

## 5,000,000 Shares



## Common Stock

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EnteroMedics Inc. is offering 5,000,000 shares of its common stock. This is our initial public offering and no public market currently exists for our shares. The initial public offering price of our common stock is \$8.00 per share.

Our common stock has been approved for quotation on the NASDAQ Global Market under the symbol “ETRM.”

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**Investing in our common stock involves risks. See “[Risk Factors](#)” beginning on page 8 of this prospectus.**

	<u>Per Share</u>	<u>Total</u>
Initial public offering price	\$ 8.00	\$40,000,000
Underwriting discounts	\$ 0.56	\$ 2,800,000
Proceeds, before expenses, to EnteroMedics Inc.	\$ 7.44	\$37,200,000

We have granted the underwriters the right to purchase up to an additional 750,000 shares of common stock to cover over-allotments.

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 underwriters expect to deliver the shares to purchasers on November 20, 2007.

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**JPMorgan**

**Morgan Stanley**

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**Cowen and Company**

**Leerink Swann**

November 14, 2007

# The Vagus Nerve and the Digestive System



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
- Controlling sensations of hunger, satisfaction and fullness

# VBLOC™

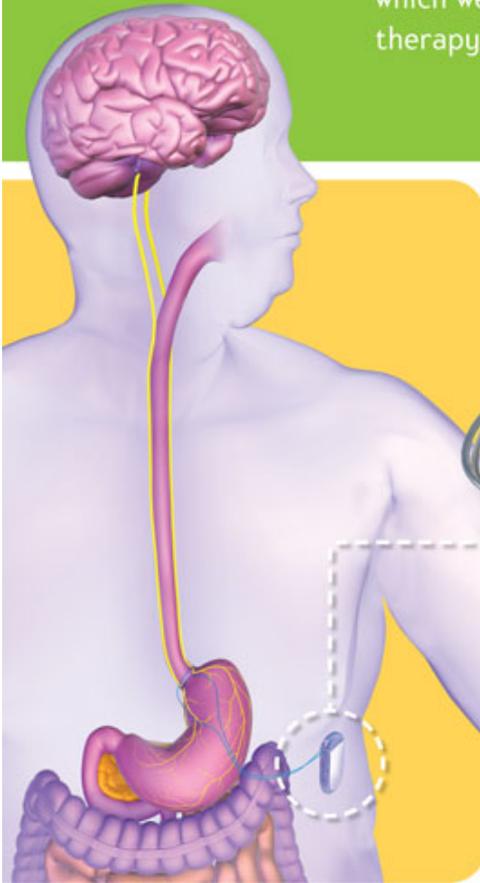
## *Therapy*

**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.



CAUTION: Investigational device. Limited by Federal law to investigational use and not for sale. The Maestro System has not been approved for sale by any regulatory authority.

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



Maestro™ System

not approved for commercial sale.

EnteroMedics™

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**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 underwriters have 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, shares of common stock 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. Our business, financial conditions, results of operations and prospects may have changed since that date.**

EnteroMedics™, Maestro™, VBLOC™ vagal blocking therapy and the EnteroMedics logo are trademarks of EnteroMedics Inc. and we have applied to register these trademarks in the United States. This prospectus contains other trade names and service marks of EnteroMedics and of other companies.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained in greater detail elsewhere in this prospectus. This summary may not contain all of the information that you should consider before investing in our common stock. You should carefully read the entire prospectus, including “Risk Factors” beginning on page 8 and the financial statements and related notes, before making an investment decision. As used in this prospectus, references to “we,” “our,” “us” and “EnteroMedics” refer to EnteroMedics Inc. and its subsidiary unless the context requires otherwise.*

### **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. 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, 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.

We are currently evaluating the Maestro System in human clinical trials conducted in Australia, Mexico, Norway and Switzerland. As of September 30, 2007, we have implanted the Maestro System in 76 subjects and have one-year clinical data on 11 subjects. To date, we have not observed any mortality or any medically serious device-related events that have required surgical attention in these subjects. Seven adverse events have been observed to date, all of which were resolved without surgical attention or permanent effects.

We recently received an investigational device exemption, or IDE, for our U.S. pivotal trial of the Maestro System, the EMPOWER trial. In the third quarter of 2007 we began to enroll and implant subjects in this 220 subject, randomized, double-blind, placebo-controlled, prospective, multi-center trial. We plan to use data from our EMPOWER trial to support our premarket approval, or PMA, application for the Maestro System, which we expect to submit in the middle of 2009. If the U.S. Food and Drug Administration, or FDA, grants us approval, we anticipate we will be able to commercialize the Maestro System in the United States in 2010. In the event that the Maestro System receives FDA approval, we expect to recruit and retain personnel responsible for commercial operations, sales and marketing, customer service, reimbursement and technical service in order to support the commercial launch of our product. Given the time required to locate and train appropriate personnel, we expect to commence that process prior to actually receiving FDA approval. We will also need to increase production volumes of our products in connection with commercialization. We rely primarily on third-party manufacturers and suppliers to produce our products and will continue to select qualified suppliers and contract manufacturers that can supply products on a commercial scale according to our proprietary specifications.

### **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 2004, the incidence of obesity had more than doubled to 32%. Currently, the Centers for Disease Control and Prevention, or CDC, estimates that there are 65 million obese adults in the United States, with approximately 42 million having a Body Mass Index, or BMI, of 30 to 35 and approximately 23 million having a BMI greater than 35. BMI is calculated by dividing a person’s weight in

kilograms by the square of their height in meters. It is estimated that by 2010, as many as 83 million Americans will suffer from obesity. Obesity is also a significant health problem outside of the United States, with as many as 400 million people worldwide estimated to be obese, according to the World Health Organization.

The CDC has identified obesity as a leading public health threat in the United States. In 2005, it was estimated that there are approximately 112,000 obesity-related deaths each year in the United States. According to data from the CDC, 76% of people with a BMI above 35 have an obesity-related disease or disorder, also called a co-morbidity. 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.

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 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 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;
- allows continued ingestion and digestion of foods found in a typical, healthy diet;
- enables non-invasive adjustability while reducing the need for frequent clinic visits;
- minimizes the risks of re-operations, malnutrition and mortality; and
- reduces the natural hunger drive of patients.

#### **EnteroMedics' Solution**

We are designing our Maestro System to meet 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 VBLOC therapy is designed to limit the expansion of the stomach and to reduce the frequency and intensity of stomach contractions by intermittently blocking, or interrupting, naturally occurring neural impulses on the vagus

nerve. In addition, we believe VBLOC therapy also reduces the absorption of calories by decreasing the secretion of digestive enzymes. We believe that the physiologic effects of VBLOC therapy produce a feeling of early and prolonged fullness following smaller meal portions and a subsequent reduction in hunger.

Our 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. The electrodes receive electrical impulses from a neuroregulator implanted under the skin in the abdominal region. The major components of the Maestro System include:

- **Neuroregulator.** The neuroregulator is an implanted device that delivers VBLOC therapy by emitting electrical pulses through the lead system.
- **Lead system.** The lead system is connected to the neuroregulator and delivers electrical pulses to the vagus nerve via the electrodes, which are implanted in contact with the vagus nerve.
- **Controller.** The controller regulates the rate and intensity of the electrical pulses delivered by the neuroregulator and maintains a log of device and treatment changes.
- **Transmit coil.** The transmit coil delivers radiofrequency energy and therapy control information across the skin into the neuroregulator.
- **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.

Our Maestro System is expected 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 in a follow-up visit approximately two weeks following implantation. VBLOC therapy is then delivered intermittently each day during the patient's waking hours.

### **Our Strategy**

Our goal is to establish VBLOC therapy, delivered via our 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 direct sales and marketing effort;
- procure appropriate coding, coverage and payment for the Maestro System;
- expand and protect our intellectual property position; and
- leverage our VBLOC technology for other disease states.

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

In order to obtain FDA approval, the results of our EMPOWER trial must show a statistically significant difference between the percentage of excess weight loss, or EWL, experienced by subjects implanted with the Maestro System and the percentage of EWL experienced by the control group. The FDA has indicated to us that they believe the appropriate efficacy endpoint for our EMPOWER trial is a 20 to 25 percentage points greater EWL between the active and control groups. The FDA's endpoint is higher than the endpoint we have established for the trial which is an average of at least 17 percentage points greater EWL between the active and control groups, with a 97.5% confidence interval of 10 to 24 percentage points of EWL. We believe the FDA's desire to see a higher percentage of EWL is based, in part, on its current assessment of the risk benefit profile associated with the Maestro System, which assessment is based on limited long-term safety data. We established

the percentage EWL target for our EMPOWER trial based on our belief that the therapeutic benefits of our VBLOC therapy will outweigh the potential risks if we are able to demonstrate a potentially favorable safety profile for the device, in addition to a statistically significant difference in the percentage EWL. In that case, we believe the FDA and its PMA advisory panel could approve our device, even if we do not achieve the percentage EWL proposed by the FDA. If our results are not sufficient to satisfy the FDA and a PMA advisory panel, however, we may not receive FDA approval, without which, we can not market or sell our Maestro System in the United States.

Our business is also subject to numerous risks discussed more fully in the section entitled “*Risk Factors*” immediately following this prospectus summary. Principal risks of our business include among others:

- We are a development stage company with a limited history of operations and no commercially 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 relevant regulatory body in any other country to market our Maestro System for the treatment of obesity and the FDA can delay, limit or deny approval of our PMA application for many reasons, including our inability to demonstrate safety or effectiveness to the FDA’s satisfaction.
- We may be unable to complete our EMPOWER 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.
- Even if we obtain regulatory approval for our Maestro System, our efforts to commercialize our product may not succeed or may encounter delays that could significantly harm our ability to generate revenue.
- 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.
- 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 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.

### The Offering

Common stock offered by us	5,000,000 shares
Common stock to be outstanding after this offering	16,309,113 shares
Over-allotment option	750,000 shares
Use of proceeds	We intend to use the net proceeds of this offering for achieving regulatory approval for our product, research and product development activities, initiating sales and marketing efforts, and other working capital and general corporate purposes. See "Use of Proceeds" for additional information.
Nasdaq Global Market symbol	ETRM

MPM Capital, Bay City Capital, Aberdare Ventures, Interwest Partners, Onset Ventures and Charter Life Sciences, which are each principal stockholders, have indicated an interest in purchasing an aggregate of approximately 1,621,250 shares of common stock in this offering. However, because these potential indications of interest are not binding agreements or commitments to purchase, any or all of these stockholders may elect not to purchase any shares in this offering, or our underwriters may elect not to sell any shares in this offering to any or all of these stockholders.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 11,309,113 shares outstanding as of September 30, 2007 and assumes the issuance by us of our shares to Mayo Foundation for Medical Education and Research. The number of outstanding shares excludes:

- 2,078,771 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2007, at a weighted average exercise price of \$3.67 per share;
- 666,244 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2007, on an as-converted basis and at a weighted average exercise price of \$4.71 per share; and
- 1,670,617 shares of common stock expected to be available for future issuance under our stock incentive plans upon completion of this offering.

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

- a 1-for-9.1 reverse split of our common stock and preferred stock effected November 8, 2007;
- the conversion of all of the outstanding shares of our preferred stock into 10,488,178 shares of common stock upon completion of this offering;
- the issuance of 206,044 shares of our common stock to Mayo Foundation for Medical Education and Research pursuant to a license agreement;
- amendments to our certificate of incorporation and bylaws to be effective upon completion of this offering; and
- no exercise by the underwriters of their 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, 2004, 2005 and 2006, except for the pro forma net loss per share and pro forma weighted average number of shares data, are derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary statement of operations data for the nine months ended September 30, 2006 and 2007, except for the pro forma net loss per share and pro forma weighted average number of shares data, the statement of operations data for the period from December 19, 2002 (inception) through September 30, 2007 and the summary balance sheet data as of September 30, 2007 have been derived from our unaudited consolidated financial statements, which are included elsewhere in 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 consolidated financial statements and related notes appearing elsewhere in this prospectus, as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the other financial information included elsewhere in this prospectus.

	Years Ended December 31,			Nine Months Ended September 30,		Period from December 19, 2002 (inception) to September 30, 2007
	2004	2005	2006	2006	2007	
	(In thousands, except per share data)					
<b>Statement of Operations Data:</b>						
Operating expenses:						
Research and development	\$ 1,755	\$ 8,833	\$ 14,361	\$ 9,933	\$ 13,894	\$ 41,196
Selling, general and administrative	1,491	2,319	3,761	2,615	5,463	13,169
Total operating expenses	<u>3,246</u>	<u>11,152</u>	<u>18,122</u>	<u>12,548</u>	<u>19,357</u>	<u>54,365</u>
Other income (expense):						
Interest income	35	110	1,136	659	1,089	2,370
Interest expense	(238)	(181)	(710)	(559)	(1,185)	(2,330)
Change in value of the convertible preferred stock warrant liability	—	—	7	—	(362)	(355)
Other, net	—	8	(1)	(18)	(14)	(7)
Net loss	<u>\$ (3,449)</u>	<u>\$ (11,215)</u>	<u>\$ (17,690)</u>	<u>\$ (12,466)</u>	<u>\$ (19,829)</u>	<u>\$ (54,687)</u>
Net loss per share – basic and diluted(1)	<u>\$ (24.36)</u>	<u>\$ (28.82)</u>	<u>\$ (34.19)</u>	<u>\$ (24.74)</u>	<u>\$ (33.01)</u>	
Weighted average number of shares used in per share calculations – basic and diluted(1)						
	<u>142</u>	<u>389</u>	<u>517</u>	<u>504</u>	<u>601</u>	
Pro forma net loss per common share (unaudited) – basic and diluted(1)						
			<u>\$ (2.20)</u>		<u>\$ (1.76)</u>	
Weighted average number of shares used in pro forma per share calculations – basic and diluted(1)						
			<u>8,043</u>		<u>11,089</u>	

- (1) Please see Note 2 to our consolidated financial statements for an explanation of the method used to calculate basic and diluted net loss per common share and the pro forma basic and diluted net loss per common share.

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	As of September 30, 2007	
	Actual	Pro Forma As Adjusted(1)
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and short-term investments	\$ 22,564	\$ 58,264
Working capital (current assets less current liabilities)	16,354	52,054
Total assets	24,658	60,358
Long-term debt, net of current portion and discounts	5,130	5,130
Convertible preferred stock	103	—
Deficit accumulated during development stage	(54,687)	(56,336)(2)
Total stockholders' equity	13,002	48,702(2)

- (1) On a pro forma as adjusted basis to give effect to the conversion of all of the outstanding shares of our preferred stock into 10,488,178 shares of our common stock upon the completion of this offering, our sale of 5,000,000 shares of common stock in this offering at the initial public offering price of \$8.00 per share, after deducting estimated underwriting discounts and commissions and offering expenses, and the application of the net proceeds from those shares.
- (2) On a pro forma as adjusted basis to give effect to the issuance of 206,044 shares of our common stock to Mayo Foundation for Medical Education and Research pursuant to a license agreement upon the completion of this offering. In connection with the issuance of these shares, we will record a one-time stock-based compensation expense of \$1.6 million, which amount has been computed using the initial public offering price of \$8.00 per share.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this prospectus before purchasing our common stock. 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 Business and Industry**

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

We are a development stage company with a limited operating history upon which you can evaluate our business. We currently do not have any products cleared or approved for commercialization or any other source of revenue, and we do not expect to have a commercialized product until at least 2010. We have been engaged in research and development since our inception in 2002 and have invested substantially all of our time and resources in developing our VBLOC therapy, which we intend to commercialize initially in the form of our Maestro System. The success of our business will depend on our ability to obtain regulatory approval to market our Maestro System and any products we may develop in the future and our ability to create product sales, successfully introduce new products, establish our sales force and control costs, all of which we may be unable to do. If we are unable to successfully develop, receive regulatory approval for and commercialize our Maestro System for its indicated use, we may never generate revenue or be profitable and we may have to cease operations. Our lack of a significant operating history also limits your ability to make a comparative evaluation of us, our products and our prospects.

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

We have incurred losses in each year since our formation in 2002. As of September 30, 2007, we had a deficit accumulated during the development stage of \$54.7 million. Our net losses applicable to common stockholders for the fiscal years ended December 31, 2004, 2005 and 2006 were \$24.36, \$28.82 and \$34.19 per share, 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. We expect our research and development expenses to increase in connection with our currently ongoing clinical trials, upcoming EMPOWER pivotal trial and trials that we may initiate in the future. We also expect our research and development expenses to increase in connection with our ongoing and future product development initiatives. In addition, if our Maestro System is approved for marketing by the U.S. Food and Drug Administration, or FDA, we expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We also expect our general and administrative expenses to increase following this offering as we implement the infrastructure to operate as a public company. For these reasons, we expect to continue to incur significant and increasing operating losses for the next several years. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with developing new medical devices, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

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

We do not have the necessary regulatory approvals to market our Maestro System in the United States or in any foreign market. We plan initially to launch our product, if approved, in the United States, but ultimately will

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also seek to commercialize our Maestro System in countries outside the United States, such as obtaining a CE Mark for marketing in the European Community.

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

- our inability to demonstrate safety or effectiveness to the FDA's satisfaction;
- the data from our preclinical studies and clinical trials may be insufficient to support approval;
- the facilities of our third-party manufacturers or suppliers may not meet applicable requirements;
- our compliance with preclinical, clinical or other regulations;
- our inability to meet the FDA's statistical requirements or changes in statistical tests or significance levels the FDA requires for approval of a medical device, including ours; and
- changes in the FDA approval policies, expectations with regard to the type or amount of scientific data required or adoption of new regulations may require additional data or additional clinical studies.

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

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

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

Our application for an investigational device exemption, or IDE, for the EMPOWER pivotal trial, a randomized, prospective, placebo-controlled multi-center trial of our Maestro System in the United States, has been approved by the FDA, allowing us to start the EMPOWER trial. In the third quarter of 2007 we began to enroll and implant subjects in the trial.

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We expect to complete enrollment in the first half of 2008. Conducting a clinical trial of this size, which involves screening, assessing, testing, treating and monitoring patients at up to 15 sites across the country, and coordinating with patients and clinical institutions, is a complex and uncertain process.

Enrollment of patients in our EMPOWER trial could be delayed for a variety of reasons, including:

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

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

- ongoing discussions with regulatory authorities regarding the scope or design of our preclinical results or clinical trial or requests for supplemental information with respect to our preclinical results or clinical trial results;
- our failure or inability to conduct the clinical trials in accordance with regulatory requirements;
- sites currently participating in the trial may drop out of the trial, which may require us to engage new sites or petition the FDA for an expansion of the number of sites that are permitted to be involved in the trial;
- patients may not enroll in, 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;
- we may be unable to obtain a sufficient supply of our Maestro System necessary for the timely conduct of the clinical trials; and
- Maestro RC requires approval of an IDE supplement by the FDA and institutional review boards, which we may not be able to secure.

