned, and may be deemed to own beneficially such shares. Mr. Klingenstein has sole voting and dispositive power of 31,848 shares, which includes 16,525 shares of Series A non-voting convertible preferred stock. Mr. Klingenstein is a member of our Board of Directors.
  - (6) Consists of information supplied to us or filed with the SEC by T. Rowe Price Associates, Inc. (Price Associates). These securities are owned by various individual and institutional investors including T. Rowe Health Sciences Fund, Inc. (which beneficially owns 420,834 shares and 166,666 warrants exercisable within 60 days of October 31, 2010, representing 5.3% beneficial ownership), which Price

## Table of Contents

Associates serves as investment adviser with power to direct investments and/or sole power to vote the securities. For purposes of the reporting requirements of the Securities Exchange Act of 1934, as amended, Price Associates is deemed to be a beneficial owner of such securities; however, Price Associates expressly disclaims that it is, in fact, the beneficial owner of such securities.

- (7) Excludes warrants issued pursuant to security purchase agreements dated September 29, 2010, that are exercisable at any time and from time to time beginning on the date that is no earlier than six months and one day after the closing of the private placement and ending five years after the closing of the private placement as follows: Bay City Capital, 1,626,016 shares; MPM Capital, 704,607 shares; Aberdare Ventures, 406,504 shares; Dr. Evinin, 704,607 shares; Dr. Goldfischer, 1,626,016 shares; Dr. Harrison, 216,802 shares; Mr. Klingenstein, 423,029 shares; and Mr. Teti, 10,840 shares.
- (8) Includes 776,359 shares of common stock issuable upon exercise of options and warrants currently exercisable or exercisable within 60 days of October 31, 2010, inclusive of the options and warrants exercisable as described in footnotes (1) and (2), respectively.
- (9) Reflects the beneficial ownership of the following shares purchased in this offering: Bay City Capital, 1,700,000 shares; T. Rowe Price, 1,700,000 shares; Dr. Knudson, 25,000 shares; and Mr. Lea, 10,000 shares.

## RELATED PARTY TRANSACTIONS

In addition to the related party transactions that are disclosed in our Definitive Proxy Statement on Schedule 14A, which was filed with the SEC on April 6, 2010 and is incorporated by reference into this prospectus, we have entered into the following related party transactions.

On September 29, 2010, we entered into binding Securities Purchase Agreements (each, a Securities Purchase Agreement) for the sale of 3,394,309 shares of our Series A Non-Voting Convertible Preferred Stock (the convertible preferred stock), together with warrants to purchase an aggregate of 3,394,309 shares of our common stock (the Up Front Warrants), in a private placement transaction with several accredited investors, including several of our directors and principal stockholders (the September 2010 Private Placement). The purchase price per share of convertible preferred stock was \$1.72 (the Original Purchase Price), which equaled the consolidated closing bid price of our common stock as reported by the NASDAQ Stock Market on September 29, 2010. The Up Front Warrants have an exercise price of \$2.15 per share, which equals 125% of the consolidated closing bid price of our common stock as reported by the NASDAQ Stock Market on September 29, 2010. The Up Front Warrants will become exercisable upon the later to occur of the following: (i) the date that is six months and one day after the issuance of the warrants, or (ii) the closing of an offering by the company of equity securities producing gross proceeds of at least \$15.0 million excluding proceeds from the sale of convertible preferred stock (an Equity Offering) and expire on the fifth anniversary of the date on which the warrants became exercisable. If the convertible preferred stock converts into common stock upon completion of an Equity Offering in accordance with the terms of the Certificate of Designations for the convertible preferred stock, each investor will purchase additional warrants from us (the Conversion Warrants) to purchase that number of shares of common stock equal to (i) the difference between the Original Purchase Price and the price per share of common stock underlying the equity securities paid by investors in an Equity Offering (the Equity Offering Purchase Price), *multiplied by* the number of shares of convertible preferred stock purchased by the investor, *divided by* (ii) the Conversion Warrant exercise price per share, which will equal \$2.06 (120% of the Original Purchase Price). The Conversion Warrants will only be issued if we complete the Equity Offering and the Original Purchase Price is more than the Equity Offering Purchase Price. The purchase price for each warrant issued pursuant to the Securities Purchase Agreements equals \$0.125 per share of common stock underlying the warrant. On September 30, 2010, we completed the final closing of the September 2010 Private Placement.