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

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

We will consider our Maestro System to be effective if the EMPOWER trial demonstrates an average of at least 17 percentage points of EWL between the active and control groups at 12 months, with a 97.5% confidence interval of 10 to 24 percentage points of EWL. The FDA has indicated to us that they believe that a 20 to 25

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percentage point greater EWL than a control group is the appropriate efficacy criterion for the EMPOWER trial. Thus, there is a risk that, even if we achieve our endpoint of an average of at least 17 percentage points of EWL between the active and control groups at 12 months, with a 97.5% confidence interval of 10 to 24 points of EWL, the FDA may not approve our Maestro System. To date, we have limited clinical data regarding the efficacy of our therapy at 12 months upon which to evaluate our ability to meet either our or the FDA's proposed efficacy endpoint. Our results and our ability to obtain approval from the FDA for our Maestro System may also depend on the measurement standards we use to evaluate the excess weight loss data. In addition, there is a risk that the FDA may require us to conduct a longer clinical trial, submit additional follow-up data, or engage in other costly and time consuming activities that may delay the FDA's approval of the Maestro System. If our clinical trials fail to produce sufficient data to support a PMA application, it will take us longer to ultimately commercialize a product and generate revenue or the delay could result in our being unable to do so. Moreover, our development costs will increase if, to achieve efficient data to support PMA, we need to perform more or larger clinical trials than planned.

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

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

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

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

If our VBLOC therapy, or any other neuroblocking therapy for other gastrointestinal diseases and disorders that we may develop, does not achieve an adequate level of acceptance by the relevant constituencies, we may not generate significant product revenue and may not become profitable. The earliest we expect to be able to commercialize our Maestro System is 2010, if at all. If we are not successful in the commercialization of our Maestro System for the treatment of obesity we may never generate any revenue and may be forced to cease operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed. If the FDA determines that our promotional materials, 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, or MDR, regulations that require us to report to the FDA or governmental authorities in other countries if our products cause or contribute to a death or serious injury or malfunction in a way that would be reasonably likely to contribute to death or serious injury if the malfunction were to recur. The FDA and similar governmental authorities in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacturing. A government mandated, or voluntary, recall by us could occur as a result of component failures, manufacturing errors or design

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defects, including defects in labeling. Any recall would divert managerial and financial resources and could harm our reputation with customers. There can be no assurance that there will not be product recalls in the future or that such recalls would not have a material adverse effect on our business. Furthermore, we may later discover previously unknown problems with our products, including medically serious device related events. For example, we do not have long-term data on the safety of the Maestro System. Thus, there is a risk that long-term use of our Maestro System could cause injuries or harm, including possible damage to the vagus nerve. Any discovery of previously unknown problems with our product, including medically serious device related events, may result in restrictions on such products, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

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

We rely entirely on third parties to manufacture our Maestro System and to supply us with all of the critical components of our Maestro System, including our leads, implantable batteries, neuroregulators and controllers. We have entered into two long-term supply arrangements that are exclusive and we are in the process of solidifying additional supply agreements. If any of our existing suppliers was 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, our EMPOWER trial or commercialization of our product could be delayed. Alternatively, if we have to switch to a replacement manufacturer or replacement supplier for any of our product components, we may face additional regulatory delays, and the manufacture and delivery of our Maestro System could be interrupted for an extended period of time, which could delay completion of our clinical trials or commercialization of our Maestro System. In addition, we may be required to obtain regulatory clearance from the FDA to use different suppliers or components.

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

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

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

We do not have a sales organization and have no experience as a company in sales, marketing and distribution of our product. To generate sales we will need to develop a sales and marketing infrastructure or contract with third parties to perform that function. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. Even if we obtain approval from the FDA to market our Maestro System, we may be unable to develop an effective sales and marketing organization on a timely basis, if at all. If we develop our own sales and marketing capabilities, our sales force will be competing with the experienced and well-funded marketing and sales organizations of our more established competitors. If we are unable to establish our own sales and marketing capabilities, we will need to contract with third parties to market and sell our product. In this event, our profit margins would likely be lower than if we performed these functions ourselves. In addition, we would necessarily be relying on the skills and efforts of others for the successful marketing of our product. If we are unable to establish and maintain effective sales and marketing capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

***We may need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.***

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on research and development, including conducting clinical trials for our Maestro System. Even before we receive regulatory approval to market our Maestro System, we expect to spend significant funds commercializing the product, including development of a direct sales force. In 2006, our cash used in operations was \$16.2 million. We expect cash used in operations will increase significantly in each of the next several years, and we may need additional funds to complete the development and commercialization of our Maestro System. We believe that the estimated net proceeds from this offering of approximately \$35.70 million, or approximately \$41.28 million if the underwriters exercise their over-allotment option in full, based on the initial public offering price of \$8.00 per share after deducting underwriting discounts and commissions and estimated offering expenses, together with our cash resources and amounts available to us under a loan agreement, will be sufficient to meet our cash needs through the end of 2009. After, and possibly prior to, such time we may need to raise substantial additional capital to: continue our research and development programs; commercialize our Maestro System, if approved by the FDA; and fund our operations in general.

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

- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of regulatory approvals;
- 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;

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- the effect of competing products and market developments;
- the cost of explanting clinical devices;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- any revenue generated by sales of our future products; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

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

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

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

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

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

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

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

Our business exposes us to a risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. The medical device industry has historically been subject to extensive litigation

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over product liability claims. We may be subject to product liability claims if our Maestro System, or any other products we may sell, causes, or appears to have caused, an injury. Claims may be made by consumers, healthcare providers, third-party strategic collaborators or others selling our products.

We have \$5 million of product liability insurance, which covers the use of our Maestro System and VBLOC therapy in our clinical trials, which amount we believe is appropriate. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost and on acceptable terms for an adequate coverage amount, or otherwise to protect against potential product liability claims, we could be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our Maestro System and VBLOC therapy in the market.

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

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

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

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

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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.

### ***Provisions of federal securities laws and regulations are likely to increase our costs.***

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

### ***The financial reporting obligations of being a public company place significant demands on our management. In addition, if we are unable to satisfy regulatory requirements relating to internal control over financial reporting, or if our internal control is not effective, our business and financial results may suffer.***

Prior to the consummation of this offering, we have never operated as a public company. The obligations of being a public company, including substantial public reporting and auditing obligations, will require significant additional expenditures, place additional demands on our management and require the hiring of additional personnel. Section 404 of the Sarbanes-Oxley Act of 2002 and the SEC rules and regulations implementing such act will require us to conduct an annual evaluation of our internal control over financial reporting and auditor attestation of internal control. This process will increase our legal and financial compliance costs, and make some activities more difficult, time consuming or costly. If we fail to have an effectively designed and operating system of internal control, we may be unable to comply with the requirements of Section 404 in a timely manner. As a result of our required compliance with Section 404, we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge to ensure such compliance.

### ***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

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and expertise in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly if they pursue competing solutions through collaborative arrangements with large and established companies, such as Allergan, Cyberonics, Johnson & Johnson, Medtronic or St. Jude Medical. Our competitors may develop and patent processes or products earlier than us, obtain regulatory approvals for competing products more rapidly than we are able to and develop more effective, safer and less expensive products or technologies that would render our products non-competitive or obsolete.

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

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

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

Our commercial success depends in part on our ability to obtain protection in the United States and other countries for our Maestro System and VBLOC therapy by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. As of October 25, 2007, we owned four issued U.S. patents, two of which pertain to treating gastrointestinal disorders, 18 U.S. patent applications (including one provisional application), two international patent applications (PCT) and three national stage patent applications, including two European applications, in foreign jurisdictions. In addition, we are the exclusive licensee to four U.S. patent applications owned by Mayo Foundation for Medical Education and Research, which are unrelated to our VBLOC therapy. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. We expect to incur substantial costs in obtaining patents and, if necessary, defending our proprietary rights. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We do not know whether we will obtain the patent protection we seek, or that the protection we do obtain will be found valid and enforceable if challenged. If we fail to obtain adequate protection of our intellectual property, or if any protection we obtain is reduced or eliminated, others could use our intellectual property without compensating us, resulting in harm to our business. We may also determine that it is in our best interests to voluntarily challenge a third party's products or patents in litigation or administrative proceedings, including patent interferences or re-examinations. In the event that we seek to enforce any of our owned or exclusively licensed patents against an infringing party, it is likely that the party defending the claim will seek to invalidate the patents we assert, which, if successful could result in the loss of the entire patent or the relevant portion of our patent, which would not be limited to any particular party. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and could divert the attention of our management and key personnel from our 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

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

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

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

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

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

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

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

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

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

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

## Risks Relating to This Offering and Ownership of Our Common Stock

*Because there has not been a public market for our common stock and our stock price may be volatile, you may not be able to resell your shares at or above the initial offering price.*

Prior to this offering, you could not buy or sell our common stock publicly. An active trading market for our common stock may not develop after completion of this offering or, if developed, may not be sustained. The price of the common stock sold in this offering will not necessarily reflect the market price of our common stock after this offering. The market for medical device stocks has been volatile. The following factors, most of which are outside of our control, could cause the market price of our common stock to decrease significantly from the price you pay in this offering:

- the denial or delay of regulatory clearances or approvals of our product or receipt of regulatory approval of competing products;
- 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 clearance, to achieve market success;
- the performance of third-party contract manufacturers and component suppliers;
- our ability to develop sales and marketing capabilities;
- actual or anticipated variations in our results of operations or those of our competitors;
- announcements of new products, technological innovations or product advancements by us or our competitors;
- developments with respect to patents and other intellectual property rights;
- sales of common stock or other securities by us or our stockholders in the future;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- trading volume of our common stock;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;
- 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.

In the past, securities class action litigation often has been initiated against a company following a period of volatility in the market price of the company's securities. If class action litigation is initiated against us, we may incur substantial costs and our management's attention may be diverted from our operations. All of these factors could cause the market price of our stock to decline, and you may lose some or all of your investment.

***If we do not achieve our projected business goals in the time frames we announce and expect, our stock price may decline.***

From time to time, we estimate and publicly announce, including in this prospectus, the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals. These statements, which are forward-looking statements, include our estimates regarding enrolling patients in our clinical trials, when we will complete our EMPOWER trial or our other clinical trials, when we will submit requests for and obtain FDA approval for our product and when we will begin to receive revenue. These estimates are and must necessarily be based on a variety of assumptions. The timing of the actual achievement of these milestones may vary dramatically compared to our estimates, in some cases for reasons beyond our control. Our failure to meet any publicly-announced goals may be perceived negatively by the public markets and, as a result, our stock price may decline. Please refer to our discussion under the caption “Special Note Regarding Forward-Looking Statements.”

***If equity research analysts do not publish research or reports about our business, or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline.***

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our common stock after the completion of this offering, and such lack of research coverage may adversely affect the market price of our common stock. The price of our stock could decline if one or more equity research analysts downgrade our stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

***Future sales of our common stock by existing stockholders could cause our stock price to decline.***

If our existing stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that our stockholders might sell shares of common stock could also depress the market price of our common stock. Substantially all of our existing stockholders prior to this offering are subject to lock-up agreements with the underwriters that restrict their ability to transfer their stock for at least 180 days after the date of this prospectus, with an extension in limited circumstances. Upon expiration of the lock-up agreements, 11,103,069 shares of our common stock will be eligible for sale in the public market pursuant to Rule 144 or Rule 701, and the volume, manner of sale and other limitations under those rules. The market price of our common stock may drop significantly when the restrictions on resale of these shares lapse and our existing stockholders are able to sell shares of our common stock into the market.

Following the offering, we also intend to increase the number of our registered shares of common stock by filing registration statements with the SEC covering all of the shares of our common stock subject to options outstanding, but not exercised, at the close of the offering and all of the shares available for future issuance under our stock incentive plan. In addition, upon completion of this offering, the holders of our preferred stock, including shares issuable upon exercise of outstanding warrants to purchase common stock and preferred stock, will hold an aggregate of 10,997,940 shares of common stock with rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to include in a company-initiated registration statement shares held by those holders pursuant to the exercise of their registration rights, the sale of those shares could impair our ability to raise needed capital by depressing the price at which we could sell our common stock.

A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities, and may cause you to lose part or all of your investment.

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***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, for achieving regulatory approval of our product, for initiating sales and marketing efforts, for research and 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.

***Our directors and executive officers will continue to have substantial control over us after this offering and could limit your ability to influence the outcome of key transactions, including changes of control.***

We anticipate that our executive officers and directors and entities affiliated with them will, in the aggregate, beneficially own 59.8% of our outstanding common stock following the completion of this offering, assuming the underwriters do not exercise their over-allotment option. Our executive officers, directors and affiliated entities, if acting together, would be able to control or influence significantly all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other significant corporate transactions. These stockholders may have interests that differ from yours, and they may vote in a way with which you disagree and that may be adverse to your interests. 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.

MPM Capital, Bay City Capital, Aberdare Ventures, InterWest Partners, Onset Ventures and Charter Life Sciences, which are each principal stockholders, have indicated an interest in purchasing an aggregate of approximately 1,621,250 shares of our common stock in this offering. The purchase of shares by these affiliated entities in the offering will reduce the public float and may adversely affect the liquidity of the trading market for our common stock from what it would have been had these shares been purchased by unaffiliated investors. However, because these potential indications of interest are not binding agreements or commitments to purchase, any or all of these stockholders may elect not to purchase any shares in this offering, or our underwriters may elect not to sell any shares in this offering to any or all of these stockholders. Assuming these purchases are completed in full, our executive officers and directors and their affiliates will together control approximately 68.8% of our outstanding common stock after this offering, based on 16,309,113 shares of common stock outstanding after this offering.

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

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

- our board of directors will be authorized, without prior stockholder approval, to create and issue preferred stock which could be used to implement anti-takeover devices;
- advance notice will be required for director nominations or for proposals that can be acted upon at stockholder meetings;
- our board of directors will be classified such that not all members of our board are elected at one time, which may make it more difficult for a person who acquires control of a majority of our outstanding voting stock to replace all or a majority of our directors;

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- stockholder action by written consent will be prohibited;
- special meetings of the stockholders will be permitted to be called only by the chairman of our board of directors or by a majority of our board of directors; and
- stockholders will not be permitted to accumulate their votes for the election of directors; and stockholders will be permitted to amend our bylaws only upon receiving a majority of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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

***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 shares of our common stock in this offering, you will experience immediate dilution of \$5.01 per share based on the initial public offering price 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. This dilution is due in large part to the fact that our earlier investors paid substantially less than the price of the shares being sold in this offering when they purchased their shares of our capital stock. If outstanding options to purchase our common stock are exercised, you will experience additional dilution. See the section entitled “Dilution” in this prospectus for a more detailed description of this dilution.

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

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

## **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, 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 5,000,000 shares of common stock in this offering will be approximately \$35.70 million, or approximately \$41.28 million if the underwriters exercise their over-allotment option in full, based on the initial public offering price of \$8.00 per share and after deducting the estimated underwriting discounts and commissions and offering expenses payable by us.

We currently expect to use our net proceeds from this offering as follows:

- approximately \$20.0 million for achieving regulatory approval of our product;
- approximately \$10.0 million for research and product development activities;
- approximately \$5.0 million for initiating sales and marketing efforts; and
- the remainder for working capital and other general corporate purposes.

This expected use of net proceeds of this offering represents our current intentions based upon our present plans and business conditions. The amounts we actually expend in these areas may vary significantly from our current intentions and will depend upon a number of factors, including FDA approval for our product, future sales growth, success of research and product development efforts, cash generated from future operations and actual expenses to operate our business.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. 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 approval for our products, future sales growth, success of research and product development efforts, 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.

## DIVIDEND POLICY

We have never declared or paid any cash dividends on our common stock and do not anticipate paying cash dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the development and expansion of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon our financial condition and operating results.

## CAPITALIZATION

The following table describes our capitalization as of September 30, 2007 on an actual basis and on a pro forma as adjusted basis to reflect:

- the conversion of all of the outstanding shares of our preferred stock into 10,488,178 shares of common stock upon completion of this offering;
- the conversion of all outstanding preferred stock warrants to common stock warrants;
- the issuance upon the completion of this offering of 206,044 shares of our common stock to Mayo Foundation for Medical Education and Research pursuant to a license;
- the filing of amendments to our certificate of incorporation effective upon completion of this offering; and
- our sale of 5,000,000 shares of common stock in this offering at the initial public offering price of \$8.00 per share, after deducting estimated underwriting discounts and commissions and offering expenses.

You should read this capitalization table together with the financial statements and related notes appearing elsewhere in this prospectus, as well as “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the other financial information included elsewhere in this prospectus.

	<u>As of September 30, 2007</u>	
	<u>Actual</u>	<u>Pro Forma as Adjusted</u>
	(In thousands, except share and per share data)	
<b>Current liabilities</b>	<b>\$ 6,526</b>	<b>\$ 6,526</b>
Notes payable, less current portion and discounts	5,130	5,130
Total liabilities	<u>11,656</u>	<u>11,656</u>
<b>Stockholders’ equity:</b>		
Series C convertible preferred stock, \$0.01 par value: 6,043,957 shares authorized, actual; 5,709,630 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma as adjusted	57	—
Series B convertible preferred stock, \$0.01 par value: 4,515,285 shares authorized, actual; 4,285,946 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma as adjusted	43	—
Series A convertible preferred stock, \$0.01 par value: 318,270 shares authorized, actual; 318,266 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma as adjusted	3	—
Preferred stock, \$0.01 par value: no shares authorized, issued or outstanding, actual; 5,000,000 shares authorized and no shares issued and outstanding, pro forma as adjusted	—	—
Common stock, \$0.01 par value: 14,505,945 shares authorized, actual; 614,891 shares issued and outstanding, actual; 50,000,000 shares authorized and 16,309,113 shares issued and outstanding, pro forma as adjusted	6	163
Additional paid-in capital	67,628	104,923
Deferred compensation	(48)	(48)
Deficit accumulated during development stage	(54,687)	(56,336)(1)
Total stockholders’ equity	<u>13,002</u>	<u>48,702</u>
Total liabilities and stockholders’ equity	<u>\$ 24,658</u>	<u>\$ 60,358</u>

(1) On a pro forma as adjusted basis to give effect to the issuance of 206,044 shares of our common stock to Mayo Foundation for Medical Education and Research pursuant to a license agreement upon the completion

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of this offering. In connection with the issuance of these shares, we will record a one-time stock-based compensation expense of \$1.6 million, which amount has been computed using the initial public offering price.

The preceding table excludes:

- 2,078,771 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2007, at a weighted average exercise price of \$3.67 per share;
- 666,244 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2007, on an as-converted basis and at a weighted average exercise price of \$4.71 per share; and
- 1,670,617 shares of common stock expected to be available for future issuance under our stock incentive plans upon completion of this offering.

All share amounts have been adjusted retroactively to give effect to a 1-for-9.1 reverse split of our common stock and preferred stock effected November 8, 2007.

## DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering. Our historical net tangible book value as of September 30, 2007 was \$13.0 million, or \$21.15 per share of common stock. Net tangible book value per share is determined by dividing our total tangible assets less our total liabilities by the number of shares of common stock outstanding. The pro forma net tangible book value of our common stock as of September 30, 2007 was approximately \$13.0 million, or approximately \$1.15 per share based on the number of shares outstanding as of September 30, 2007 after giving effect to the conversion of all outstanding preferred stock into common stock and the issuance of 206,044 shares of common stock to the Mayo Foundation for Medical Education and Research upon closing of this offering.