The following directors and principal stockholders, each purchased shares of convertible preferred stock and warrants in our September 2010 Private Placement. The convertible preferred shares and warrants purchased, together with the proceeds, before expenses to us, are shown in the table below:

<u>Beneficial Owner</u>	<u>Shares of Convertible Preferred Stock Purchased</u>	<u>Up Front Warrants Purchased</u>	<u>Net Proceeds, Before Expenses to the Company</u>
MPM Capital	704,607	704,607	\$ 1,300,000
Bay City Capital	1,626,016	1,626,016	\$ 3,000,000
Aberdare Ventures	406,504	406,504	\$ 750,000
Charter Life Sciences	216,802	216,802	\$ 400,000
Paul H. Klingenstein	16,525	16,525	\$ 30,488
Nicholas L. Teti, Jr.	10,840	10,840	\$ 20,000

Luke Evnin, Ph.D. is one of our directors and is a member of MPM BioVentures III LLC and a manager of MPM Asset Management Investors 2002 BVIII LLC. Carl Goldfischer, M.D. is one of our directors and is a managing director of Bay City Capital LLC. Paul H. Klingenstein is one of our directors and is a managing partner of the Aberdare Funds. Donald C. Harrison, M.D. is one of our directors and is a managing partner of Charter Life Sciences, L.P. Nicholas L. Teti, Jr. is one of our directors and serves as a consultant to the company.

## DESCRIPTION OF SECURITIES

### General

The following description of our securities is intended as a summary only and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus forms a part, and to the applicable provisions of the Delaware General Corporation Law. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

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, of which 3,600,000 have been designated as Series A Non-Voting Convertible Preferred Stock (the convertible preferred stock). As of October 31, 2010, we had outstanding 7,478,079 shares of common stock and 3,394,309 shares of convertible preferred stock. All shares of the convertible preferred stock outstanding will convert to common stock upon the closing of this offering. As of October 31, 2010, we also had an aggregate of 812,515 shares of common stock reserved for issuance upon exercise of outstanding stock options granted under our 2003 Stock Incentive Plan, and an aggregate of 4,903,728 shares of common stock reserved for issuance upon the exercise of outstanding common stock warrants.

### Common Stock

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 outstanding or 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, and the shares to be issued by us upon exercise of the warrants to be issued in this offering in accordance with the terms of the warrants, will be when issued and paid for, validly issued, fully paid and nonassessable.

### Preferred Stock

The following description of our convertible preferred stock is intended as a summary only and is qualified in its entirety by reference to our certificate of designations for the convertible preferred stock, which is filed as an exhibit to the registration statement of which this prospectus forms a part.

The holders of our convertible preferred stock generally do not have any voting rights except as may be required by law. However, so long as 10% of the shares of convertible preferred stock are outstanding, in addition to any other vote or approval required under our certificate of incorporation or bylaws, the Company will not, without the written consent of the holders of at least 75% of the convertible preferred stock, either directly or by amendment, merger, consolidation, or otherwise: (i) create or authorize the creation of or issue any other security convertible into or exercisable for any equity security, having rights, preferences or privileges senior to or on parity with the convertible preferred stock, or increase the authorized number of shares of



## [Table of Contents](#)

convertible preferred stock; or (ii) purchase or redeem or pay any dividend on any capital stock prior to the convertible preferred stock, other than stock repurchased from former employees or consultants in connection with the cessation of their employment/services, at the lower of fair market value or cost; other than as approved by the board of directors.

Dividends will be paid on the convertible preferred stock on an as-converted basis when, as, and if paid on our common stock.

In the event of any liquidation, dissolution or winding up of the Company, any distributions to holders of our outstanding equity shall be made as follows: first, to the holder of any share of convertible preferred stock up to 150% of the Original Purchase Price (as defined in the certificate of designations) plus declared and unpaid dividends on each share of convertible preferred stock, and then pro rata to the holders of the common stock and convertible preferred stock on an as converted basis.

The convertible preferred stock may be converted on a 1:1 basis into shares of common stock at any time at the option of the holder, subject to adjustments for stock dividends, splits, combinations and similar events; provided, however, that no holder will be permitted to convert an amount of convertible preferred stock that would result in such holder owning more than 19.99% of our outstanding common stock upon conversion.

Each share of convertible preferred stock will automatically be converted on a 1:1 basis into shares of common stock (subject to adjustments for stock dividends, splits, combinations and similar events): (i) immediately after the closing of an offering by us of equity securities producing gross proceeds of at least \$15.0 million excluding proceeds from the sale of convertible preferred stock (an Equity Offering), or (ii) upon the written consent of the holders of 75% of the convertible preferred stock; provided, however, that in the case of (i) and (ii) above, no holder will be permitted to convert an amount of convertible preferred stock that would result in such holder owning more than 19.99% of our outstanding common stock upon conversion.

## **Warrants**

### ***Warrants Sold in this Offering***

Each share of common stock is being sold together with one warrant exercisable for one share of common stock at an exercise price of \$2.19 per share (125% of the aggregate offering price for a share of common stock and corresponding warrant). The shares of common stock and warrants are immediately separable after purchase and will be issued separately. The warrants are exercisable beginning 181 days after the closing date of this offering and ending on the fifth anniversary of the date on which the exercise period begins. The warrants do not allow for cashless exercise.

The warrants are non-transferable and will not be listed on the NASDAQ Capital Market or any other securities exchange. Therefore, the warrant holders will have to hold the warrants they purchase in this offering, until such time, if any, as they wish to exercise 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 are not required to issue fractional shares upon the exercise of the warrants. Instead, we may choose to purchase the fraction for an amount in cash equal to the current value of the fraction computed on the basis of the closing market price of a share of our common stock on the NASDAQ Capital Market on the trading day immediately preceding the exercise date of the warrant.

## Table of Contents

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.

### ***Warrants Issued to the Underwriter***

We have also agreed to issue the underwriter warrants to purchase a number of shares of common stock equal to 2.0% of the number of shares of common stock sold in this offering. The terms of these warrants are the same as the terms described above for the warrants sold in the offering, except that the end of the exercise period of the underwriter's warrants will be five years from the date of effectiveness of the registration statement relating to this offering rather than five years from the date on which the warrants first become exercisable to comply with FINRA requirements and the underwriter's warrants will be issued in a private placement transaction exempt from registration in reliance on Section 4(2) of the Securities Act. We have agreed to register the shares underlying these warrants as described below under "Registration Rights" and in "Underwriting" beginning on page 91 of this prospectus.

### ***Warrants Outstanding***

As of October 31, 2010, we had the following warrants outstanding:

- Warrants to purchase 41,605 shares of our common stock at exercise prices ranging from \$2.76 to \$23.68, issued in connection with bridge loan financing arrangements in late 2003 through 2005. These warrants expire between November 2010 and June 2011. These warrants contain a cashless exercise feature, which allows the warrant holder to pay the exercise price of the warrant by forfeiting a portion of the exercised warrant shares with a value equal to the aggregate exercise price. The holders of these warrants also have the right to require us to register the shares issuable upon exercise of the warrants under the Securities Act under the certain circumstances pursuant to the Investors Rights Agreement described in more detail below under the heading "Registration Rights—Investors Rights Agreement."
- Warrants to purchase 24,605 shares of common stock at an exercise price of \$48.56, issued on July 6, 2006 in connection with our Series C Preferred Stock financing. This warrant expires on July 6, 2013. These warrants contain a cashless exercise feature, which allows the warrant holder to pay the exercise price of the warrant by forfeiting a portion of the exercised warrant shares with a value equal to the aggregate exercise price.
- Warrants to purchase 22,650 shares of common stock at an exercise price of \$48.56, issued to fund our capital growth. These warrants expire on August 31, 2014. These warrants contain a cashless exercise feature, which allows the warrant holder to pay the exercise price of the warrant by forfeiting a portion of the exercised warrant shares with a value equal to the aggregate exercise price.
- Warrants to purchase 1,128,892 shares of common stock at an exercise price of \$8.28, issued in a private placement transaction on February 24, 2009. These warrants expire on February 24, 2013. These warrants do not contain a cashless exercise feature.
- Warrants to purchase 3,394,309 shares of common stock at an exercise price of \$2.15, issued in a private placement transaction on September 30, 2010. These warrants become exercisable on the later to occur of: (i) March 29, 2011 or (ii) the closing of an Equity Offering (defined above) and expire on the fifth anniversary of the date on which the warrants become exercisable. These warrants do not contain a cashless exercise feature. Pursuant to the terms of the Securities Purchase Agreement described in more detail below, following the completion of an Equity Offering, we have agreed to register for resale the common stock issuable upon the exercise of these warrants.

## Table of Contents

- Warrants to purchase 141,025 shares of common stock at an exercise price of \$3.90, issued in connection with a loan agreement in November 2008 and April 2009. These warrants expire between November 2018 and April 2019. The exercise price of the warrants contained down round protection provisions that expired on May 18, 2010. These warrants contain a cashless exercise feature, which allows the warrant holder to pay the exercise price of the warrant by forfeiting a portion of the exercised warrant shares with a value equal to the aggregate exercise price.
- Warrants to purchase 150,642 shares of common stock at an exercise price of \$2.10, issued in connection with an amendment to a loan agreement on July 8, 2010. These warrants expire on July 8, 2020. These warrants contain a cashless exercise feature, which allows the warrant holder to pay the exercise price of the warrant by forfeiting a portion of the exercised warrant shares with a value equal to the aggregate exercise price.