After giving effect to our sale of 5,000,000 shares of common stock at the initial public offering price of \$8.00 per share and after deducting estimated underwriting discounts and commissions and offering expenses, our pro forma as adjusted net tangible book value as of September 30, 2007 would have been \$48.7 million, or \$2.99 per share. This amount represents an immediate increase in net tangible book value to our existing stockholders of \$1.84 per share and an immediate dilution to new investors of \$5.01 per share. The following table illustrates this per share dilution:

The initial public offering price per share		\$8.00
Historical net tangible book value per share as of September 30, 2007		\$ 21.15
Pro forma decrease in net tangible book value per share attributable to conversion of convertible preferred stock and issuance of shares to the Mayo Foundation		(20.00)
Pro forma net tangible book value per share before this offering		1.15
Pro forma increase in net tangible book value per share attributable to investors participating in this offering		<u>\$ 1.84</u>
Pro forma as adjusted net tangible book value per share after this offering		2.99
Pro forma dilution per share to investors participating in this offering		<u><u>\$5.01</u></u>

If the underwriters exercise their over-allotment option to purchase additional shares in this offering, our pro forma as adjusted net tangible book value at September 30, 2007 would be \$54.3 million, or \$3.18 per share, representing an immediate increase in pro forma as adjusted net tangible book value to our existing stockholders of \$2.03 per share and an immediate dilution to investors participating in this offering of \$4.82 per share.

The following table summarizes as of September 30, 2007, on a pro forma as adjusted basis, the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by our existing stockholders and by investors participating in this offering, based upon the initial public offering price of \$8.00 per share and before deducting estimated underwriting discounts and commissions and offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	11,309,113	69.3%	\$ 65,217,063	62.0%	\$ 5.77
Investors participating in this offering	5,000,000	30.7	40,000,000	38.0	8.00
<b>Total</b>	<u>16,309,113</u>	<u>100%</u>	<u>\$105,217,063</u>	<u>100%</u>	<u>\$ 6.45</u>

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The above discussion and tables also assume no exercise of any outstanding stock options or warrants except as set forth above. There were:

- 2,078,771 shares of common stock issuable upon the exercise of outstanding options as of September 30, 2007 with a weighted average exercise price of \$3.67 per share;
- 666,244 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2007 with a weighted average exercise price of \$4.71 per share; and
- 1,670,617 shares of common stock reserved for future issuance under our stock incentive plans upon completion of this offering.

Assuming the exercise in full of the outstanding options and warrants, pro forma net tangible book value before this offering at September 30, 2007 would be \$1.69 per share, representing no dilution to our existing stockholders and, after giving effect to the sale of shares in this offering, there would be immediate dilution of \$4.88 per share to new investors in this offering.

The following table summarizes, on a pro forma basis as of September 30, 2007, after giving effect to the exercise of all stock options and warrants outstanding as of September 30, 2007, the differences between the number of shares of common stock purchased from us, the total consideration and the weighted average price per share paid by existing stockholders and by investors participating in this offering at the initial public offering price of \$8.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses:

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Weighted Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing stockholders	14,054,128	73.8%	\$ 75,984,162	65.5%	\$ 5.41
Investors participating in this offering	5,000,000	26.2	40,000,000	34.5	8.00
<b>Total</b>	<b>19,054,128</b>	<b>100%</b>	<b>\$115,984,162</b>	<b>100%</b>	<b>\$ 6.09</b>

The number of shares of common stock outstanding in the table above is based on the pro forma number of shares outstanding as of September 30, 2007 and assumes no exercise of the underwriters' over-allotment option. If the underwriters' over-allotment option is exercised in full, the number of shares of common stock held by existing stockholders will be reduced to 71.0% of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be increased to 5,750,000 shares or 29.0% of the total number of shares of common stock to be outstanding after this offering.

Effective upon the closing of this offering, an aggregate of 1,670,617 shares of our common stock will be reserved for future issuance under our benefit plans. To the extent that any of these options or warrants are exercised, new options are issued under our benefit plans or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

## SELECTED FINANCIAL DATA

The following selected financial data should be read together with our consolidated financial statements and accompanying notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” appearing elsewhere in this prospectus. The selected financial data in this section is not intended to replace our consolidated financial statements and the accompanying notes. Our historical results are not necessarily indicative of our future results.

Except for the pro forma net loss per share and pro forma weighted average number of shares data, we derived the statements of operations data for the years ended December 31, 2004, 2005 and 2006, and the balance sheet data as of December 31, 2005 and 2006 from our audited consolidated financial statements appearing elsewhere in this prospectus. Except for the pro forma net loss per share and pro forma weighted average number of shares data, the statement of operations data for the nine months ended September 30, 2006 and 2007 and for the period from December 19, 2002 (inception) through September 30, 2007 and the balance sheet data as of September 30, 2007 have been derived from our unaudited consolidated financial statements included elsewhere in this prospectus. The statements of operations data for the year ended December 31, 2003 and for the period from December 19, 2002 (inception) through December 31, 2002 and the balance sheet data as of December 31, 2002, 2003 and 2004 are derived from our unaudited consolidated financial statements not included in this prospectus.

	Period from December 19, 2002 (inception) to December 31, 2002	Years Ended December 31,				Nine Months Ended September 30,		Period from December 19, 2002 (inception) to September 30, 2007
		2003	2004	2005	2006	2006	2007	
<b>Statements of Operations Data:</b>								
(In thousands, except per share data)								
Operating expenses:								
Research and development	\$ 603	\$ 1,750	\$ 1,755	\$ 8,833	\$ 14,361	\$ 9,933	\$ 13,894	\$ 41,196
Selling, general and administrative	—	135	1,491	2,319	3,761	2,615	5,463	13,169
Total operating expenses	603	1,885	3,246	11,152	18,122	12,548	19,357	54,365
Other income (expense):								
Interest income	—	—	35	110	1,136	659	1,089	2,370
Interest expense	—	(16)	(238)	(181)	(710)	(559)	(1,185)	(2,330)
Change in value of the convertible preferred stock warrant liability	—	—	—	—	7	—	(362)	(355)
Other, net	—	—	—	8	(1)	(18)	(14)	(7)
Net loss	\$ (603)	\$ (1,901)	\$ (3,449)	\$ (11,215)	\$ (17,690)	\$ (12,466)	\$ (19,829)	\$ (54,687)
Net loss per share—basic and diluted(1)	\$ (2.75)	\$ (11.96)	\$ (24.36)	\$ (28.82)	\$ (34.19)	\$ (24.74)	\$ (33.01)	
Weighted average number of shares used in per share calculations—basic and diluted(1)	220	159	142	389	517	504	601	
Pro forma net loss per common share (unaudited)—basic and diluted(1)					\$ (2.20)		\$ (1.76)	
Weighted average number of shares used in pro forma per share calculations—basic and diluted(1)					8,043		11,089	

(1) Please see Note 2 to our consolidated financial statements for an explanation of the method used to calculate basic and diluted net loss per common share and the pro forma basic and diluted net loss per common share.

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	As of December 31,					As of
	2002	2003	2004	2005	2006	September 30, 2007
	(In thousands)					
<b>Balance Sheet Data:</b>						
Cash, cash equivalents and short-term investments	\$ —	\$ 664	\$ 5,332	\$ 10,719	\$ 34,732	\$ 22,564
Working capital (current assets less current liabilities)	20	448	5,025	8,640	29,921	16,354
Total assets	20	717	5,699	11,561	36,064	24,658
Long-term debt, net of current portion and discounts	—	1,155	—	7,344	1,727	5,130
Convertible preferred stock	1	2	26	46	103	103
Deficit accumulated during development stage	(603)	(2,504)	(5,952)	(17,168)	(34,858)	(54,687)
Total stockholders' equity (deficit)	20	(670)	5,327	1,975	28,574	13,002

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes and the other financial information appearing elsewhere in this prospectus. This discussion and analysis contains forward-looking statements that involve risk, uncertainties and assumptions. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of many factors, including those discussed in "Risk Factors" and elsewhere in this prospectus.*

### Overview

We are a development stage medical device company focused on the design and development of devices that use neuroblocking technology to treat obesity 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. We have a limited operating history and we currently have no products approved for sale. Our initial product under development is the Maestro System, which uses VBLOC therapy to limit the expansion of the stomach, reduce the frequency and intensity of stomach contractions and produce a feeling of early and prolonged fullness. We were formerly known as Beta Medical, Inc. and were incorporated in Minnesota on December 19, 2002. We later changed our state of incorporation to Delaware on July 22, 2004. Since inception, we have devoted substantially all of our resources to the development and commercialization of our Maestro System.

Based on our understanding of vagal nerve function and nerve blocking from our preclinical studies and the results of our initial clinical trials, we believe the Maestro System may offer obese patients a minimally invasive treatment alternative that has the potential to result in significant and sustained weight loss. We believe that our Maestro System will allow bariatric surgeons to help obese patients who are concerned about the risks and complications associated with gastric banding and gastric bypass surgery. We are continuing to evaluate the Maestro System in human clinical trials conducted internationally. We began to enroll and implant subjects in our first U.S. pivotal trial, the EMPOWER trial, in the third quarter of 2007. As we receive approval from the other institutional review boards, we will continue to enroll patients at our other anticipated clinical trial sites. We expect to complete enrollment in the first half of 2008. We plan to use data from our EMPOWER trial to support our premarket approval, or PMA, application for the Maestro System, which we expect to submit in the middle of 2009. We anticipate commercialization in the United States beginning in 2010 if and when the FDA grants us PMA. We have implanted the Maestro System in 76 subjects as of September 30, 2007.

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 following commercialization.

To date, we have generated no revenue from the sale of products, and we have incurred net losses in each year since our inception. As of September 30, 2007, we had a deficit accumulated during the development stage of \$54.7 million. We expect our losses to continue and to increase as we continue our development activities and expand our commercialization activities. We have financed our operations primarily through private placement of our equity securities and issuance of debt.

## **Critical Accounting Policies and Significant Judgments and Estimates**

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

### ***Stock-Based Compensation***

Through December 31, 2005, we have accounted for stock-based employee compensation arrangements using the intrinsic value method in accordance with the recognition and measurement provisions of Accounting Principles Board Opinion, or APB, No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, including the Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB Opinion No. 25*. For periods prior to December 31, 2005, we have complied with the disclosure-only provisions required by Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*, an amendment to SFAS No. 123.

Under APB No. 25, we were not required to recognize stock-based compensation expense for employee stock options granted from inception through 2005 as the exercise prices, for financial reporting purposes, were determined to be at or above the deemed fair value of the underlying common stock on the date of grant. The fair value of our common stock was assessed and approved by our board of directors, the members of which have extensive experience in the life sciences industry and all but one of whom are non-employee directors. In determining the appropriateness of the fair value of our common stock, the board of directors considered several factors, such as our life cycle, results of research and development, recent financings and financial projections.

While our consolidated financial statements through December 31, 2005 account for stock option grants pursuant to APB No. 25, in accordance with SFAS No. 123, we disclose in the notes to our consolidated financial statements the pro forma impact on our net loss had we accounted for stock option grants using the minimum value method of accounting. We account for stock-based compensation arrangements with non-employees in accordance with SFAS No. 123, as amended by SFAS No. 148, and Emerging Issues Task Force, or EITF, No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, using a fair value approach. For stock options granted to non-employees, the fair value of the stock options is estimated using the Black-Scholes valuation model. This model utilizes the estimated fair value of common stock and requires that, at the date of grant and each subsequent reporting period until the services are completed or a significant disincentive for nonperformance occurs, we make assumptions with respect to the expected term of the option, the volatility of the fair value of our common stock, risk free interest rates and expected dividend yields of our common stock. Different estimates of volatility and expected life of the option could materially change the value of an option and the resulting expense.

### ***Adoption of SFAS No. 123R***

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, or SFAS No. 123R, which requires compensation costs related to share-based transactions, including

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employee stock options, to be recognized in the financial statements based on fair value. SFAS No. 123R revises SFAS No. 123, as amended, and supersedes APB No. 25. We adopted SFAS No. 123R using the prospective transition method. Under this method, compensation cost is recognized for all share-based payments granted or modified subsequent to December 31, 2005. Prior to January 1, 2006, we used the minimum value method to determine values for our pro forma stock-based compensation disclosures. We have not utilized the minimum value method subsequent to our adoption of SFAS No. 123R on January 1, 2006, and the fair value of our options will be higher as a result. Our net loss for the nine months ended September 30, 2007 and for the year ended December 31, 2006, was higher than if we had continued to account for employee stock-based compensation under APB No. 25 by \$633,064 and \$47,479, respectively.

We selected the Black-Scholes pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model will be affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our estimated common stock fair value, expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rates, forfeitures and expected dividends.

The fair value of our common stock was assessed and approved by our board of directors. In determining the appropriateness of the fair value of our common stock, the board of directors considered several factors, including valuations performed by Gemini Valuation Services, LLC, or Gemini, an unrelated valuation specialist, our life cycle, results of research and development, recent financings and financial projections. The expected term represents the weighted-average period that our stock options are expected to be outstanding. The expected term is currently based on the “simplified” method described in the SEC Staff Accounting Bulletin, Topic 14: Share-Based Payment. As we have been operating as a private company since inception, we are unable to use actual price volatility data. Therefore, we estimate the volatility of our common stock based on volatility of similar publicly-held entities. We base the risk-free interest rate that we use in the option pricing model on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options. We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option pricing model. We are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. We had a choice of two attribution methods for allocating compensation costs under SFAS No. 123R: the “straight-line method,” which allocates expense on a straight-line basis over the requisite service period of the last separately vesting portion of an award, or the “graded vesting attribution method,” which allocates expense on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in substance, multiple awards. We chose the former method and amortized the fair value of each option on a straight-line basis over the requisite service period.

Calculating stock-based compensation expense requires the input of highly subjective assumptions, which represent our best estimates and involve inherent uncertainties and the application of management’s judgment. These estimates are consistent with the plans and estimates that we use to manage the business. There is inherent uncertainty in making these estimates. We received valuations from Gemini to support the valuation of the common stock as of April 20, 2006, July 6, 2006, January 31, 2007, February 28, 2007, April 30, 2007, May 21, 2007, June 7, 2007, July 31, 2007 and August 31, 2007. These valuations were contemporaneous with those dates with the exception of the April 20, 2006 valuation which was retrospective. We did not obtain contemporaneous documentation on the April 20, 2006 date because, at the time of issuances of stock options during this period, our efforts were focused on research and product development. Estimates of stock-based compensation expenses are significant to our consolidated financial statements, but these expenses are non-cash expenses.

The guidance in SFAS No. 123R and Staff Accounting Bulletin No. 107 is relatively new, and best practices are not well established. The application of these principles may be subject to further interpretation and refinement over time. There are significant differences among option valuation models, and this may result in a lack of comparability with other companies that use different models, methods and assumptions. If factors change and we employ different assumptions in the application of SFAS No. 123R in future periods, or if we

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decide to use a different valuation model, the compensation expense that we record in the future under SFAS No. 123R may differ significantly from what we have recorded in the current period and could materially affect our operating loss, net loss and net loss per common share.

The intrinsic value of the options outstanding as of September 30, 2007, was \$10.1 million, of which \$4.7 million related to vested options and \$5.4 million related to unvested options. The intrinsic value was computed using the initial public offering price.

### ***Net Operating Losses and Tax Credit Carryforwards***

At December 31, 2006, we had federal net operating loss carryforwards of approximately \$17.9 million each. These net operating loss carryforwards will expire in varying amounts from 2022 through 2026, if not utilized. Under the provisions of Section 382 of the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards and certain tax credits that can be utilized annually in the future to offset taxable income. A valuation allowance has been established to reserve the potential benefits of these carryforwards and tax credits in our consolidated financial statements to reflect the uncertainty of future taxable income required to utilize available tax loss carryforwards and other deferred tax assets. If a change in our ownership is deemed to have occurred or occurs in the future, our ability to use our net operating loss carryforwards and tax credits in any fiscal year may be significantly limited.

## **Financial Overview**

### ***Revenue***

To date, we have not commercialized any products and we have not generated any revenue. We do not expect to generate revenue until 2010 and only if we receive FDA approval of our Maestro System. Any revenue from initial sales of a new product is difficult to predict and in any event will only modestly reduce our continued and increasing losses resulting from our research and development and other activities.

### ***Research and Development Expenses***

Our research and development expenses primarily consist of engineering, product development and clinical and regulatory expenses, incurred in the development of our Maestro System. Research and development expenses also include employee compensation, including stock-based compensation, consulting services, outside services, materials, supplies, depreciation and travel. We expense research and development costs as they are incurred. From inception through September 30, 2007, we have incurred a total of \$41.2 million in research and development expenses.

### ***Selling, General and Administrative Expenses***

Our selling, general and administrative expenses consist primarily of compensation for executive, finance, market development and administrative personnel, including stock-based compensation. Other significant expenses include costs associated with attending medical conferences, professional fees for legal, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, and accounting services, cash management fees, consulting fees and travel expenses. From inception through September 30, 2007, we have incurred \$13.2 million in selling, general and administrative expenses.

## Results of Operations

### *Comparison of the Nine-Month Periods Ended September 30, 2006 and 2007*

*Research and Development Expenses.* Research and development expenses were \$13.9 million for the nine months ended September 30, 2007, compared to \$9.9 for the nine months ended September 30, 2006. The increase of \$4.0 million, or 39.9%, is primarily due to a \$1.3 million increase in compensation expenses associated with increased headcount and a \$1.6 million increase in professional services primarily associated with additional resources needed to complete development of the Maestro RC System. Supplies and other information technology expenses increased \$1.1 million due to EMPOWER clinical start-up expenses. Included in research and development expenses during the first nine months of 2007 was \$632,000 of stock-based compensation due to the adoption of SFAS No. 123R and non-employee stock compensation charges compared to \$89,000 in the first nine months of 2006. The increase of \$543,000 is the result of adopting the prospective method prescribed in SFAS No. 123R and an increase in the estimated fair value of our common stock from January 1, 2006 through September 30, 2007. We expect our research and development expenses to increase as we initiate the EMPOWER clinical trial and continue development of the Maestro RC System. We also expect a significant increase to occur in the quarter in which this offering is completed as a result of the issuance of 206,044 shares of common stock to the Mayo Foundation for Medical Education and Research, resulting in a one-time stock-based compensation expense of \$1.6 million, which amount has been computed using the initial public offering price.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$5.5 million for the nine months ended September 30, 2007, compared to \$2.6 million for the nine months ended September 30, 2006. The increase of \$2.9 million or 108.9% is primarily due to a \$1.5 million increase in stock-based compensation as a result of adopting the prospective method prescribed in SFAS No. 123R, an increase in the number of options granted, and an increase in the fair value of our common stock from January 1, 2006 through September 30, 2007. Additional components of the increase include a \$397,000 increase in compensation expense associated with increased headcount and a \$511,000 increase in professional services. The increase in professional services is related to patent filing fees and general patent support, audit fees associated with our initial public offering, public relations and reimbursement activities and employee recruiting fees. We expect our selling, general and administrative expenses to increase substantially due to increased headcount necessary to support our continued growth in operations, the costs associated with operating as a publicly-traded company and the cost associated with the expected commercial launch of our Maestro System.

*Interest Income.* Interest income was \$1.1 million for the nine months ended September 30, 2007, compared to \$659,000 for the nine months ended September 30, 2006. The increase of \$430,000 was primarily due to higher cash, cash equivalents and short-term investment balances as a result of the closing of our \$46.2 million Series C preferred stock financing, debt funding and higher interest rates. We expect our interest income to increase as a result of the proceeds of this offering.

*Interest Expense.* Interest expense was \$1.2 million for the nine months ended September 30, 2007, compared to \$559,000 for the nine months ended September 30, 2006. The increase of \$626,000 was primarily due to the new loan agreements entered into during 2007 and the associated debt commitment fees.

*Change in Value of the Convertible Preferred Stock Warrant Liability.* Change in value of the convertible preferred stock warrant liability was \$362,000 for the nine months ended September 30, 2007, compared to none for the nine months ended September 30, 2006. The preferred stock warrant liability was recorded on December 11, 2006 when we sold an additional 123,569 shares of Series C preferred stock. Upon closing of the sale, we had insufficient authorized and unissued shares of Series C preferred stock available to share settle outstanding warrants to purchase Series C preferred stock, resulting in the warrants being reclassified as a liability at the estimated fair value of \$735,000 on December 11, 2006. The warrants were subsequently

re-measured as of December 31, 2006. On May 14, 2007 we filed an amended certificate of incorporation to increase the number of authorized shares of Series C preferred stock to 6,043,957. As a result of the amendment, we had sufficient authorized and unissued shares of Series C preferred stock available to share settle the warrants. The fair market value of the warrants on May 14, 2007 was determined to be \$1.1 million. The \$362,000 change in fair value from December 31, 2006 to the amendment date was recorded as expense and the convertible preferred stock liability was reclassified to additional paid-in capital.

**Comparison of the Years Ended December 31, 2005 and 2006**

*Research and Development Expenses.* Research and development expenses were \$14.4 million for the year ended December 31, 2006, compared to \$8.8 million for the year ended December 31, 2005. The increase of \$5.6 million, or 62.6%, was primarily due to a \$1.5 million increase in compensation related expenses associated with increased headcount and a \$3.9 million increase in professional services expenses associated with the continued development of our Maestro RF System and the beginning of our international clinical trials. Included in research and development expenses during 2006 was \$121,000 of stock-based compensation due to the adoption of SFAS No. 123R and non-employee stock compensation charges compared to \$0 in 2005.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$3.8 million for the year ended December 31, 2006, compared to \$2.3 million for the year ended December 31, 2005. The increase of \$1.5 million, or 62.1%, was primarily due to a \$405,000 increase in compensation related expenses associated with increased headcount, a \$511,000 increase in professional services and a \$161,000 increase in facility expenses as a result of increased rent costs. Included in selling, general and administrative expenses during 2006 was \$43,000 of stock-based compensation due to the adoption of SFAS No. 123R and non-employee stock compensation charges compared to \$25,000 in 2005.

*Interest Income.* Interest income was \$1.1 million for the year ended December 31, 2006, compared to \$110,000 for the year ended December 31, 2005. The increase of \$1.0 million was primarily due to higher cash, cash equivalents and short-term investment balances during 2006 as a result of the closing of our \$46.2 million Series C preferred stock financing and higher interest rates.

*Interest Expense.* Interest expense was \$710,000 for the year ended December 31, 2006, compared to \$181,000 for the year ended December 31, 2005. The increase of \$529,000 was primarily due to 2006 having a full year of interest on loan agreements entered into during the last half of 2005 and additional loan agreements entered into in the first half of 2006.

**Comparison of the Years Ended December 31, 2004 and 2005**

*Research and Development Expenses.* Research and development expenses were \$8.8 million for the year ended December 31, 2005, compared to \$1.8 million for the year ended December 31, 2004. The increase of \$7.0 million was primarily the result of product development activities associated with our Maestro RF System and increased activity in preparation of launching our international clinical trials. Specifically, compensation related expenses increased \$1.3 million as a result of increased headcount, consulting related expenses increased \$1.7 million and travel expenses increased \$215,000. There was also an increase of \$3.4 million in product development costs.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$2.3 million for the year ended December 31, 2005, compared to \$1.5 million for the year ended December 31, 2004. The increase of \$828,000, or 55.5%, was primarily due to a \$265,000 increase in compensation related expenses associated with increased headcount, a \$233,000 increase in office supply related purchases, a \$180,000 increase in professional services due mainly to audit and legal fees and a \$71,000 increase in market development expenses.

## **Liquidity and Capital Resources**

We have incurred losses since our inception in December 2002 and, as of September 30, 2007 we had a deficit accumulated during the development stage of \$54.7 million. We have financed our operations to date principally through sale of capital stock, debt financing and interest earned on investments. Through September 30, 2007, we have received net proceeds of \$63.2 million from the sale of common stock and preferred stock and \$13.3 million in debt financing from a lender that provides \$746,000 to finance equipment purchases and \$12.5 million to finance working capital. As of September 30, 2007, we had \$22.6 million in cash, cash equivalents and short-term investments. Our cash and investment balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, corporate bonds, commercial paper, variable rate demand notes and money market funds. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

The remaining unpaid balance of the \$13.3 million in debt financing is collateralized by a first security priority lien on all of our assets, excluding intellectual property. We have entered into account control agreements in order to perfect the lender's first security interest in our cash and investment accounts. In the event we have less than four remaining months of liquidity, we are required to grant a temporary lien on our intellectual property. The number of remaining months of liquidity is calculated by dividing cash and cash equivalents as of the end of any particular month by the sum of our total operating expenses for each of the immediately preceding four months. There are no additional covenants that we are required to maintain under the terms of our debt financing agreements.

### ***Net Cash Used in Operating Activities***

Net cash used in operating activities was \$16.2 million, \$10.3 million and \$3.1 million for the years ended December 31, 2006, 2005 and 2004, respectively. Net cash used in operating activities was \$17.2 million and \$11.8 million for the nine months ended September 30, 2007 and 2006, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, which was partially offset by depreciation and amortization, stock-based compensation and changes in operating assets and liabilities.

### ***Net Cash Provided by or Used in Investing Activities***

Net cash used in investing activities was \$17.7 million, \$450,000 and \$242,000 for the years ended December 31, 2006, 2005 and 2004, respectively. Net cash used in investing activities for the year ended December 31, 2006 was primarily related to the purchase of short-term investments and, to a lesser extent, purchase of property and equipment offset somewhat by the proceeds from the maturity of short-term investments. Net cash used in investing activities for the years ended December 31, 2005 and 2004 was related to the purchase of property and equipment. Net cash provided by investing activities was \$10.0 million for the nine months ended September 30, 2007 compared to net cash used in investing activities of \$20.5 million for the nine months ended September 30, 2006. Net cash provided by investing activities for the nine months ended September 30, 2007 was primarily related to the proceeds from the maturity of short-term investments partially offset by the purchase of short-term investments and, to a lesser extent, the purchase of property and equipment.

### ***Net Cash Provided by or Used in Financing Activities***

Net cash provided by financing activities was \$40.7 million, \$16.1 million and \$8.0 million for the years ended December 31, 2006, 2005 and 2004, respectively. Net cash provided by financing activities was \$5.6 million and \$40.3 million for the nine months ended September 30, 2007 and 2006, respectively. Net cash provided by financing activities was primarily attributable to the issuance of Series B preferred stock in the years ended December 31, 2005 and 2004, the issuance of Series C preferred stock in the year ended December 31, 2006 and proceeds from debt financing in the years ended December 31, 2006 and 2005. Net cash provided by financing activities for the nine months ended September 30, 2006 was primarily related to proceeds from the issuance of Series C preferred stock, debt financing and from the exercise of common stock options, partially offset by repayments made on outstanding loan amounts. Net cash provided by financing activities for the nine months ended September 30, 2007 was primarily attributable to proceeds from debt financing and the exercise of common stock options, partially offset by repayments made on outstanding loan amounts.

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We entered into two separate growth capital loans on March 31, 2006 with a combined face amount of \$2.5 million payable in 23 equal principal and interest installments beginning October 1, 2006 through August 2008 with a final payment of \$238,875 on September 1, 2008 at an annual percentage rate of 9.49%, an effective rate of 14.07%. Interest only payments for the first six months of the loan are at an annual percentage rate of 10.999%. On May 17, 2007 we entered into a \$15.0 million debt facility with the same lender of the other notes payable. The initial commitment under the debt facility is for \$10.0 million and allows for two \$5.0 million draw periods, the first of which was required upon closing. The debt facility agreement entered into on May 17, 2007 was amended on August 28, 2007 to provide for two draw periods on the second \$5.0 million that is available to us under the terms of the original agreement. As amended, \$2.5 million was available to us through August 31, 2007 and the remaining \$2.5 million was available to us through October 31, 2007. We completed the initial \$5.0 million draw by entering into two separate growth capital loans on May 22, 2007 with a combined face amount of \$5.0 million payable in 29 equal principal and interest installments beginning December 1, 2007 through April 1, 2010 with a final payment of \$343,050 on May 1, 2010 at an annual percentage rate of 10.25%. Interest only payments for the first six months of the loan are at an annual percentage rate of 12.48%. On August 31, 2007, we completed the \$2.5 million draw that was available to us through that date by entering into two separate growth capital loans with a combined face amount of \$2.5 million. The amount is payable in 29 equal principal and interest installments beginning March 1, 2008 through July 1, 2010 with a final payment of \$171,525 on August 1, 2010 at an annual percentage rate of 10.25%. Interest only payments for the first six months of the loan are at an annual percentage rate of 12.48%. On October 31, 2007, we completed the \$2.5 million draw that was available to us through that date by entering into two separate growth capital loans with a combined face amount of \$2.5 million. The amount is payable in 29 equal principal and interest installments beginning March 1, 2008 through July 1, 2010 with a final payment of \$171,525 on August 1, 2010 at an annual percentage rate of 10.25%. Interest only payments for the first four months of the loan are at an annual percentage rate of 12.48%. The final \$5.0 million commitment available to us under the terms of the debt facility is subject to us closing a next round of financing and would be available to be drawn on by us through 2008. We are not required to pay any additional equity consideration for this portion of the facility unless it is utilized.

### ***Operating Capital and Capital Expenditure Requirements***

To date, we have not commercialized any products and we have not earned any operating revenues. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our products, prepare for the potential commercial launch of our Maestro System, develop the corporate infrastructure required to sell our products and operate as a publicly-traded company as well as pursue additional applications for our technology platform.

We do not expect to generate significant product revenue until 2010. We do not anticipate generating any product revenue in the United States unless and until we successfully obtain FDA approval for our Maestro System. We believe the net proceeds from this offering, together with our cash, cash equivalents and short-term investment balances and interest income we earn on these balances will be sufficient to meet our anticipated cash requirements through the end of 2009. If our available cash, cash equivalents and investment balances and net proceeds from this offering are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or enter into a credit facility. The sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of products and the cost to commercialize our products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in the "Risk Factors" section of this prospectus. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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Because of the numerous risks and uncertainties associated with the development of medical devices, such as our Maestro System, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to complete the development of the products and successfully deliver a commercial product to the market. Our future capital requirements will depend on many factors, including but not limited to the following:

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

### **Contractual Obligations**

The following table summarizes our contractual obligations as of September 30, 2007 and the effect those obligations are expected to have on our financial condition and liquidity position in future periods:

<b>Contractual Obligations</b>	<b>Payments Due By Period</b>				
	<b>Total</b>	<b>Less Than 1 Year</b>	<b>1-3 Years</b>	<b>3-5 Years</b>	<b>More than 5 Years</b>
Operating lease	\$ 139,152	\$ 139,152	\$ 0	\$ 0	\$ 0
Long-term debt	11,634,639	5,382,451	6,252,188	0	0
Other long-term liabilities	500,000	250,000	250,000	0	0
Total contractual cash obligations	<u>\$12,273,791</u>	<u>\$5,771,603</u>	<u>\$6,502,188</u>	<u>\$ 0</u>	<u>\$ 0</u>

Our operating lease commitments relate to our corporate headquarters in St. Paul, Minnesota. Other long-term liabilities consist of obligations required under the terms of our license agreement with the Mayo Foundation for Medical Education and Research, or Mayo Foundation.

Under terms of our license agreement, the Mayo Foundation receives an annual \$250,000 retainer fee which commenced in 2005 and continues through January 2009. The Company may also be obligated to pay the Mayo Foundation, contingent upon the occurrence of certain future events, earned royalty payments, including a minimum annual royalty as defined by the agreement, for the commercial sale of products developed and patented by the Mayo Foundation, jointly patented by the Company and the Mayo Foundation, or a product where the Mayo Foundation provided know-how as defined by the agreement. If no products are patented, the minimum royalty is not due. While we have licensed-in four obesity-related patent applications from Mayo Clinic, none of these patents cover medical technology relating to our VBLOC technology.

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We are also obligated to issue up to 206,044 shares of common stock to the Mayo Foundation as consideration if future Mayo Foundation patents are issued or if the FDA approves a product patented by the Mayo Foundation or jointly patented by the Mayo Foundation and us. Upon the completion of this offering, the 206,044 shares of common stock become immediately issuable to the Mayo Foundation and we will record a one-time stock-based compensation expense of \$1.6 million, which amount has been computed using the initial public offering price.

### **Off-balance-sheet Arrangements**

Since our inception, we have not engaged in any off-balance-sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K of the SEC.

### **Quantitative and Qualitative Disclosures About Market Risk**

Our exposure to market risk is confined to our cash, cash equivalents and short-term investments which have maturities of less than one year. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio are not leveraged, are classified as either available for sale or held-to-maturity and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio.

### **Recent Accounting Pronouncements**

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*, which clarifies the accounting for uncertainty in tax positions. FIN 48 requires that we recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of our 2007 fiscal year, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. The adoption of FIN 48 had no impact on our consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. Earlier adoption is permitted, provided we have not yet issued financial statements, including for interim periods, for that fiscal year. We are currently evaluating the impact of SFAS 157.

In September 2006, the United States Securities and Exchange Commission issued Staff Accounting Bulletin No. 108 (SAB 108), *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements*, which provides interpretive guidance on how registrants should quantify financial statement misstatements. Under SAB 108, registrants are required to consider both a “rollover” method which focuses primarily on the income statement impact of misstatements and the “iron curtain” method which focuses primarily on the balance sheet impact of misstatements. The adoption of SAB 108 had no impact on our consolidated financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The amendment to SFAS 115 applies to all entities with investments in available-for-sale or trading securities. The statement is effective for fiscal years beginning after November 15, 2007. We have not yet determined the effect SFAS 159 will have on our consolidated financial statements.

## BUSINESS

### Overview

We are a development stage medical device company focused on the design and development of devices that use neuroblocking technology to treat obesity 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, 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 sustained weight loss.

We believe that our Maestro System will allow bariatric surgeons to help obese patients who are concerned about the risks and complications associated with gastric banding and gastric bypass surgery. We are continuing to evaluate the Maestro System in human clinical trials conducted in Australia, Mexico, Norway and Switzerland. We recently received an investigational device exemption, or IDE, for our first U.S. pivotal trial, the EMPOWER trial and began to enroll and implant subjects in the third quarter of 2007. As we receive approval from the other institutional review boards, we will continue to enroll patients at our other anticipated clinical trial sites. We expect to complete enrollment in the first half of 2008. We plan to use data from our EMPOWER trial to support our application for premarket approval, or PMA, for the Maestro System, which we expect to submit in the middle of 2009. If the U.S. Food and Drug Administration, or FDA, grants us approval, we anticipate we will be able to commercialize the Maestro System in the United States in 2010. As of September 30, 2007, we have implanted the Maestro System in 76 subjects and have one-year clinical data on 11 subjects. To date, we have not observed any mortality or any medically serious device-related events that have required surgical attention in the 76 subjects we have implanted with the Maestro System. Seven adverse events have been observed to date, all of which were resolved without surgical attention or permanent effects.

Our 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. The electrodes deliver the appropriate VBLOC therapy algorithm as programmed by a neuroregulator implanted under the skin in the abdominal region. 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 an approximate two-week healing period following implantation. VBLOC therapy is then delivered intermittently each day during the patient's waking hours.

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. Initially, we anticipate that our sales representatives will exclusively target selected bariatric surgery Centers of Excellence and nationally recognized bariatric surgery centers. Outside the United States we currently intend to use direct, dealer and distributor sales models as the targeted geography best dictates.

We believe we are the only company applying neuroblocking therapy to the vagus nerve for the treatment of obesity. We believe that two of our issued patents and our patent applications broadly cover the use of neuroblocking therapy for obesity and other disorders and we intend to continue to pursue further intellectual property protection through U.S. and foreign patent applications.

## 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 the National Health and Nutrition Examination Survey. By 2004, the incidence of obesity had more than doubled to 32%. Currently, the Centers for Disease Control and Prevention, or CDC, estimates that there are 65 million obese adults in the United States, with approximately 42 million having a Body Mass Index, or BMI, of 30 to 35 and approximately 23 million having a BMI greater than 35. BMI is calculated by dividing a person's weight in kilograms by the square of their height in meters. It is estimated that by 2010, as many as 83 million Americans will suffer from obesity. Obesity is also a significant health problem outside of the United States, with as many as 400 million people worldwide estimated to be obese according to the World Health Organization.

The CDC has identified obesity as a leading public health threat in the United States and estimated that there are approximately 112,000 obesity-related deaths each year in the United States. According to data from the CDC, 76% of people with a BMI above 35 have an obesity-related disease or disorder, also called a co-morbidity. 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.

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 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.

## Existing Obesity Treatments and Limitations

Existing options for the treatment of obesity include behavioral modification, pharmaceutical therapy and bariatric surgery. While behavioral modification, including nutritional and exercise counseling, is an important component in the treatment of obesity, most patients find it difficult to achieve and maintain significant weight loss with a regimen of diet and exercise alone. Studies have shown that behavioral modification alone is an ineffective treatment for obesity in approximately 95% of patients. As a result, there is a significant need for other treatments such as pharmaceutical therapy or bariatric surgery. However, we believe these alternatives have seen limited adoption to date as physicians and patients remain dissatisfied with the tradeoffs between efficacy and safety of existing treatment options.

**Pharmaceutical therapy.** Several pharmaceutical products have been approved by the FDA for obesity therapy in the United States. These drug therapies often represent a first option in the treatment of obese patients within lower BMI ranges, but may carry significant safety risks or troublesome side-effects, such as high blood pressure, increased heart rate or diarrhea. In addition, patients using pharmaceutical therapy often experience a weight loss plateau after six months. We believe these side-effects and shortcomings have led to limited adoption of pharmaceutical therapy, as reflected in a September 2006 Frost & Sullivan report, which states that in 2005 less than two percent of the obese population in the United States was treated with pharmaceuticals.

**Bariatric surgery.** In the more severe cases of obesity, patients may pursue more aggressive surgical treatment options. Gastric bypass and gastric banding, the most commonly employed bariatric surgeries, promote weight loss by surgically restricting the stomach's capacity and its outlet size. Gastric bypass also affects weight loss by restricting the body's ability to absorb nutrients. However, according to American Society for Bariatric Surgery estimates in 2006, despite recent increases in the number of bariatric surgical procedures, less than two

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percent of the 15 million surgically-eligible obese population underwent a bariatric surgical procedure. We believe this low adoption rate is largely due to the numerous short and long-term safety risks presented by these procedures.

The most common form of gastric bypass accounts for approximately 70% of all bariatric surgeries in the United States. Gastric bypass typically involves the surgical division of the stomach and small intestine. The surgeon creates a small walnut-sized pouch out of the upper segment of the stomach, which is connected to the severed downstream section of the small intestine, thereby bypassing the lower part of the stomach and much of the front end of the small intestine. Gastric bypass is a highly invasive, anatomy-altering surgery and patients may face many of the following:

- potentially fatal post-surgical complications including pulmonary embolism, or blood clots that travel to the lungs, as well as leaks that may lead to post-surgical infection, which occur at the juncture between newly-joined or repaired sections of the digestive system;
- re-operations to repair sections of the digestive system and to dilate or further reduce the surgically-created passageway between the stomach and the intestine;
- nutrient deficiency resulting from the reduced capacity to absorb vitamins and minerals in the bypassed section of the small intestine;
- intolerance to common foods; and
- extended hospitalization.