### **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 certain circumstances pursuant to an Amended and Restated Investor Rights Agreement dated July 6, 2006 (the Investor Rights Agreement). In addition, in connection with a private placement we completed in September 2010 (described under the section “Related Party Transactions”), we have agreed to register the common stock issued upon conversion of the convertible preferred stock and issuable upon the exercise of certain warrants following the completion of an Equity Offering pursuant to the terms of the Securities Purchase Agreement dated September 29, 2010 (the Securities Purchase Agreement). We have also agreed to register the shares underlying the warrants issued to the underwriter in connection with this offering. See “Underwriting.” After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. The following descriptions of the terms and registration rights provisions of the Investor Rights Agreement and the Securities Purchase Agreement are intended as a summary only and are qualified in their entirety by reference to the Investor Rights Agreement and the Securities Purchase Agreement which are filed as exhibits to the registration statement of which this prospectus forms a part.

#### ***Investor Rights Agreement***

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

***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

## [Table of Contents](#)

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.

### ***Registration Rights with Respect to September 2010 Private Placement***

Pursuant to the Securities Purchase Agreement, we agreed to file a registration statement with the SEC within 45 days following completion of an Equity Offering (the Required Filing Date), registering for resale the shares of common stock issued upon conversion of the convertible preferred stock and issuable upon the exercise of the warrants purchased by the investors in this private placement for an offering to be made on a continuous basis pursuant to Rule 415 promulgated by the SEC pursuant to the Securities Act. This offering will qualify as an Equity Offering under the Securities Purchase Agreement. We also agreed to use our best efforts, subject to receipt of necessary information from the investors, to cause the registration statement to become effective as soon as practicable after the registration statement is filed by us, but in any event no later than 4:00 p.m. Eastern Time on the 90th day after the Required Filing Date, or if the registration statement is reviewed by the SEC, on the 135th day after the Required Filing Date. We have agreed to maintain the registration statement's effectiveness until the earlier of (i) the first anniversary of the closing date of this private placement (such period of time to be extended by any period of time that the shares are not listed for trading on the NASDAQ Stock Market), (ii) the date on which the registrable securities may be sold pursuant to Rule 144 without limitations on volume or manner of sales or (iii) such time as all registrable securities purchased by such investor in this private placement have been sold pursuant to a registration statement or Rule 144.

### **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 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

## Table of Contents

- at or after the time the stockholder became interested, the business combination was approved by the board and authorized at a stockholder meeting by the affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

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

## [Table of Contents](#)

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

### **Liability Limitations and Indemnification**

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

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

### **The NASDAQ Capital Market Listing**

Our common stock is listed on the NASDAQ Capital Market under the trading symbol "ETRM."

### **Transfer Agent and Registrar**

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

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES

The following is a discussion of the material U.S. federal income tax consequences applicable to the purchase, ownership and disposition of shares of common stock and warrants and the exercise and expiration of the warrants. This discussion applies only to holders who hold the common stock and warrants as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the Code).

This discussion does not address any federal estate or gift tax consequences, the Medicare tax on net investment income, or any state, local or foreign income or other tax consequences. In addition, this discussion does not describe all of the tax consequences that may be relevant to holders in light of their particular circumstances or to holders subject to special tax rules, such as:

- dealers in securities or currencies;
- traders in securities;
- financial institutions or insurance companies;
- persons holding stock or warrants as part of a hedge, straddle, conversion or other “synthetic security” or integrated transaction;
- U.S. holders whose functional currency is not the U.S. dollar;
- real estate investment trusts;
- regulated investment companies;
- certain U.S. expatriates;
- entities that are tax-exempt for U.S. federal income tax purposes;
- persons subject to the alternative minimum tax; and
- partnerships and other pass-through entities.

If a partnership or other entity treated as a partnership for U.S. federal income tax purposes holds the common stock and warrants, the tax treatment of a partner will generally depend on the status of the partner and on the activities of the partnership. We encourage partners of partnerships holding common stock and warrants to consult their tax advisors.