Gastric bypass is performed as an open surgical procedure or a laparoscopic procedure. Length of stay averaged 3.7 days for open bariatric surgical procedures and 2.5 days for laparoscopic bariatric procedures. Although laparoscopic surgery can reduce the risks associated with gastric bypass surgery, it does not eliminate them entirely. These risks may include: breathing problems, irregular heart rhythm, bleeding, injury of abdominal organs including the lower esophagus, blood clots in legs and lungs, infection, temporary abdominal discomfort and loss of appetite and, in rare cases, death. The 30-day mortality rates in patients with gastric bypass range from 0.3% to over one percent. A study of 16,155 Medicare patients who underwent bariatric surgery from 1997 to 2002 showed 12-month mortality rates to be over twice as high as the 30-day rates. We believe that the perceived risk presented by these mortality rates represents a substantial barrier to adoption.

Gastric banding typically involves implantation of a silicone band around the upper portion of the stomach to restrict stomach capacity and stomach outlet size, usually to less than one centimeter. The silicone band can be adjusted by a surgeon through a needle-accessible port to restrict the diameter of the stomach pouch outlet. Although less invasive than gastric bypass, with gastric banding, patients and surgeons may face many of the following:

- re-operations to correct slippage of the stomach through the band or to correct erosions of the band through the wall of the stomach. Bands that are too loose or that slip become ineffective, while those that are too tight tend to cause nausea and vomiting. Recent European research indicates that band-related complications and re-operations may occur throughout the life of the gastric band at a rate of nearly five percent per year;
- intolerance to common foods such as meats and certain breads that can obstruct the restricted passageway and require patients to vomit to clear the obstruction;
- ongoing clinical visits to receive physician-controlled, sometimes uncomfortable, band adjustments that require significant time for the patient and the surgeon and increase surgical staffing requirements;

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- complications generally associated with laparoscopic procedures as well as device failure or malfunction with possible need for additional surgery; and
- an in-patient hospital stay.

We believe that gastric banding has not been more widely accepted because of the high rate of re-operation, the frequent nausea and vomiting experienced by patients, the restrictive post-operative diet and the post-operative burden placed on both the patient and physician for frequent follow-up visits.

**Neurostimulation as a Treatment for Obesity:** Because of the side effects and limitations involved with bariatric surgery, efforts have been made to develop alternative treatments for obesity. One alternative treatment that has been explored is neurostimulation, which uses low-frequency, electrical stimulation of either the vagus nerve or the smooth muscles and nerves of the stomach to slow the emptying of the stomach or induce a feeling of fullness. However, reports of two recent clinical studies have not shown neurostimulation to be effective in treating obesity:

- In 2003, researchers using Cyberonics' VNS system reported inconclusive results of a pilot study using bilateral vagal nerve stimulation in a small human series following earlier promising results in canines.
- In December 2005, Medtronic announced that it did not meet the efficacy endpoint in the U.S. pivotal clinical trial for its gastric stimulation device.

We believe that these results suggest that stimulation therapies have limited application in the treatment of obesity.

Given the limitations of pharmaceutical therapy, bariatric surgery and neurostimulation, we believe there is a substantial need among physicians and obese individuals for a safe and effective solution that:

- preserves normal anatomy;
- allows continued ingestion and digestion of foods found in a typical, healthy diet;
- enables non-invasive adjustability while reducing the need for frequent clinic visits;
- minimizes the risks of re-operation, malnutrition and mortality; and
- reduces the natural hunger drive of patients.

## **EnteroMedics' Solution**

We are designing our Maestro System to address many of the unmet needs of physicians and patients for an effective long-term obesity treatment that minimizes the complications presented by existing alternatives. The Maestro System delivers VBLOC therapy, which we believe is the first therapy of its kind for the treatment of obesity using neuroblocking. VBLOC therapy interrupts nerve signals along the vagus nerve to selectively block the gastrointestinal effects of the vagus nerve, unlike neurostimulation, which attempts to increase neural activity through stimulation to impact the digestive system.

### ***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;

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- 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 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 and a subsequent reduction in hunger. 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.** Our system is designed to block 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.
- **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, we have not observed any mortality or any

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medically serious device-related events that have required surgical attention in the 76 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 the 11 patients who have been using the Maestro System for 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 Business Strategy**

Our goal is to establish VBLOC therapy, delivered via our 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.*** We have received an Investigational Device Exemption, or IDE, from the FDA for use of the Maestro System in the United States in our EMPOWER pivotal trial, but have yet to receive regulatory approval to market the Maestro System. We began to enroll and implant subjects in the EMPOWER trial in the third quarter of 2007. As we receive approval from the other institutional review boards, we will continue to enroll patients at our other anticipated clinical trial sites. If we achieve favorable results from the EMPOWER pivotal trial, we plan to use the data from this trial to obtain a PMA from the FDA to allow us to commence sales in the United States in 2010. We also plan to complete the regulatory submissions required to enable the eventual sale of our systems internationally.

***Drive the Adoption and Endorsement of VBLOC Therapy Through Key Opinion Leaders.*** Our clinical development strategy is to collaborate closely with regulatory bodies, physician opinion leaders and scientific experts. We have established credible and open relationships with physician opinion leaders and scientific experts and we believe these key opinion leaders and scientific experts will be important in promoting patient awareness and gaining widespread adoption once the Maestro System is approved and commercialized.

***Commercialize Our Products using a Direct Sales and Marketing Effort.*** 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 294 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.

***Procure Appropriate Coding, 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 Centers for Medicare and Medicaid Services, or 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 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.



Note: Transmit coil and clinician programmer are not pictured.

The major components of the Maestro System include:

- **Neuroregulator.** The neuroregulator 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 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

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System, the controller is an external unit. In the Maestro RC System, the external controller is replaced by an external mobile charger designed to be worn approximately three hours once per week and the control logic is contained within the implanted neuroregulator.

- **Transmit coil.** The transmit coil is positioned over the implanted neuroregulator and delivers radiofrequency energy and therapy control information across the skin into the device. The coil is held in position over the neuroregulator using either an adhesive or an adjustable elastic belt worn around the torso.
- **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.

The Maestro RF System and the Maestro RC System differ in the following ways:

- The 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 70 cubic centimeters in volume to accommodate its internal battery. An external mobile charger is connected to the external transmit coil to recharge the battery and needs to be worn approximately three hours once per week in order to recharge the internal battery. The mobile charger is recharged using AC wall power.

We intend to evaluate each system as part of our clinical trial plan.

**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 described above 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 after an approximate two-week healing period following 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

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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, which is generally recharged approximately once a week.

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.

### **Maestro Clinical Development**

We are developing our Maestro System to deliver VBLOC therapy for the long-term treatment of obesity. Based on our preliminary 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 internationally and began to enroll and implant subjects in our first U.S. pivotal trial, the EMPOWER trial, in the third quarter of 2007. We plan to use data from our EMPOWER trial to obtain FDA approval and anticipate filing our PMA application by the middle of 2009.

#### ***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 93% of all nerve fibers 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 May 2006, the American Society for Bariatric Surgery meeting in June 2006, and the International Federation for Surgery of Obesity meeting in August 2006.

#### ***Clinical Experience***

We began evaluating VBLOC therapy with our initial Maestro System, the RF1 system, in a clinical trial in February 2006 and have now implanted the Maestro System, including the next generation RF2 system, in a total of 76 subjects as of September 30, 2007. The 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. 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, or EWL, is reported as the percentage of excess weight that is lost by the subject.

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We have not observed any mortality or any medically serious device-related events that have required surgical attention 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.

We initiated enrollment of our pivotal clinical study, the EMPOWER trial, in July 2007 upon receipt of approval from the first institutional review board. We expect to complete enrollment in the first half of 2008. The EMPOWER trial is a multi-center, randomized, double-blind, prospective, placebo-controlled pivotal study and will be conducted in the United States and selected international centers. Upon receipt of all enrolled patients' one-year endpoint data, we intend to use the data from this study to support our PMA application for the Maestro System for the treatment of obesity in the United States. In addition, we expect to use our clinical studies in a submission to our Notified Body for a CE Mark that would allow us to commercialize our Maestro System in the European Union.

The following table is a summary of our planned, ongoing and completed clinical studies:

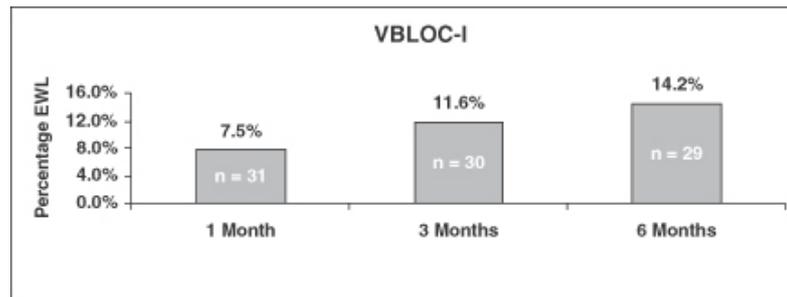
<b>Clinical Study</b>	<b>Maestro System</b>	<b>Description</b>	<b>Sites</b>	<b>Number of Subjects</b>	<b>Status</b>
VBLOC-I	RF1	Initial safety and efficacy trial VBLOC therapy with six month follow-up	3	31	Complete
VBLOC-EC	RF1, RF2	Continuation of VBLOC-I for 18 months	2	11	In follow-up
VBLOC-GF	RF2	Assessment of VBLOC therapy on gastric function	1	12	In follow-up
VBLOC-RF2	RF2	Assessment of Maestro System intended for use in pivotal trial	4	33	In follow-up
VBLOC-RC	RC	Initial trial of Maestro RC System	Up to 2	Up to 10	Enrollment beginning first half of 2008
EMPOWER	RF2, RC	Trial focused on obtaining safety and efficacy clinical data for PMA application	Up to 15	Minimum 220	RF2 enrollment began July 2007

### **VBLOC-I**

The VBLOC-I trial was our initial clinical trial and was designed to evaluate the safety and efficacy of the Maestro System in treating patients with obesity. We also gathered data for guidance in selection of the appropriate parameters for VBLOC therapy delivery. The trial was an international, open-label, prospective, multi-center study, involving 31 subjects with a mean BMI of 41. Of the 31 subjects, five were men and 26 were women. Additionally, none of these subjects were enrolled in any diet, behavior modification, or exercise programs so that we could focus on and isolate the impact of VBLOC therapy on weight reduction. We evaluated the efficacy of VBLOC therapy by measuring the average percentage EWL at one, three and six months. We completed our VBLOC-I trial with six months of follow-up in December 2006.

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We believe the VBLOC-I trial demonstrated the feasibility of the Maestro System in treating subjects with obesity. The table below shows the average percentage EWL at follow-up months one, three and six.



In addition to its demonstrated clinical benefits, we also believe that VBLOC-I demonstrated the safety of the Maestro System in this subject population. No deaths or medically serious device related events were reported during the study. Two subjects were excluded from the data for non-compliance due to lack of system use. Two readily reversible serious events related to the implant procedure occurred. One subject contracted a post-operative lower respiratory tract infection and one subject contracted a localized, subcutaneous infection at the neuroregulator site not requiring system removal. These events required a single day's hospitalization. A third and unrelated event included an extended overnight hospitalization as the subject required additional time to make arrangements to return home. A fourth and unrelated serious adverse event occurred in one subject who experienced severe diarrhea from bacterial infection. Three other serious adverse events that were readily resolved included an upper airway infection, a case of fluid collection at the neuroregulator site and a case of trauma that occurred as a result of a motor vehicle accident that did not require hospitalization. Other nonserious adverse events were adequately resolved without permanent effects and these patients remained in the trial.

Because of the investigational stage of our Maestro System, we were required to provide subjects the opportunity to transition from VBLOC therapy to a surgical alternative once they had undergone a minimum of six months of VBLOC therapy. Of the 31 subjects in this trial, five elected to convert to an alternative procedure. Two subjects were successfully converted to an adjustable gastric band and three subjects were successfully converted to gastric bypass after six months. We believe the therapy conversions of these subjects demonstrate that the neuroregulator and the implanted leads of the Maestro System can be removed in a short laparoscopic procedure.

As part of the VBLOC-I study, we also conducted two sub-studies to evaluate secondary endpoints among subsets of the subjects enrolled in the trial.

- **Sub-Study 1: Weight Loss, Calorie Intake, Hunger and Fullness.** This sub-study assessed the impact of VBLOC therapy on calorie intake, hunger and fullness at one site in a population of ten female subjects with an age range of 31 to 60 years and a BMI range of 33 to 48. This sub-study analyzed a series of seven-day diet diaries, computerized calorie calculations, hunger and fullness visual analogue scales and weight before and during VBLOC therapy. Participants in this sub-study had an average percentage EWL of 23% after six months of treatment with a reduction in calorie intake determined from detailed dietary analysis. Subjects reported reduced hunger, earlier fullness and reduced food intake using validated visual analogue scales. We believe that the results of this sub-study indicate that VBLOC therapy may be effective in reducing calorie intake even though no diet, exercise or behavior modification programs of any kind were provided. VBLOC therapy may also be effective in reducing hunger and increasing feelings of fullness during a period of reduced calorie intake and sustained weight loss.
- **Sub-Study 2: Pancreatic Polypeptide Response.** This sub-study assessed the impact of VBLOC therapy on pancreatic function, which is a test often used to evaluate vagal nerve function, in a population of 20 women and five men at two sites with an age range of 30 to 58 years and a BMI range of 33 to 48. The exocrine pancreas is responsible for production and secretion of digestive enzymes in the small intestine

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that are responsible for food digestion, resulting in food absorption. This sub-study showed at the three month follow-up that implantation of the Maestro System and the use of VBLOC therapy blunted the pancreatic polypeptide response, an indicator of successful vagal blocking. The mean EWL percentage for this study was 13.1%.

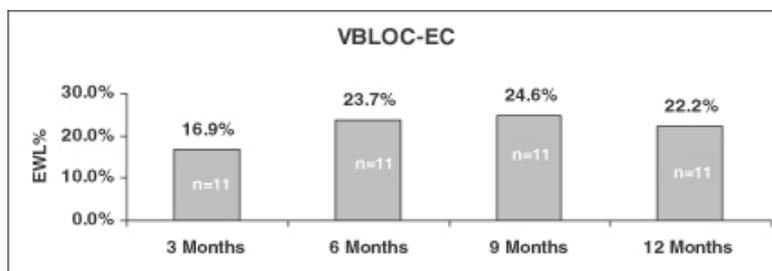
### ***VBLOC-EC Trial***

VBLOC-EC is an efficacy continuation of VBLOC-I. Twenty-six of the 31 VBLOC-I subjects were assigned to a long-term safety evaluation and two sites and 11 subjects met the criteria for inclusion in the efficacy continuation arm. Enrollment in VBLOC-EC began in the first quarter of 2007. As subjects of the VBLOC-I study reached their six month follow-up point, the subjects that consented were enrolled in VBLOC-EC. To participate in the VBLOC-EC trial, subjects were required to consent to long-term follow-up, to be compliant in their use of the system and to be enrolled in sites that had implemented a formal bariatric patient follow-up program. These EC subjects started receiving diet, behavior modification and exercise advice after the first six months of VBLOC therapy.

The intent of our VBLOC-I trial was to determine the effects of VBLOC therapy alone without medical weight management. We incorporated a medical weight management program into our VBLOC-EC and VBLOC-RF2 trials because we believe it is important to reinforce the impact of VBLOC therapy combined with medical weight management education. Additionally, the FDA requested that we include a medical weight management program in our EMPOWER trial with patients with VBLOC therapy turned on and patients with VBLOC therapy turned off and we wanted to have experience using a medical weight management program with VBLOC therapy prior to commencing EMPOWER.

Since we have not designed a study comparing medical weight management alone against VBLOC therapy, we will not be able to determine the effect of a medical weight management program on efficacy in VBLOC-EC or VBLOC-RF2 other than a historical comparison. Despite this, we believe that medical weight management will be supplemental to VBLOC therapy and part of the recommended treatment in our future PMA application. To date, no deaths or medically serious device related events have been reported during the VBLOC-EC study and the safety profile is similar to VBLOC-I. Other nonserious adverse events have been as expected.

The table below shows the average percentage EWL for the 11 subjects enrolled in VBLOC-I who continued on into the VBLOC-EC trial. The follow-up periods for the VBLOC-EC trial are at nine, 12 and 24 months after implantation in the VBLOC-I trial. In general, the EWL for the subjects in VBLOC-EC was higher than in VBLOC-I at the three-month and six-month periods. We believe this is due to the fact that the centers participating in VBLOC-EC had formal bariatric programs. The formal bariatric program was managed by a multi-disciplinary team that helped subjects implement various diet, exercise and behavior modification techniques. We believe the improved results of VBLOC-EC are also due to participation of patients who had been better educated regarding our program criteria. Prior to VBLOC-EC, we believe some subjects in our VBLOC I trial had an expectation for more dramatic EWL based on gastric bypass results and realized that, according to study protocol, they could drop out of the VBLOC trial early and thereby move up on a gastric bypass waiting list. In subsequent studies, VBLOC-EC and VBLOC-RF2, we attempted to select patients who, after being educated on the risks and benefits of VBLOC therapy, had a genuine interest in receiving VBLOC therapy as opposed to using temporary participation in our trial as a means to receive gastric bypass more quickly.



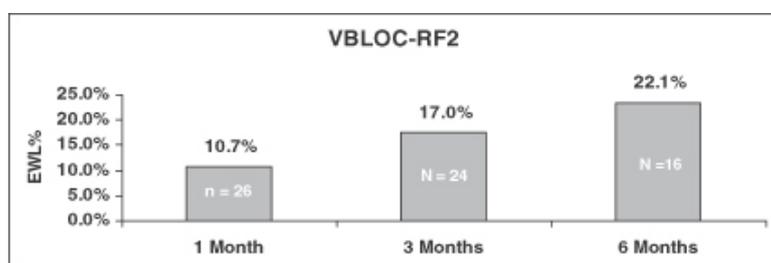
**VBLOC-GF Trial**

We initiated the VBLOC-GF trial to study the effects of VBLOC therapy on gastric function in 12 subjects who consented to gastric function testing prior to system implantation and at least two times after implant. Gastric function in response to interrupted VBLOC therapy will be assessed at several points throughout the trial. The gastric function testing uses a nutrient drink test to measure the amount of food required to feel full at meals and a trace radio-labeled standard solid meal protocol to measure gastric emptying. We anticipate completion of VBLOC-GF in the second half of 2009. To date, no deaths or medically serious device related events have been reported during the VBLOC-GF trial. Other nonserious adverse events have been as expected.

**VBLOC-RF2 Trial**

Enrollment of 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 24 months. The trial is an international, open-label, prospective, multi-center study, involving 33 patients. Of the 33 subjects currently enrolled, five are men and 28 are women, with a mean BMI of 40.2. One subject was excluded from the data for noncompliance due to lack of system use. We are implementing medical weight management programs and plan to evaluate the efficacy of the VBLOC therapy by measuring average percentage EWL at one month, three, six, 12 and 24 months. 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 more consistent weight loss. To date, no deaths or medically serious device related events have been reported during the VBLOC-RF2 trial and the safety profile is similar to VBLOC-I.

The following table summarizes current average percentage EWL data from this ongoing trial. We anticipate completion of VBLOC-RF2 in the second half of 2008 and will be periodically reporting safety and EWL data during the trial in appropriate medical publications. The follow-up periods for the VBLOC-RF2 trial are at follow-up months one, three, six, 12 and 24.