This discussion is based on U.S. federal income tax law, including the provisions of the Code, Treasury regulations, administrative rulings and judicial authority, all as in effect as of the date of this document. Subsequent developments in U.S. federal income tax law, including changes in law or differing interpretations, which may be applied retroactively, could have a material effect on the U.S. federal income tax consequences of purchasing, owning and disposing of the stock and warrants and the exercise or expiration of the warrants as described in this discussion.

We have not sought, and do not intend to seek, any rulings from the Internal Revenue Service (the IRS) with respect to the tax consequences of the purchase, ownership or disposition of the common stock and warrants and the exercise or expiration of the warrants. This discussion is not binding on the IRS, and the IRS is not precluded from taking a position that is different from, and contrary to, the positions taken in this discussion.

**We encourage you to consult your own tax advisor regarding the particular U.S. federal, state, local and foreign income and other tax consequences of purchasing, owning and disposing of the common stock and warrants and the exercise or expiration of the warrants that may be applicable to you.**

## **U.S. Holders**

The following is a summary of the material U.S. federal income tax consequences that will apply to a U.S. holder of shares of our common stock and warrants. You are a “U.S. holder” for purposes of this discussion if you are a beneficial owner of stock or warrants and you are for U.S. federal income tax purposes:

- a citizen or resident of the United States,
- a corporation, or other entity treated as a corporation, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia,
- an estate, the income of which is subject to U.S. federal income taxation regardless of the source of that income, or
- a trust (1) if a U.S. court is able to exercise primary supervision over the trust’s administration and one or more U.S. persons are authorized to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury regulations to be treated as a U.S. person.

### ***Common Stock***

*Distributions.* Distributions, if any, made on our common stock generally will be included in your income as ordinary dividend income to the extent of our current and accumulated earnings and profits. Distributions in excess of our current and accumulated earnings and profits will be treated as a return of capital to the extent of your adjusted tax basis in the common stock and thereafter as capital gain from the sale or exchange of such common stock. Dividends received by a corporation may be eligible for a dividends received deduction, subject to applicable limitations. Dividends received by a non-corporate U.S. holder may be eligible for reduced rates of tax if the U.S. holder meets certain holding period and other applicable requirements.

*Dispositions.* If you sell or otherwise dispose of common stock, you generally will recognize capital gain or loss equal to the difference between (1) the amount of cash and the fair market value of any property received and (2) your adjusted tax basis in the common stock. Your initial tax basis in the common stock acquired in this offering will generally equal the amount you paid for the common stock. (See “Warrants—Cash Exercise” below for a discussion of tax basis with respect to common stock received upon exercise of a warrant.) The capital gain or loss will be long-term capital gain or loss if your holding period for the common stock is more than one year at the time of the taxable disposition. The deductibility of capital losses is subject to significant limitations.

### ***Warrants***

*Dispositions.* If you sell or otherwise dispose of a warrant, you will generally recognize capital gain or loss equal to the difference between (1) the amount of cash and the fair market value of any property received and (2) your adjusted tax basis in the warrant. Your initial tax basis in the warrants acquired in this offering will generally be equal to the amount you paid for the warrant. The capital gain or loss will be long-term capital gain or loss if your holding period for the warrant is more than one year at the time of the taxable disposition. In the event a warrant lapses unexercised, you will recognize a capital loss in an amount equal to your adjusted tax basis of the warrant. Such capital loss will be a long-term capital loss if your holding period for the warrant was more than one year at the time of lapse. The deductibility of capital losses is subject to significant limitations.

*Cash Exercise.* The warrants may only be exercised for cash. Your tax basis in shares of common stock received upon exercise of a warrant for cash generally will equal the adjusted tax basis of the warrant, increased by the amount paid upon exercise of the warrant. Your holding period for shares of common stock received upon exercise of a warrant will begin on the day following the date on which the warrant is exercised.

*Constructive Distributions.* Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on exercise of a warrant, or an adjustment to the exercise price of the warrants, may be treated as a constructive distribution to you if, and to the extent that, such adjustment has the effect of



## [Table of Contents](#)

increasing your proportionate interest in the earnings and profits or assets of the Company, depending on the circumstances of the adjustment. (See “Common Stock—Distributions,” above for a more detailed discussion of the rules applicable to distributions made by the Company.) Adjustments made pursuant to a bona fide reasonable adjustment formula that have the effect of preventing dilution of the interests of the holders of the warrants, however, will generally not be considered to result in a constructive distribution.