**VBLOC-RC Trial**

VBLOC-RC is intended to demonstrate that the clinical performance of the Maestro RC is similar to that of the RF2 System. It is also intended to demonstrate that the subject can effectively recharge the implanted RC device on a weekly basis and the physician and staff can perform device programming and operation. The trial will study between four and ten subjects at sites outside the United States. Medical weight management programs such as diet, behavior modification, or exercise programs will be implemented. We plan to evaluate system performance and efficacy by measuring average percentage EWL at one, three and six months. We anticipate beginning enrollment in the first half of 2008 and will be periodically reporting safety and weight loss data during the trial in appropriate medical publications. Subjects will also be enrolled for long-term follow-up out to 24 months after completion.

### **EMPOWER Trial**

We have received IDE approval from the FDA for use of the Maestro System in our pivotal EMPOWER clinical trial. The EMPOWER trial is designed as a randomized, double-blind, placebo-controlled, prospective, multi-center study including a minimum of 220 subjects at 10 to 15 U.S. and international sites. We are in discussions with the FDA in response to questions raised as part of the IDE approval. We are in the process of submitting the trial protocol to the institutional review boards at our anticipated trial sites. We received the first institutional review board approval and started enrollment in July 2007. All EMPOWER subjects will be implanted with the Maestro System and randomized on a 2:1 basis to an active group, where therapy is turned on, or a control group, where therapy is turned off. A limited number of diabetic subjects will also be included in the trial and randomized 1:1.

The purpose of the EMPOWER trial is to measure the safety and efficacy of our Maestro System in obese subjects after 12 months of VBLOC therapy. The EMPOWER trial as currently approved is designed to evaluate the following objectives:

- The primary efficacy objective is to demonstrate a significantly greater percentage EWL with the Maestro System after 12 months of VBLOC therapy in the active group as compared to the control group. The trial is designed to demonstrate, with greater than 80% power, that there is an average of at least 17% EWL difference using the 1983 Metropolitan Life Tables, with a 97.5% confidence interval of 10% to 24%, between the active and control groups at 12 months. The Metropolitan Life Tables, introduced in 1943 and revised in 1983, set forth “ideal” weight ranges for adult men and women between the ages of 25 and 59 based on height and frame size. The underlying assumptions for the study are based on an average EWL of 25% or more at 12 months for the active group versus an EWL of 8% or less for the control group, with an actual difference between groups of at least seventeen percentage points. These assumptions are based on an extrapolation of the six month data from our VBLOC-I study.
- A secondary efficacy objective is to demonstrate a significant difference between the active group and the control group in the proportion of subjects who achieve an EWL of 25% or more at 12 months post-randomization. The power associated with this evaluation exceeds 95%.
- The primary safety objectives are to estimate the rate of serious system and procedure-related adverse events associated with the Maestro System and to estimate the rate of serious, therapy-related adverse events.

We intend to submit IDE supplements to the FDA proposing to increase the number of subjects to 300 and to relax the enrollment criteria for patients with the treated co-morbidities of hypertension and hyperlipidemia. We also intend to submit an IDE supplement to the FDA for the Maestro RC System as part of the EMPOWER trial.

The EMPOWER clinical data required for the PMA application is expected to be completed in the middle of 2009. Assuming these data are favorable, we intend to prepare and file our PMA application with the FDA. If approved, we would expect to commercially launch our Maestro System in the United States in 2010. Because the EMPOWER trial will be blinded, we will not be routinely reporting safety and EWL data until after the first year of the trial. After the first year, the trial will be unblinded and all subjects, including those in the control group, will have 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 and report on average percentage EWL and safety during this extended period.

Even if we complete the EMPOWER trial it may not produce results that are sufficient to support approval of a PMA application, or the FDA may require higher efficacy endpoints to approve our Maestro System. For example, the FDA has indicated to us that they believe that a 20 to 25 percentage point greater EWL than a control group is the appropriate efficacy criterion for the EMPOWER trial. Thus, there is a risk that, even if we achieve our endpoint, the FDA may not approve our system. To date, we have limited clinical data regarding the efficacy of our therapy at 12 months upon which to evaluate our ability to meet either our or the FDA’s proposed efficacy endpoint. Our results and our ability to obtain approval from the FDA for our Maestro System may also depend on the measurement standards we use to evaluate the EWL data. In addition, there is a risk that the FDA may require us to conduct a longer clinical trial, submit additional follow-up data, or engage in other costly and time consuming activities that may delay the FDA’s approval of the Maestro System.

## Research and Development

We have an experienced, 42-person 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 \$14.4 million in 2006, \$8.8 million in 2005 and \$1.8 million in 2004. We expect our research and development expenditures to increase as we continue to commit resources to developing our vagal neuroblocking technology.

### *Other Diseases and Disorders*

We believe that our VBLOC therapy may be used to treat a number of additional gastrointestinal disorders, including the following:

- **Metabolic Syndrome.** 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 as there appeared to be a beneficial relationship between EWL and diabetic control in our VBLOC-I trial. We plan to enroll a larger subset of diabetic patients in our EMPOWER trial to further explore the efficacy of VBLOC therapy in this patient population.
- **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 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.

We are considering, but have not yet initiated, studies of VBLOC therapy in these indications.

### *Mayo Clinic Relationship*

Our research and development team works with clinicians from Mayo Clinic Rochester, Minnesota pursuant to an exclusive know-how, license, and consulting agreement. 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 agreement with Mayo Clinic also includes 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. The Mayo Foundation receives an annual \$250,000 retainer fee which commenced in 2005 and continues through January 2009. We have also licensed-in four 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. In addition to the retainer fee we also issued 219,780 shares of common stock to the Mayo Foundation upon execution of the agreement in 2005. These

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shares were issued as partial consideration for Mayo patents and future patents and the obesity group know-how. We may also be obligated to issue up to 206,044 shares of common stock as consideration if future Mayo patents are issued or if the FDA approves a product patented by Mayo or jointly patented by Mayo and us. The issuance of these 206,044 shares of common stock will be accelerated in the event of an initial public offering, regardless of whether the conditions precedent to such issuance have been achieved or satisfied.

At any time after February 3, 2008, Mayo can terminate the license agreement without cause and upon such termination, the licenses granted to us by Mayo will become non-exclusive. Mayo Clinic Rochester has indicated that it will not participate in clinical trials, including our EMPOWER trial, due to its conflicts of interest guidelines. However, other Mayo Clinic locations may participate in our clinical trials and one such Mayo Clinic location is participating in our EMPOWER trial.

### **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 Safety Monitoring Board and our Therapy Algorithm Panel;
- 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.

As of September 30, 2007, our medical advisory group consisted of the following individuals:

<b>Name</b>	<b>Specialty</b>	<b>Institution</b>
Mehran Anvari, M.D., Ph.D.	Laparoscopic surgery	McMaster University
Charles J. Billington, M.D.	Bariatrics, endocrinology	University of Minnesota
Michael Camilleri, M.D.	Neurogastroenterology	Mayo Clinic Rochester
James W. Freston, M.D., Ph.D.	Gastroenterology, pharmacology	University of Connecticut
Miguel Herrera, M.D.	Bariatric surgery	Instituto Nacional de la Nutricion, SZ (Mexico)
Samuel Klein, M.D.	Bariatrics, gastroenterology/nutrition	Washington University
David E. Larson, M.D.	Gastroenterology	Mayo Clinic Rochester
Frank G. Moody, M.D.	Bariatric surgery	University of Texas Health Science Center
Michael Sarr, M.D.	Bariatric surgery	Mayo Clinic Rochester

We retain each medical advisor according to the terms of an advisory agreement. Under such agreements, we pay advisory fees (including in the form of grants of stock options) to, and reimburse the expenses of, members of our medical advisory group for the services they provide to us, with the amounts varying depending on the nature of the services. Our medical advisors are employed by institutions other than ours, and therefore may have commitments to, or consulting or advisory agreements with, other entities or academic institutions that may limit their availability to us. We paid to, or on behalf of, the current members of our medical advisory group aggregate advisory fees and reimbursements of \$198,890, \$263,334 and \$217,811 in the first nine months of 2007, and in years 2006 and 2005, respectively. In addition, we granted options to purchase 8,243 shares of our common stock in total to current members of our medical advisory group in each of 2006 and 2005. We also granted 8,242 shares of common stock in each of 2006 and 2005, respectively. We have not granted any shares or options in 2007.

## **Sales and Marketing**

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. Given the time required to locate and train appropriate personnel, we expect to commence that process prior to actually receiving FDA approval.

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 October 25, 2007, there were approximately 294 bariatric surgery Centers of Excellence approved by the Surgical Review Corporation and 45 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.

The primary focus of our sales efforts will be in 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.

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.

## **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.

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, Inc. as Meridia, and Orlistat, marketed by Roche as Xenical. In addition, numerous pharmaceutical companies are working on additional drug therapies that may prove effective in addressing obesity.

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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.

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 filed for FDA approval in April 2007 and received approval September 28, 2007 of their gastric band product known as the Swedish 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;
- 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;
- established distribution networks;
- greater experience in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals, obtaining reimbursement and marketing approved products; and

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- 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, or 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 relatively straight-forward as important structural elements are already in place. Physician claims for payment use Current Procedural Terminology, Fourth Edition, or 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, or 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. 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 four issued U.S. patents, two of which pertain to treating gastrointestinal disorders and we believe provide us with broad intellectual property protection covering electrically-induced vagal blocking and for treating obesity. Material among these is our U.S. Patent No. 7,167,750. Assuming timely payment of maintenance fees as they become due, this patent will expire in 2023. We also have 18 U.S. patent applications (including one provisional application), two international patent applications (PCT) and three national stage patent applications (including two European applications) in foreign jurisdictions. 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 four pending U.S. patent applications on medical device obesity treatments, which are unrelated to our VBLOC therapy.

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We also register the trademarks and trade names through which we conduct our business. To date, we have applied to register the trademarks “EnteroMedics”, “Maestro” and “VBLOC” vagal blocking therapy in the United States. Those applications have been published by the U.S. Patent and Trademark Office. In addition, we have trademark registrations or pending applications for our name and mark in Australia, China, Mexico, and the European Community. We may file additional trademark applications from time to time as deemed appropriate by management.

Our technology is the subject of several international patent applications we have filed in addition to our U.S. patents and applications. We are dedicated to continuing our patent activity to ensure that our patent portfolio remains reflective of our intellectual property development. New developments and modifications of prior developments are periodically reviewed to identify necessary additions and modifications to our patent portfolio.

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 for our Maestro RF System, which is the only system we have manufactured to date, 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.

Atrotech, located in Finland, currently manufactures our Maestro RF neuroregulators and coils under a supply agreement that extends through September 2010. Atrotech is contractually obligated to manufacture our products according to our purchase forecasts and to provide us with a one-year notice of any significant changes in its business that may negatively impact our supply of product, in which case we would receive an option to make a one-time purchase of devices in sufficient quantity to continue business with uninterrupted product supply for three years. We may solicit bids for the manufacture of our neuroregulators and coils at any time and are not required to notify Atrotech of the relevant terms of a superior bid. If we use Atrotech for commercial release of our device, Atrotech must be registered with the FDA and subject to related FDA factory inspection.

In the event that the Maestro System receives FDA 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. This plan relies on the experience, certification levels and large scale production capabilities of the suppliers and manufacturers that support the medical device market. 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.

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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. We plan to address potential future supply interruptions by ordering sufficient inventory stock to complete our pivotal EMPOWER trial. A delay in the approval process with the FDA for our Maestro System or a delay in our EMPOWER trial 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.

We believe that our current manufacturing and supply arrangements will be adequate to complete our EMPOWER trial. 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, or FDCA, and the regulations promulgated under the FDCA. Pursuant to the FDCA, 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, or 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

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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 FFCDA provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FFCDA, 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, or PMA, 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, but certain companies, like EnteroMedics, may qualify 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 or 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. We have received an IDE approval from the FDA for use of the Maestro System in our pivotal EMPOWER clinical trial in a letter dated June 22, 2007.

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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, or 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***

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, or 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 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 intend to apply for CE marking approval for sale of the Maestro System and expect to have final CE marking approval during 2008. 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 involves 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 will include a clinical evaluation of the conformity of the device with applicable regulatory requirements. We intend to use KEMA in the Netherlands as the Notified Body for our CE marking approval process.

### **Employees**

As of September 30, 2007, we had a total of 55 employees, consisting of 2 employees in reimbursement and marketing, 42 employees in research and development, including clinical, regulatory affairs and quality, and 11 employees in general and administrative functions. 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**

Our headquarters in St. Paul, Minnesota comprise approximately 11,130 square feet of leased space, which we sublease from Restore Medical, Inc. In addition, we share an additional 8,517 square feet of common space with Restore Medical, Inc. The leased space includes furnished office space and various research and development labs. The sublease agreement for our St. Paul facility expires on September 30, 2008.

### **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. 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 September 30, 2007:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Mark B. Knudson, Ph.D.	59	President, Chief Executive Officer, Chairman and Director
Greg S. Lea	55	Senior Vice President and Chief Financial Officer
Adrianus (Jos) Donders	54	Senior Vice President of Operations
Russ Felkey	57	Senior Vice President of Clinical, Quality and Regulatory Affairs
Katherine S. Tweden, Ph.D.	47	Vice President of Research
Mark R. Stultz	47	Vice President of Market Development and Reimbursement
Dennis D. Kim, M.D.	37	Vice President, Medical Affairs and Chief Medical Officer
Luke Evnin, Ph.D.(1)(2)	44	Director
Catherine Friedman(3)	47	Director
Carl Goldfischer, M.D.(2)(3)	49	Director
Bobby I. Griffin	70	Director
Donald C. Harrison, M.D.	73	Director
Paul H. Klingenstein(2)(3)	51	Director
Ellen Koskinas(1)	40	Director
Nicholas L. Teti, Jr.(1)	55	Director

(1) Member of compensation committee.

(2) Member of nominating and governance committee.

(3) Member of audit 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 serves as President and Chief Executive Officer of Venturi Group LLC and Venturi Development Inc., positions he has held since 1999 and 2001, respectively. From 1999 to the present, Dr. Knudson has also served as Chairman of the board of Restore Medical, Inc., a publicly-held medical device company focused on the treatment of sleep disordered breathing. Dr. Knudson is 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.

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*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.

*Russ Felkey* has served as our Senior Vice President of Clinical, Quality and Regulatory Affairs since April 2007 and our Vice President of Clinical, Quality and Regulatory Affairs since January 2005. From 2003 to 2005, Mr. Felkey was Group Vice President, Cardiovascular Regulatory Affairs for Boston Scientific Corporation. From 2002 to 2003, Mr. Felkey was Senior Director of Quality Assurance and Regulatory Affairs for Medtronic Inc. Mr. Felkey also served as Executive Vice President, Secretary to the board of directors for ATS Medical from 1991 to 2002. Prior to that Mr. Felkey held regulatory positions at Cardiovascular Imaging Systems, Inc., GV Medical, Inc. and Medtronic, Inc. Mr. Felkey received a Bachelor of Science in chemistry from the University of Iowa.

*Katherine S. Tweden, Ph.D.* has served as our Vice President of Research since January 2003. 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. 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.

*Mark R. Stultz* has served as our Vice President of Market Development and Reimbursement since April 2006 and as a consultant from July 2005 to April 2006. From April 2004 to July 2005, he served as Director of the Women's Health Business Unit at Gyrus Medical and from December 2001 to January 2004 he served as Director of Marketing for Female Pelvic Health at American Medical Systems. Prior to 2002, Mr. Stultz served in various management positions at Medtronic and at Advanced Bionics where he was involved in the marketing and development of multiple active implantable technologies including spinal cord stimulation, deep brain stimulation and cochlear stimulation. Mr. Stultz received a Bachelor of Science in physical therapy and a Masters degree in human factors engineering and ergonomics from the University of Wisconsin, Madison.

*Dennis D. Kim, M.D.* is a board-certified endocrinologist and has served as our Vice President, Medical Affairs and Chief Medical Officer since August 24, 2007. Prior to joining us he held various senior management positions at Amylin Pharmaceuticals, Inc., where he served since June of 2002, most recently as the Executive Director of Corporate Strategy. Prior to this, Dr. Kim was the program medical lead at Amylin for development and commercialization of Byetta<sup>®</sup> (exenatide) for treatment of type 2 diabetes. Dr. Kim has been an Assistant Professor of Medicine, Endocrinology/Metabolism at UCSD School of Medicine and San Diego VA Healthcare Systems since June of 2001. Dr. Kim received a Bachelor of Science in biology and animal behavior from the University of California at Los Angeles and a M.D. from the University of Health Sciences, The Chicago Medical School.

*Luke Evnin, Ph.D.* has served as one of our directors since inception in 1999. Dr. Evnin has served as a General Partner at MPM Capital since he joined as a co-founder in 1998. Prior to joining MPM, Dr. Evnin was at Accel Partners from 1991 to 1997 serving as a General Partner from 1994 to 1997. Dr. Evnin is also a director of Metabasis Therapeutics, Inc., a publicly-held biopharmaceutical company and Restore Medical, Inc., a publicly-held medical device company focused on the treatment of sleep disordered breathing. Dr. Evnin has served as director of other public companies, including Epix Medical, Inc., Sonic Innovations, Inc., and Signal Pharmaceuticals, Inc. and is currently a director of several private healthcare companies.

*Catherine Friedman* has served as one of our directors since May 2007. Ms. Friedman currently is an independent financial consultant serving private and public companies in the lifesciences. Prior to that, Ms. Friedman held numerous positions over a 24 year investment banking career with Morgan Stanley. Most

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recently, Ms. Friedman was 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 is currently a member of the board of XenoPort Inc., a publicly-held biopharmaceutical company, and also serves on its audit committee.

*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 Chief Financial Officer of ImClone Systems Incorporated, a public-held biotechnology company focused on developing therapeutic oncology products. 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 also serves on the boards and audit committees of several private companies.

*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 Corporation, 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 Sapient 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.

*Donald C. Harrison, M.D.* has served as one of our directors since September 2003. He is currently Managing Partner of Charter Life Sciences, a venture capital firm, where he has served since 2003. From 1986 to 2003, Dr. Harrison was Chief Executive Officer of the University of Cincinnati Medical Center. Dr. Harrison 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.

*Paul H. Klingenstein* has served as one of our directors since July 2006. He has served as Managing Partner of Aberdare Ventures since its formation 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. Mr. Klingenstein serves on the boards and audit committees of several private companies.

*Ellen Koskinas* has served as one of our directors since July 2006. Ms. Koskinas currently serves as a Partner with InterWest Partners, a venture capital firm focused on early stage investments in the medical technology sector. She joined InterWest in May 2002. Prior to joining InterWest, Ms. Koskinas was a Managing Director of a private equity firm in San Francisco and also started a new business in minimally invasive cardiac surgery for Guidant Corporation. Earlier in her career, she was an Engagement Manager for McKinsey & Company, managing consulting projects for a range of health care clients. Ms. Koskinas serves on the boards of several private companies.

*Nicholas L. Teti, Jr.* has served as one of our directors since May 2007. Mr. Teti is currently Chairman of the Board and Chief Executive Officer of Isolagen, Inc., a biotechnology company which develops emergent, novel skin and tissue rejuvenation technologies, positions he has held since June 2006. From 2001 to 2006, Mr. Teti was President and Chief Executive Officer of Inamed Corporation, primarily an aesthetics based company with business in saline and silicone breast implants, collagen and hyaluronic-based wrinkle correcting devices and the LAP-BAND® Adjustable Gastric Banding System, a surgically implantable device for obesity treatment. Mr. Teti also served as a member of 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 CEO of DuPont Pharmaceuticals.

There are no family relationships among any of our directors or our executive officers. Each executive officer is elected or appointed by, and serves at the discretion of, our board of directors.

## **Board of Directors**

Our board of directors currently consists of nine directors, all of whom were elected as directors pursuant to a voting agreement among the Company and its stockholders that is contained within the Company's investors rights agreement. The provisions of the voting agreement will terminate upon the completion of the offering made by this prospectus. We have not yet adopted procedures by which security holders may elect nominees to our board of directors, but plan to do so upon the completion of this offering. Dr. Knudson is currently Chairman of our board.

Upon completion of this offering, our bylaws will be amended and restated to provide that the authorized number of directors may be changed only by resolution of the board of directors. Upon the closing of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election or until their earlier death, resignation or removal. Our directors have been divided among the three classes as follows:

- Class I directors will be Drs. Goldfischer and Harrison and Ms. Koskinas, and their terms will expire at the annual meeting of stockholders to be held in 2008;
- Class II directors will be Messrs. Griffin and Klingenstein and Dr. Evnin, and their terms will expire at the annual meeting of stockholders to be held in 2009; and
- Class III directors will be Dr. Knudson, Ms. Friedman and Mr. Teti, and their terms will expire at the annual meeting of stockholders to be held in 2010.

This classification of the board of directors, together with the ability of the stockholders to remove our directors only for cause and the inability of stockholders to call special meetings, may have the effect of delaying or preventing a change in control or management. See "Description of Capital Stock—Anti-takeover Provisions" for a discussion of other anti-takeover provisions found in our certificate of incorporation.

Commencing in fiscal year 2007, our board of directors will review at least annually the independence of each director. During these reviews, the board will consider transactions and relationships between each director (and his or her immediate family and affiliates) and our company and its management to determine whether any such transactions or relationships are inconsistent with a determination that the director is independent. This review will be based primarily on responses of the directors to questions in a directors' and officers' questionnaire regarding employment, business, familial, compensation and other relationships with EnteroMedics and our management.

In July 2007, our board of directors determined that no transactions or relationships existed that would disqualify any of our directors under Nasdaq Stock Market rules or require disclosure under Securities Exchange Commission rules, with the exception of Dr. Knudson, our President and Chief Executive Officer, because of his employment relationship with EnteroMedics, and Mr. Griffin and Dr. Harrison, because of their consulting relationships with EnteroMedics. Based upon that finding, our board determined that Drs. Evnin and Goldfischer, Mses. Friedman and Koskinas and Messrs. Klingenstein and Teti are "independent" and that the composition of our board of directors meets the requirements for independence under the current requirements of the Nasdaq Global Market. Each of our Audit, Nominating and Governance and Compensation Committees is composed only of independent directors. As required by the Nasdaq Global Market, we anticipate that our independent directors will meet in regularly scheduled executive sessions at which only independent directors are present. We intend to comply with future governance requirements to the extent they become applicable to us.

## **Corporate Governance**

We believe that good corporate governance is important to ensure that, as a public company, we will be managed for the long-term benefit of our stockholders. In preparation for the offering being made by this prospectus, we and our board of directors have been reviewing the corporate governance policies and practices of

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other public companies, as well as those suggested by various authorities in corporate governance. We have also considered the provisions of the Sarbanes-Oxley Act and the rules of the SEC and the Nasdaq Global Market.

Based on this review, our board of directors has taken steps to implement many of these provisions and rules. In particular, we have established and adopted charters for the audit committee, compensation committee and nominating and corporate governance committee, as well as a code of business conduct and ethics applicable to all of our directors, officers and employees.

### **Board Committees**

Our board of directors has established a standing audit committee, a compensation committee, and a nominating and governance committee. In July 2007, our board determined that the members of each of these standing committees were independent as defined under the rules of the Nasdaq Global Market and, in the case of the audit committee, satisfied the independence requirements contemplated by Rule 10A-3 under the Securities Exchange Act of 1934, as amended.

*Audit Committee.* Ms. Friedman, Dr. Goldfischer and Mr. Klingenstein serve on our audit committee. Ms. Friedman serves as chair of the audit committee and Ms. Friedman and Dr. Goldfischer are the audit committee's financial experts within the meaning of the regulations of the SEC. In July 2007, our board determined that all members of the audit committee met the composition requirements of the Nasdaq Global Market, including the requirements regarding financial literacy and financial sophistication. The audit committee's primary responsibilities include:

- appointing, approving the compensation of, and assessing the qualifications and independence of our independent registered public accounting firm, which currently is Deloitte & Touche LLP;
- overseeing the work of our independent registered public accounting firm, including the receipt and assessment of reports from the independent registered public accounting firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statements;
- monitoring our internal control over financial reporting, disclosure controls and procedures;
- reviewing our risk management status;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting related complaints and concerns;
- meeting independently with our independent registered public accounting firm and management; and
- monitoring compliance with the code of ethics for financial management.

All audit and non-audit services must be approved in advance by the audit committee. Our board of directors has adopted a written charter for the audit committee which will be available on our website at [www.enteromedics.com](http://www.enteromedics.com) upon the completion of this offering.

*Compensation Committee.* Ms. Koskinas, Mr. Teti and Dr. Evnin serve on our compensation committee. Dr. Evnin is the chair. Dr. Knudson and Dr. Harrison may be invited as observers on the compensation committee at the discretion of the committee. Dr. Knudson is not present during voting or deliberations by the committee regarding his compensation. The compensation committee's responsibilities include:

- annually reviewing and approving corporate goals and objectives relevant to compensation of our chief executive officer;

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- determining the compensation of our chief executive officer;
- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our other executive officers;
- overseeing an evaluation of our senior executives; and
- overseeing and administering our cash and equity incentive plans.

The Chief Executive Officer makes compensation recommendations for our other executive officers and initially proposes the corporate and departmental performance objectives under our Management Incentive Plan to the compensation committee. From time to time, the compensation committee may use outside compensation consultants to assist it in analyzing our compensation programs and in determining appropriate levels of compensation and benefits, although the compensation committee has not used the services of a compensation consultant to date. For more information on the processes and procedures followed by the compensation committee for the consideration and determination of executive compensation see the section entitled “Compensation Discussion and Analysis.” Our board of directors has adopted a written charter for the compensation committee which will be available on our website at [www.enteromedics.com](http://www.enteromedics.com) upon the completion of this offering.

*Nominating and Governance Committee.* Drs. Goldfischer and Evin and Mr. Klingenstein serve on our nominating and governance committee. Dr. Goldfischer is the chair. Mr. Griffin may be invited as an observer on the nominating and governance committee at the discretion of the committee. The nominating and governance committee’s responsibilities include:

- identifying individuals qualified to become members of our board of directors;
- recommending to our board the persons to be nominated for election as directors and to each of our board’s committees;
- reviewing and making recommendations to our board with respect to management succession planning;
- developing, updating and recommending to our board corporate governance principles and policies;
- overseeing the evaluation of our board; and
- reviewing and making recommendations to our board with respect to director compensation.

Our board of directors has adopted a written charter for the nominating and governance committee which will be available on our website at [www.enteromedics.com](http://www.enteromedics.com) upon the completion of this offering.

### **Compensation Committee Interlocks and Insider Participation**

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or its compensation committee. None of the current members of the compensation committee of our board has ever been one of our employees.

### **Director Compensation**

Prior to this offering, non-employee members of our board of directors did not receive any cash compensation for service on our board, including attending board meetings. However, we did reimburse our non-employee directors for travel, lodging and other reasonable expenses incurred in attending board and committee meetings. In addition, from time to time we have granted stock options to some of our directors. In

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fiscal year 2006, Bobby I. Griffin was the only non-employee director who received compensation in the form of equity in connection with his service as a non-employee director. We granted Mr. Griffin an option to purchase 109,891 shares of our common stock at \$1.91 per share in September 2006 pursuant to our 2003 Stock Incentive Plan. Mr. Griffin's stock option vests twenty-five percent on the first anniversary of the grant with the remainder vesting monthly thereafter in 36 equal monthly installments.

Upon the effectiveness of this offering, each of our non-employee directors who has been a member of our board of directors for at least one year prior to completion of this offering will receive an option to purchase 25,000 shares of our common stock at an exercise price equal to the offering price to the public of our common stock. Twenty-five percent of these options will vest immediately with the remainder to vest in 36 equal monthly installments following the effectiveness of the registration statement of which this prospectus is a part. Following this offering, each non-employee director will receive an annual retainer of \$7,500. In addition, each non-employee director will receive \$2,500 per meeting of the board of directors attended in person or \$1,000 per meeting attended telephonically, and each committee member will receive \$750 per meeting attended of their respective committees.

Each non-employee director who serves on the audit committee, other than the chairperson of the audit committee, will receive an additional annual retainer of \$1,500. The chairpersons of the audit committee, the compensation committee and the nominating and corporate governance committee will also receive additional annual retainers of \$10,000, \$4,000 and \$4,000, respectively.

Each non-employee director who first becomes a member of our board of directors after the completion of this offering will be granted an option to purchase 25,000 shares of our common stock. Twenty-five percent of these options will vest immediately with the remainder to vest in 36 equal monthly installments following the offering. After the completion of this offering, each non-employee director that continues as a non-employee director will be entitled to receive an annual option grant to purchase 10,000 shares of our common stock. Twenty-five percent of these options will vest immediately with the remainder to vest in 36 equal monthly installments following the offering. Each such option will have an exercise price equal to the price of the last trade of our common stock on the date of grant and will have a ten-year term subject to earlier termination in connection with a termination of directorship.

The following table sets forth a summary of the compensation received by our only non-employee director who received compensation during our fiscal year ended December 31, 2006:

### Director Compensation

<u>Name</u>	<u>Option Awards (\$)</u> <u>(1)</u>	<u>Total (\$)</u>
Bobby I. Griffin	\$ 7,949	\$7,949

- (1) The amount in this column is the compensation cost recognized by us in fiscal year 2006 related to grants of stock options, as prescribed under the SFAS 123R and based on the financial statement compensation expense as reported in our consolidated statements of operations for the fiscal year ended December 31, 2006, excluding the impact of forfeitures. For a discussion of valuation assumptions, see Note 13 (Stock Options) to our audited consolidated financial statements for the fiscal year ended December 31, 2006 included as part of this prospectus. Mr. Griffin received a stock option grant in 2006 of 109,891 shares with a SFAS 123R grant date fair value based on the Black-Scholes model of option valuation of \$1.1557 per share. This option vests over a four-year period with 25% vesting on the one-year anniversary and the remainder vesting monthly thereafter for three years. As of December 31, 2006, Mr. Griffin was our only non-employee director with outstanding options. He held 164,837 options as of that date.

## EXECUTIVE COMPENSATION

### **Compensation Discussion and Analysis**

This Compensation Discussion and Analysis describes the compensation policies and programs for our named executive officers, which consist of our Chief Executive Officer, our Controller, who served as our principal financial and accounting officer during fiscal year 2006, our three next most highly paid executive officers as determined under the rules of the SEC, and Virginia M. Kirby, our former Vice President of Clinical and Reimbursement, and Richard R. Wilson, our former Vice President of Clinical and Chief Medical Officer, who would have been one of our three most highly paid executive officers as of December 31, 2006, but whose employment ended effective April 14, 2006 and July 15, 2006, respectively.

From July 2006 to April 2007, the compensation committee, acting together with the board of directors, determined the compensation programs for our executive officers. Commencing April 27, 2007, our board of directors appointed independent directors to the compensation committee and formally adopted a charter outlining the responsibilities of the committee. This new compensation committee oversees 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 the compensation programs and all forms of compensation for our other executive officers. The Chief Executive Officer participates as an observer at the compensation committee's meetings at the committee's request. He also makes recommendations with respect to other executives' compensation. The Chief Executive Officer does not make a recommendation as to his own compensation, however, and although he may respond to the compensation committee's proposal for his compensation, he has no authority with respect to the determination of his own compensation. His compensation package is set by the compensation committee in its sole discretion.

### ***Compensation Philosophy***

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 that are contingent upon our achievement of specific pre-determined performance objectives as communicated to the executives following their determination by 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.

### ***Compensation Determination Process and Components***

During 2006 and prior years, compensation was based generally on programs and compensation levels that were historically in place. Thus, 2006 salaries reflect salaries in place in 2005 and prior years. Historically, the board of directors established the performance objectives of the annual cash incentive Management Incentive Plan during the first half of the year. 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

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the review of our annual performance. For the 2007 compensation review process, the compensation committee began by reviewing the 2006 MEDIC Executive Compensation Survey, a third-party survey, using base salaries paid by comparably-sized, private and publicly-traded medical device companies with annual revenues less than \$100 million to benchmark our competitive position. Although we have not adopted any formal guidelines for benchmarking base salaries or other forms of compensation, we believe that our executives' base salaries are generally at the 50<sup>th</sup> percentile, compared to such companies. Base salaries for our executive officers were set preliminarily using the 2006 MEDIC Executive Compensation Survey as a reference point. The 2006 MEDIC Executive Compensation Survey covers compensation at 53 public and 12 private medical device companies for benchmarking purposes. Our policy for determining the allocation between long-term and currently-paid compensation is to ensure adequate base compensation to attract and retain our executive officers, while providing incentives to maximize long-term value for the company and our stockholders. We provide cash compensation in the form of base salary that is competitive with the base salaries paid by comparable companies and provide cash bonus compensation to reward performance against specific short-term goals. These short-term goals vary depending on the individual executive and also vary year-to-year as they are established by the compensation committee annually. They relate generally to strategic, financial and operational factors such as clinical trial progress, research and development projects, continued establishment of intellectual property and implementation of appropriate financing strategies. For a description of the short-term goals set for fiscal 2006 and 2007, see the "Annual Cash Incentives" section below. The compensation committee believes that the annual performance bonus provides incentives necessary to retain executive officers and reward them for our short-term company performance.

In particular, with respect to our Chief Executive Officer, the compensation committee reviews and approves corporate goals and objectives relevant to the Chief Executive Officer's compensation, evaluates the Chief Executive Officer's performance in light of those goals and objectives and determines and approves the Chief Executive Officer's compensation based on this evaluation.

The Chief Executive Officer participates as an observer in the compensation committee's meetings at the committee's request. Management does not participate in the determination of the amount or form of executive compensation, except that the Chief Executive Officer makes compensation recommendations for the other executive officers, which the compensation committee may, but is not required to, consider. In addition, 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's compensation package is set by the compensation committee in its sole discretion. For 2006, the Chief Executive Officer's base salary and annual cash incentive were consistent with his executive employment agreement entered into on June 22, 2005, and his stock-based incentive award was determined by the compensation committee without the participation or response of the Chief Executive Officer.

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 following this offering.

### **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 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. The base salaries for each of our named executive officers for 2006, except Dr. Tweden and Mr. Brooks, were determined by the board of directors at the time of hire and were unchanged in 2006. Our Chief Executive Officer set the amount of base

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compensation received in 2006 by Dr. Tweden and Mr. Brooks. The agreement with our Chief Executive Officer, which was entered into in June 2005, provides for a minimum base salary of \$300,000. In 2007, the compensation committee reviewed each individual's experience, each individual's performance during the prior year, market factors including the salary levels of comparable positions in the medical device industry using third-party survey information, and other publicly available data of comparable companies. For 2007, the compensation committee approved an across the board salary increase of four percent for all named executive officers, except for Mr. Brooks who received a \$5,000 market-based compensation adjustment and a five percent increase of his adjusted salary. The four percent across the board salary increase was based on the judgment of the compensation committee, taking into account the 50<sup>th</sup> percentile of the average 2007 projected salary merit increase in the 2006 MEDIC Executive Compensation Survey.

The compensation committee has adopted a practice of reviewing base salaries annually. Additionally, we 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.

### **Annual Cash Incentives**

Our Management Incentive Plan, which commenced with our 2005 fiscal year, is designed to provide executive officers with annual incentive compensation based on the achievement of certain pre-established corporate and departmental performance objectives. This program blends objective and subjective performance factors critical to our success. At the beginning of each year, the plan's performance objectives are initially proposed by our Chief Executive Officer. In 2005 and 2006, the objectives were then reviewed, revised and approved by the board of directors. Beginning in 2007, the objectives were recommended by the compensation committee and approved by the board of directors. "Target" objectives are assigned to each performance measure to determine payouts. If targets are not met, the board of directors has the discretion to consider the extent to which the targets were met in awarding bonuses, if any. As necessary, the compensation committee may modify or re-weight the objectives during the course of the fiscal year to reflect changes in our business plan. No modifications were made during 2006.

For fiscal year 2006, our performance objectives consisted of the corporate goals of enrolling our target of 31 subjects in our VBLOC-I clinical trial and obtaining data on excess weight loss at one, three and six months following implantation as well as the financial goal of closing our Series C financing. The financial goal was weighted to represent 33% of the total bonus, and the corporate goals were weighted to represent an aggregate 67% of the total bonus. These percentages were determined at the time that the performance objectives were set and were based upon a relative-weighting concept whereby the compensation committee determined that the achievement of the Company's strategic corporate goals was of greater benefit to the Company's overall performance given the Company's development stage status. If these objectives were met, the named executive officers were entitled to receive a bonus equal to a certain percentage of their base salary for the year set forth in the table below:

Mark B. Knudson	30%
Adrianus (Jos) Donders	25%
Russ Felkey	20%
Katherine S. Tweden	20%
David Brooks	15%

At its February 6, 2007 meeting, the compensation committee reviewed the achievement of the financial and corporate objectives in awarding bonuses under the Management Incentive Plan, and concluded that 100% of the 2006 performance objectives had been met. The board of directors, upon the recommendation of the compensation committee, approved the bonus awards for FY 2006 performance on February 6, 2007. As a result, bonus awards of \$90,000, \$17,081, \$58,750, \$46,000 and \$40,000 were awarded to Dr. Knudson, Mr. Brooks, Mr. Donders, Mr. Felkey and Dr. Tweden during the first quarter of fiscal year 2007. Ms. Kirby and Dr. Wilson did not receive bonus awards under the 2006 Management Incentive Plan because their employment with us was terminated on April 14, 2006 and July 15, 2006, respectively.

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In the first half of 2006, the board, after review of the company's accomplishments and performance, established an employee bonus pool and awarded bonuses to persons who were not participants in the Management Incentive Plan for fiscal 2005. As a result, Mr. Brooks and Dr. Tweden were awarded bonuses out of the employee pool of \$700, and \$2,500, respectively.

In the first quarter of 2007, the compensation committee established the performance objectives under the Management Incentive Plan for 2007 and included an individual performance component for certain executive officers, weighted as follows:

<u>Title</u>	<u>Corporate Objective Weighting</u>	<u>Individual Objective Weighting</u>
President and CEO	100%	0%
Senior Vice President	90%	10%
Vice President	75%	25%
Controller	40%	60%

In addition, the compensation committee established corporate performance objectives for 2007 consisting of the completion of certain milestones related to our VBLOC clinical trials, including our EMPOWER pivotal trial, expanding our management team and meeting financial budgetary goals related to revenue and expense objectives. In the event that some but not all of the corporate goals are achieved, the board, in its discretion, may determine to award partial 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. In 2003, we also sold shares of restricted stock to our executive officers and other employees for \$0.09 per share, the then fair market value of the common stock, which shares were subject to a Share Restriction Agreement, that gives us the option to repurchase all unvested shares when the executive ceases to provide services to us. The shares vest 1/48<sup>th</sup> per month.