### ***Information Reporting and Backup Withholding***

Information reporting requirements generally will apply to payments of dividends on shares of common stock or constructive dividends on warrants and to proceeds from the sale of a share of common stock or warrant, unless you are an exempt recipient such as a corporation. Backup withholding will apply to those payments if you are not otherwise exempt from withholding and you fail to make required certifications and provide your correct taxpayer identification number or you have been notified by the IRS that you have failed to report in full payments of interest and dividend income. Any amounts withheld under the backup withholding rules will be allowable as a refund or a credit against your U.S. federal income tax liability provided required information is furnished timely to the IRS.

### **Non-U.S. Holders**

The following is a summary of the material U.S. federal income tax consequences that will apply to a non-U.S. holder of shares of our common stock and warrants. The term “non-U.S. holder” means a beneficial owner of shares of our common stock and warrants that is not a U.S. holder (as defined above).

### ***Common Stock and Warrants***

*Distributions on Common Stock.* In general, any distribution we make to you with respect to our common stock that constitutes a dividend for U.S. federal income tax purposes will be subject to U.S. withholding tax at a rate of 30% of the gross amount, unless you are eligible for a reduced rate of withholding tax under an applicable income tax treaty and you provide certification of your eligibility for such reduced rate on a properly completed Form W-8BEN (or other applicable IRS form). A distribution will constitute a dividend for U.S. federal income tax purposes to the extent of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Any distribution not constituting a dividend will be treated first as reducing your adjusted tax basis in our common stock and, to the extent it exceeds your adjusted tax basis in our common stock, as gain from the sale or exchange of such shares.

If you are engaged in a trade or business in the United States, and if dividends paid to you are effectively connected with the conduct of this trade or business (and, if an income tax treaty applies, such dividend is attributable to a permanent establishment maintained by you in the United States), although exempt from the 30% withholding tax discussed in the preceding paragraph (provided you comply with the certification requirement described in the following sentence), you will generally be subject to U.S. federal income tax on a net income basis at applicable graduated U.S. federal income tax rates in the same manner as if you were a resident of the United States. You will be required to provide us with a properly executed IRS Form W-8ECI (or other applicable IRS form) to claim an exemption from the withholding tax. A corporate non-U.S. holder receiving effectively connected dividends may also be subject to an additional “branch profits tax” imposed at a rate of 30% (or a lower treaty rate if applicable).

*Dispositions of Common Stock and Warrants.* Subject to the discussion below concerning backup withholding and the recently enacted legislation relating to foreign accounts, you generally will not be subject to U.S. federal income tax or withholding tax on the gain realized on a sale or other disposition of our common stock and warrants unless:

- the gain is effectively connected with the conduct of a trade or business by you in the United States (and, if an income tax treaty applies, such gain is attributable to a permanent establishment maintained by you in the United States),

## Table of Contents

- you are an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met; or
- the Company is or has been a “United States real property holding corporation” for U.S. federal income tax purposes during your holding period for the common stock or the warrants.

If you are an individual described in the first bullet point, you will generally be subject to tax on the net gain at regular graduated U.S. federal income tax rates. If you are a foreign corporation that is described in the first bullet point, you will be subject to tax on your net gain in the same manner as if you were a U.S. person as defined under the Code and, in addition, you may be subject to the branch profits tax at a rate of 30% of your effectively connected earnings and profits (or a lower treaty rate if applicable). If you are an individual described in the second bullet point, you will generally be subject to a flat 30% tax on the gain, which may be offset by U.S. source capital losses. The Company believes that it is not, and does not anticipate becoming, a “U.S. real property holding corporation” for U.S. federal income tax purposes.

*Constructive Distributions on Warrants.* Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on exercise of a warrant, or an adjustment to the exercise price of the warrants, may be treated as a constructive distribution to you if, and to the extent that, such adjustment has the effect of increasing your proportionate interest in the earnings and profits or assets of the Company, depending on the circumstances of the adjustment. (See “Distributions on Common Stock,” above for a more detailed discussion of the rules applicable to distributions made by the Company.) Adjustments made pursuant to a bona fide reasonable adjustment formula that have the effect of preventing dilution of the interests of the holders of the warrants, however, will generally not be considered to result in a constructive distribution. Because any constructive distribution would not give rise to any cash from which any applicable withholding tax could be satisfied, it is possible that this tax would be withheld from any amount owed to you, including, but not limited to, cash or shares of common stock otherwise due on exercise of warrants, dividends or sales proceeds subsequently paid or credited to you.

### ***Recent Legislation Relating to Foreign Accounts***

Recently enacted legislation imposes withholding taxes on certain types of payments made to “foreign financial institutions” and certain other non-U.S. entities. The legislation imposes a 30% withholding tax on dividends on, and gross proceeds from the sale or other disposition of, common stock paid to a foreign financial institution or to a foreign non-financial entity, unless (i) the foreign financial institution undertakes certain diligence and reporting obligations or (ii) the foreign non-financial entity either certifies it does not have any substantial U.S. owners or furnishes identifying information regarding each substantial U.S. owner. If the payee is a foreign financial institution, it must enter into an agreement with the U.S. Treasury requiring, among other things, that it undertake to identify accounts held by certain U.S. persons or U.S.-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to account holders whose actions prevent it from complying with these reporting and other requirements. The legislation will apply to payments made after December 31, 2012. Prospective investors should consult their tax advisors regarding this legislation.

### ***Information Reporting and Backup Withholding***

Generally, we must report to the IRS and to you the amount of dividends (or constructive dividends) paid to you and the amount of tax, if any, withheld with respect to those payments. Copies of the information returns reporting such interest payments and any withholding may also be made available to the tax authorities in the country in which you reside under the provisions of an applicable income tax treaty.

In general, you will not be subject to backup withholding with respect to payments of dividends (or constructive dividends) that we make to you provided that we do not have actual knowledge or reason to know that you are a U.S. person, as defined under the Code, and you provided us with a properly executed IRS Form W-8BEN (or other applicable IRS form) and you certify, under penalties of perjury, that you are not a U.S. person or (b) you hold your common stock and warrants through certain foreign intermediaries and satisfy the certification requirements of applicable U.S. Treasury regulations.

---

[Table of Contents](#)

In general, no information reporting or backup withholding will be required regarding the proceeds of the sale of common stock or warrants made within the U.S. or conducted through certain U.S.-related financial intermediaries, if the payor receives the statement described in the previous paragraph and does not have actual knowledge or reason to know that you are a U.S. person, as defined under the Code, or you otherwise establish an exemption.

Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against your U.S. federal income tax liability provided the required information is timely furnished to the IRS.

## UNDERWRITING

The underwriter named below has agreed to buy, subject to the terms of the purchase agreement, the number of shares of common stock and warrants to purchase up to the number of shares of common stock listed opposite its name below. The underwriter is committed to purchase and pay for all of the shares and warrants if any are purchased, other than those shares and warrants covered by the over-allotment option we describe below. The underwriting agreement also provides that if the underwriter defaults, this offering of our securities may be terminated.

<u>Underwriter</u>	<u>Number of Shares of Common Stock</u>	<u>Number of Shares of Common Stock Underlying Warrants</u>
Craig-Hallum Capital Group	14,800,000	14,800,000

The underwriter has advised us that it proposes to offer the shares of common stock to the public at \$1.74 per share and to offer each warrant to purchase a share of common stock to the public at \$0.01, for an aggregate purchase price for each share and corresponding warrant of \$1.75. Each purchaser of a share of common stock will be required to purchase a corresponding warrant to purchase 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 \$0.063 for each share and corresponding warrant. After the offering, these figures may be changed by the underwriter.

We have granted to the underwriter an option to purchase up to an additional 2,220,000 shares of common stock and warrants to purchase up to an additional 2,220,000 shares of common stock from us at the same prices to the public, and with the same aggregate underwriting discount, as set forth in the table below. The underwriter may exercise this option any time during the 30-day period after the date of this prospectus, but only to cover over-allotments, if any. To the extent the underwriter exercises the option, the underwriter will become obligated, subject to certain conditions, to purchase the shares and warrants for which it exercises the option.

The table below summarizes the underwriting discounts that we will pay to the underwriter. These amounts are shown assuming both no exercise and full exercise of the over-allotment option. In addition to the underwriting discount, we have agreed to pay up to \$140,000 of the fees and expenses of the underwriter, which may include up to \$125,000 of 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. As additional compensation, and in exchange for \$50 cash consideration, we have agreed to issue to the underwriter warrants to purchase up to a total of 2.0% of the shares of common stock sold in this offering at an exercise price of 125% of the price to the public of the aggregate price of each share and corresponding warrant sold in this offering. The underwriter's warrant, which is a warrant to purchase common stock, will be exercisable beginning 181 days after the closing date of this offering and ending on the fifth anniversary of the date of effectiveness of the registration statement relating to this offering. In addition, pursuant to Rule 5110(g) of the Financial Industry Regulatory Authority, Inc., the underwriter's warrant may not be sold during this offering, or sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the underwriter's warrant, or the shares acquirable upon exercise thereof, by any person for a period of 180 days immediately following the effective date of the registration statement relating to this offering, except as provided in paragraph (g)(2) of Rule 5110(g) of the Financial Industry Regulatory Authority, Inc. We have agreed to prepare, file and keep effective with the SEC a registration statement with respect to the shares underlying the underwriter's warrant such that the owner of shares acquired upon exercise of the underwriter's warrant may resell those shares to the public for a period of time at least equal to the term of the underwriter's warrant plus two years following the expiration date thereof. The underwriter's warrant contains the same terms as the warrants issued in this offering.

## Table of Contents

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 underwriting discount and other items of compensation the underwriter will receive were determined through arms' length negotiations between us and the underwriter.

	<u>Total with no Over-Allotment</u>	<u>Total with Over-Allotment</u>
Underwriting discount to be paid to the underwriter by us	\$ 1,554,000	\$ 1,787,100

We estimate that the total expenses of the offering, excluding underwriting discounts and commissions, will be \$360,000. This includes \$140,000 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 of 1933, 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. These "lock-up" agreements cover approximately an aggregate of 5,449,078 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. 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.

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 or by exercising the over-allotment option granted to the underwriter. 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.

## [Table of Contents](#)

### **Selling Restrictions**

#### ***European Economic Area***

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State, no offer of our common stock has been made or will be made to the public in that Relevant Member State, except that, with effect from and including such date, an offer of our common stock may be made to the public in the Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000; and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or
- in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of our common stock to the public” in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase any such shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

#### ***United Kingdom***

In the United Kingdom this document is being distributed only to, and is directed only at, Qualified Investors who are permitted to carry on regulated activity in the United Kingdom by the U.K. Financial Services Authority under the Financial Services and Markets Act 2000 (as amended), persons whose ordinary activities for the purpose of their businesses involve them in buying, selling, subscribing for or underwriting such securities or making arrangements for another person to do so (whether as principal or agent) or advising on investments or other persons who are Investment Professionals within the meaning given in paragraph 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. Persons who are not permitted to carry on such regulated activity may not rely on this document.

### **LEGAL MATTERS**

The validity of the securities offered by this prospectus will be passed on 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 by reference from our Annual Report on Form 10-K for the year ended December 31, 2009 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report thereon 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

## [Table of Contents](#)

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 have filed with the SEC a registration statement on Form S-1 under the Securities Act, as amended, with respect to the common stock and warrants offered by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock and warrants, you should refer to the registration statement and the exhibits and schedules filed with the registration statement. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

We are subject to the informational requirements of the Securities Exchange Act and file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at [www.sec.gov](http://www.sec.gov). You may also read and copy any document we file with the SEC at its Public Reference Room at 100 F Street, N.E., Washington, D.C., 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Room of the SEC at 100 F Street, N.E., Washington, D.C., 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facility.

### **INCORPORATION OF DOCUMENTS BY REFERENCE**

We have elected to incorporate by reference certain information in this prospectus in accordance with the Securities and Exchange Act of 1934. 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;
- Definitive Proxy Statements on Schedule 14A filed with the SEC on April 6, 2010 and October 1, 2010;
- Quarterly Reports on Form 10-Q filed with the SEC on May 7, 2010, August 6, 2010 and November 8, 2010; and
- Current Reports on Form 8-K filed with the SEC on January 15, 2010, January 20, 2010, January 21, 2010, February 10, 2010, February 12, 2010, February 23, 2010, March 15, 2010, March 17, 2010, April 19, 2010, May 11, 2010, May 19, 2010, June 29, 2010, July 13, 2010, August 2, 2010; October 5, 2010, October 22, 2010, October 29, 2010 and November 1, 2010.

These filings, our other annual, quarterly, and current reports, our proxy statements, and our other SEC filings may be examined, and copies may be obtained, at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference room by calling the SEC at (800) SEC-0330. Our SEC filings are also available to the public on the SEC's website at [www.sec.gov](http://www.sec.gov).

Our internet address is [www.enteromedics.com](http://www.enteromedics.com) and the investor relations section of our website is located at <http://ir.enteromedics.com>. We make available free of charge, on or through the investor relations section of our website, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information contained on our website is not part of this prospectus.

---

[Table of Contents](#)

We hereby undertake to provide without charge to each person, including any beneficial owner, to whom a prospectus is delivered, upon written or oral request of any such person, a copy of any and all of the information that has been incorporated by reference in this prospectus, but not delivered with the prospectus. Requests for such copies should be sent to us at the following address:

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





**14,800,000 Shares of Common Stock  
Warrants to Purchase 14,800,000 Shares of Common Stock**

---

**PROSPECTUS**

---

**Craig-Hallum Capital Group**

---

---