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 has used stock options, rather than other forms of long-term incentives, because they create value for the executive 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.

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 generally vest twenty-five (25%) percent on the first anniversary of the date of grant, or the date of hire if it is associated with a new hire grant, 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 some stock options issued to our executive officers 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 board of directors approves the option grant.

The board of directors does not award stock options according to a prescribed formula or target. In determining the number of stock options granted to executive officers, individual responsibilities and experience,

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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.

In April 2006, the compensation committee recommended, and the board of directors approved, stock option grants for 40,660, 34,616, 24,726, 15,935 and 2,199 shares to Dr. Knudson, Mr. Donders, Mr. Felkey, Dr. Tweden and Mr. Brooks, respectively. 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. In December 2006, the compensation committee recommended, and the board of directors approved, a stock option grant for 27,154 shares to Mr. Brooks based on his promotion from Assistant Controller to Controller, the job responsibilities of Mr. Brooks in such position, and the compensation committee's subjective determination of the appropriate level of equity incentives commensurate with Mr. Brooks' expertise and responsibilities.

### ***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 Dr. Knudson and Messrs. Lea, Donders and Felkey. These agreements establish a specified minimum base compensation and a maximum percentage of annual incentive compensation that may be earned by the each of these executive officers in a given year. In addition, these agreements provide for the payment of severance benefits upon certain termination events with Dr. Knudson and Messrs. Lea, Donders and Felkey 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

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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 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 will not be allowed a federal income tax deduction for compensation paid to certain executive officers to the extent that compensation exceeds \$1 million per officer in any one year. This limitation will apply to all compensation paid to the covered executive officers which is not considered to be performance-based. Compensation which does qualify as performance-based compensation will 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 2006 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 year ended December 31, 2006.

#### **Summary Compensation Table**

<b>Name and Principal Position</b>	<b>Year</b>	<b>Salary (\$)</b>	<b>Bonus \$(1)</b>	<b>Option Awards \$(2)</b>	<b>Non- equity Incentive Plan Compensation \$(3)</b>	<b>All Other Compensation \$(4)</b>	<b>Total (\$)</b>
Mark B. Knudson <i>President and Chief Executive Officer</i>	2006	\$300,000	\$ —	\$ 1,911	\$90,000	\$ 5,073	\$396,984
David C. Brooks(5) <i>Controller</i>	2006	109,417	700	862	17,081	—	128,060
Adrianus (Jos) Donders <i>Senior Vice President of Operations</i>	2006	235,000	—	1,627	58,750	5,546	300,923
Russ Felkey <i>Senior Vice President of Clinical, Quality and Regulatory Affairs</i>	2006	230,000	—	1,162	46,000	5,627	282,789
Katherine S. Tweden <i>Vice President of Research</i>	2006	191,875	2,500	749	40,000	5,546	240,670
Virginia M. Kirby(6) <i>Former Vice President of Clinical and Reimbursement</i>	2006	63,461	—	1,224	—	86,145(7)	150,830
Richard R. Wilson(8) <i>Former Vice President of Clinical and Chief Medical Officer</i>	2006	123,933	—	10,922	—	101,602(9)	236,457

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- (1) Under current reporting rules, only discretionary or guaranteed bonuses are disclosed in this column. Mr. Brooks and Dr. Tweden received bonus payments in 2006 related to the employee bonus pool. Employee bonuses are paid at the discretion of the board.
- (2) The amount in this column is based on the compensation cost we recognized for financial statement reporting purposes with respect to the year ended December 31, 2006 in accordance with SFAS 123R, excluding the impact of forfeitures and assuming that we used the minimum value method prescribed by APB 25 for reporting awards granted prior to January 1, 2006. The assumptions we used for calculating the compensation cost are disclosed in Note 13 (Stock Options) to our consolidated financial statements for the fiscal year ended December 31, 2006 included as part of this prospectus. The amounts in this column reported for Ms. Kirby and Dr. Wilson are the compensation costs related to options that were revalued during fiscal year 2006 in accordance with SFAS 123R as a result of modifications to the original stock option grants. See footnotes (6) and (7) to the “Grants of Plan-Based Awards” table for more details regarding these revaluations.
- (3) Represents bonuses earned in 2006 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.”
- (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 in 2006. 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.
- (5) Mr. Brooks served as our principal financial and accounting officer during fiscal year 2006. On May 17, 2007, Gregory S. Lea accepted our offer as Senior Vice President and Chief Financial Officer and commenced his employment with us effective May 21, 2007.
- (6) Ms. Kirby’s employment with the company was terminated effective April 14, 2006.
- (7) Includes \$11,583 for paid time off (PTO) that was cashed out upon Ms. Kirby’s termination and \$71,375 paid to Ms. Kirby pursuant to a consulting agreement she entered into with the company to provide three-months of transition services following her departure. Ms. Kirby did not receive any severance payments in connection with her termination.
- (8) Mr. Wilson’s employment with the company was terminated effective July 15, 2006.
- (9) Includes \$26,400 for paid time off (PTO) that was cashed out upon Dr. Wilson’s termination and \$71,500 paid to Dr. Wilson pursuant to a consulting agreement he entered into with the company following his termination. Dr. Wilson continues to provide services to us pursuant to this agreement. Dr. Wilson did not receive any severance payments in connection with his termination.

**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 2006.

**Grants of Plan-Based Awards**

Name	Grant Date	Estimated future payouts under non-equity incentive plan awards(1)			All other option awards: number of securities underlying options (#)	Exercise or base price of option awards (\$/Sh)	Grant date fair value of option awards \$(2)
		Threshold (\$)	Target (\$)	Maximum (\$)			
Mark B. Knudson	2/16/06	\$ —	\$90,000	\$ —	—	\$ —	\$ —
	4/20/06	—	—	—	40,660(3)	0.46	11,467
David C. Brooks	2/16/06	—	17,081	—	—	—	—
	4/20/06	—	—	—	550(4)	0.46	132
	4/20/06	—	—	—	—	0.46	465
	12/7/06	—	—	—	1,649(3)	1.91	31,311
				27,154(5)			
Adrianus (Jos) Donders	2/16/06	—	58,750	—	—	—	—
	4/20/06	—	—	—	34,616(3)	0.46	9,762
Russ Felkey	2/16/06	—	46,000	—	—	—	—
	4/20/06	—	—	—	24,726(3)	0.46	6,973
Katherine S. Tweden	2/16/06	—	40,000	—	—	—	—
	4/20/06	—	—	—	15,935(3)	0.46	4,494
Virginia M. Kirby	2/16/06	—	44,000	—	—	—	—
	—	—	—	—	—	—	1,224(6)
Richard R. Wilson	2/16/06	—	45,760	—	—	—	—
	—	—	—	—	—	—	10,922(7)

- (1) Represents the potential value of bonuses that could have been earned under our Management Incentive Plan. The target bonus for each executive officer will be a percentage of the respective base salary for the executive officer. Under the Management Incentive Plan for 2006, Dr. Knudson could have earned a bonus up to 30% of his base salary, Mr. Donders could have earned a bonus of 25% of his base salary, Mr. Felkey and Drs. Wilson and Tweden and Ms. Kirby could have earned a bonus of 20% of each of their respective base salaries and Mr. Brooks could have earned a bonus of 15% of his base salary. Under the Management Incentive Plan, the board of directors establishes certain target financial and corporate objectives for each fiscal year. If these objectives are met, then the target bonus is payable. If any of the objectives are not met, or if they are exceeded, the board of directors has the discretion to make appropriate adjustments, but the plan does not provide for any formulaic adjustments or payments to be made in those circumstances. Commencing in 2007, the bonuses 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 executive officers in 2006 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 under SFAS 123R. The assumptions used to arrive at the Black-Scholes value are disclosed in Note 13 (Stock Options) to our consolidated financial statements for the fiscal year ended December 31, 2006 included as part of this prospectus, excluding the impact of forfeitures.
- (3) These stock options were granted under our 2003 Stock Incentive Plan and vest 25% on the first anniversary of the date of grant, and 1/36<sup>th</sup> per month for 36 months thereafter.

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- (4) This stock option was granted under our 2003 Stock Incentive Plan and vests 100% upon the date of grant.
- (5) This stock option was granted under our 2003 Stock Incentive Plan and vests 25% on December 1, 2007, and 1/36<sup>th</sup> per month for 36 months thereafter.
- (6) In connection with Ms. Kirby's termination, the board of directors approved a modification to her stock options on April 20, 2006, which eliminated the cliff vesting to give her the right to exercise the six months worth of options she had vested through her termination date. The amount in the table above represents the incremental fair value for this modification to the original stock option grant computed as of April 20, 2006 in accordance with SFAS 123R.
- (7) Following his termination, Dr. Wilson entered into a consulting agreement pursuant to which his remaining outstanding options continued to vest in accordance with our standard vesting terms. As a non-employee, these options are remeasured at the end of each reporting period under SFAS 123R and pursuant to the guidance of EITF 96-18. The amount in the table above represents the incremental fair value for the remeasurements on September 30, 2006 and December 31, 2006, which was \$5,484 and \$5,438, respectively.

## Employment Agreements

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

On June 22, 2005, we entered into an executive employment agreement with Dr. Knudson, our Chief Executive Officer and President. 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 exceed 30% of his base salary for that year. Dr. Knudson's executive employment agreements 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 Russ Felkey*

In 2007, 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 Mr. Felkey, our Senior Vice President of Clinical, Quality and Regulatory Affairs. 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 establish that the target amount of these executives' annual incentive compensation may not exceed 25% of their respective base salary for that year.

Greg S. Lea	\$ 245,000
Adrianus (Jos) Donders	235,000
Russ Felkey	230,000

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, 2006. Virginia M. Kirby did not hold any outstanding equity awards on December 31, 2006, due to the termination of her employment on April 14, 2006.

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

Name	Option awards				Stock awards	
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock Held That Have Not Vested (#)(1)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(2)
Mark B. Knudson	54,250	15,201(3)	\$ 0.46	8/16/14	—	\$ —
	47,495	—(4)	0.46	4/27/15	4,121(7)	32,968
	—	40,660(5)	0.46	4/20/16	—	—
David C. Brooks	3,200	8,614(8)	0.46	11/21/15	—	—
	550	—(9)	0.46	4/20/16	—	—
	—	1,649(5)	0.46	4/20/16	—	—
	—	27,154(6)	1.91	12/7/16	—	—
Adrianus (Jos) Donders	36,631	51,282(8)	0.46	4/11/15	—	—
	21,979	—(4)	0.46	4/27/15	—	—
	—	34,616(5)	0.46	4/20/16	—	—
Russ Felkey	7,625	21,176(8)	0.46	1/1/15	—	—
	—	24,726(5)	0.46	4/20/16	—	—
Katherine S. Tweden	44,190	16,964(10)	0.46	8/16/14	366(7)	2,928
	1,099	—(4)	0.46	4/27/15	441(11)	3,528
	—	15,935(5)	0.46	4/20/16	—	—
Richard R. Wilson(12)	—	21,061(13)	0.46	8/16/14	—	—

- (1) Represents shares purchased by the executive in 2003 and currently unvested pursuant to Share Restriction Agreements. The unvested shares are subject to a right of repurchase that lapses as to 1/48<sup>th</sup> of the shares on the last day of each month beginning on a date specified in the agreements. See footnotes (6) and (10) below. The repurchase right allows us to purchase the unvested shares from the named executive officer at the original purchase price from such officer in the event that he or she no longer provides services to us as either an employee or consultant. Such repurchase right also lapses in full in the event of a change in control and such officer's employment is involuntary or constructively terminated.
- (2) The market value of the shares of stock that have not vested has been calculated by multiplying the number of shares times \$8.00, the initial public offering price.
- (3) Stock options vest 32,968 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.
- (4) 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, besides the ten-year term of the option. The milestone was achieved in March 2006.
- (5) 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.
- (6) Stock options vest 25% on December 1, 2007, and 1/36<sup>th</sup> per month for 36 months thereafter.

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- (7) The right to repurchase with respect to these shares lapses, as described in footnote (1) above, beginning on April 30, 2003.
- (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. The hire dates related to these options are November 21, 2005, April 11, 2005 and January 1, 2005 for Messrs. Brooks, Donders and Felkey, respectively.
- (9) Stock options vest 100% immediately upon the date of grant.
- (10) Stock options vest 20,440 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) The right to repurchase with respect to these shares lapses, as described in footnote (2) above, beginning on November 30, 2003.
- (12) Dr. Wilson’s employment with the company was terminated effective July 14, 2006. Dr. Wilson subsequently entered into a consulting agreement with the company pursuant to which his remaining outstanding options continued to vest in accordance with our standard vesting terms.
- (13) Stock options continue to vest at 1/36<sup>th</sup> per month.

### Option Exercises and Stock Vested

The following table summarizes the option exercises by our named executive officers and the vesting of stock options held by such officers during our fiscal year ended December 31, 2006:

#### Option Exercises and Stock Vested

Name	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)(1)	Number of Shares Acquired on Vesting (#)(2)	Value Realized on Vesting (\$)(3)
Mark B. Knudson	—	\$ —	12,363	\$ 98,904
David C. Brooks	—	—	—	—
Adrianus (Jos) Donders	—	—	—	—
Russ Felkey	17,353	130,928	—	—
Katherine S. Tweden	—	—	1,580	12,640
Virginia M. Kirby	5,082	38,344	—	—
Richard R. Wilson	17,949	135,425	—	—

- (1) The value realized is determined by multiplying the number of shares acquired on exercise by \$8.00, the initial public offering price, net of the exercise price for acquiring the shares.
- (2) Vesting relates to shares purchased by the executives in 2003 and subject to Share Restriction Agreements dated October 3, 2003 and October 20, 2003. The shares are subject to a right of repurchase by the company that lapses as to 1/48<sup>th</sup> of the shares on the last day of each month beginning on April 30, 2003 or November 30, 2003 as specified in the agreements. The right of repurchase fully lapsed with respect to Dr. Knudson’s 49,450 shares and Dr. Tweden’s 4,396 shares as of April 30, 2007. The right of repurchase will fully lapse with respect to Dr. Tweden’s additional 1,923 shares as of November 30, 2007.
- (3) The value realized is determined by multiplying the number of shares vested by \$8.00, the initial public offering price.

### 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 have entered into Executive Employment Agreements with Mark B. Knudson, Greg S. Lea, Adrianus (Jos) Donders and Russ Felkey providing 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 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 12 months of continued health benefits. In the event that Messrs. Donders or Felkey'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 12 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 his termination, and (3) receive continued health benefits for a period of 12 months following the termination date. In the event that Messrs. Lea, Donders or Felkey 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. Dr. Knudson and Messrs. Lea, Donders and Felkey's 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 in which the employment of these executive officers is not terminated, the agreement provides 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 either 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.

In addition, in the event of a change in control and termination of employment, our right to repurchase shares of restricted stock subject to the Share Restriction Agreements will immediately and fully lapse. The only named executive officers holding such shares are Drs. Knudson and Tweden. At December 31, 2006, the value of the shares held by Drs. Knudson and Tweden for which this repurchase right had not lapsed is provided above in the "Outstanding Equity Awards at Fiscal Year-End" table. On April 30, 2007, the repurchase right fully lapsed with respect to Dr. Knudson's 4,121 shares and Dr. Tweden's 366 shares and on November 30, 2007, it will fully lapse with respect to Dr. Tweden's other 441 shares.

**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 and Mr. Lea upon termination without cause, resignation for good reason and change in control of EnteroMedics, with or without termination, based on the initial public offering price. The amounts shown assume that termination or change in control was effective as of December 29, 2006, the last business day of the fiscal year, assuming that each executive's employment agreement was effective as of such date 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 2006. Also excluded are benefits payable to all employees, such as accrued vacation and life insurance premiums. The actual amounts to be paid can only be determined at the actual time of an executive officer's termination.

Name(1)	Type of Payment	Payments Upon Change in Control With Termination (\$)(2)	Payments Upon Change in Control Without Termination (\$)(2)	Payments Upon Termination Without Cause or Resignation for Good Reason (\$)
Mark B. Knudson	Severance Pay	\$ —	\$ —	\$ 300,000
	Value of Stock Options Accelerated(3)	421,471	210,736	196,653
	Health Care Benefits(5)	—	—	17,110
	<b>Total</b>	<u>421,471</u>	<u>210,736</u>	<u>513,763</u>
Greg S. Lea	Severance Pay	\$ —	\$ —	\$ 122,500
	Value of Stock Options Accelerated(3)(4)	—	—	—
	Health Care Benefits(5)	—	—	7,667
	<b>Total</b>	<u>—</u>	<u>—</u>	<u>130,167</u>
Adrianus (Jos) Donders	Severance Pay	\$ —	\$ —	\$ 117,500
	Value of Stock Options Accelerated(3)	648,100	324,050	274,653
	Health Care Benefits(5)	—	—	9,527
	<b>Total</b>	<u>648,100</u>	<u>324,050</u>	<u>401,680</u>
Russ Felkey	Severance Pay	\$ —	\$ —	\$ 115,000
	Value of Stock Options Accelerated(3)	346,331	173,165	154,439
	Health Care Benefits(5)	—	—	9,929
	<b>Total</b>	<u>346,331</u>	<u>173,165</u>	<u>279,368</u>

- (1) We entered into executive employment agreements with Messrs. Lea, Donders and Felkey on May 21, 2007, February 9, 2007 and May 16, 2007, respectively, however, we have included in this table the benefits that would have been paid to them under these agreements assuming these agreements were in effect as of the assumed termination or change in control date of December 29, 2006.
- (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 \$8.00, the initial public offering price, and the exercise price for each option accelerated.
- (4) No values have been included for Mr. Lea because he commenced his employment with us on May 21, 2007 and did not have any stock options by which to value this benefit as of the assumed termination or change in control date of December 29, 2006.
- (5) 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 12 or six month severance period, as applicable, based on current premiums paid.

### ***Other Termination Arrangements***

Effective as of April 14, 2006, Virginia M. Kirby terminated her employment and entered into a three-month consulting agreement under which she agreed to provide us with certain transition-related services for a total payment of \$71,375. Ms. Kirby was not entitled to any severance benefits under this agreement or any other agreement with the company; however, pursuant to her departure, on April 20, 2006, the board approved a modification to her stock options, which eliminated the cliff vesting to give her the right to exercise the six months worth of options she had vested through her termination date.

Effective as of July 15, 2006, Richard R. Wilson terminated his employment and entered into a consulting agreement with us, which provides fee payments of \$3,000 per week, based on 20 hours per week. Dr. Wilson continues to provide services to us in connection with this agreement. In addition, pursuant to his entering this consulting agreement, Dr. Wilson's outstanding options were reclassified as non-qualified stock options and continue to vest in accordance with the terms of his stock option agreement.

### **Employee Benefit Plans**

#### ***2003 Stock Incentive Plan***

Our 2003 Stock Incentive Plan, which we refer to as our 2003 plan, was adopted in October 2003. Our stockholders have approved an amendment to the 2003 plan to be effective upon the completion of this offering, whereby the number of shares of common stock authorized for issuance under the 2003 plan will be 3,901,103 shares. As of September 30, 2007, options to purchase an aggregate of 2,078,771 shares of common stock were outstanding under the 2003 plan and an aggregate of 151,715 shares of common stock had been issued upon the exercise of stock options under the 2003 plan. Any options granted under the 2003 plan that expire or are terminated prior to exercise and any shares of common stock that were purchased by exercise of options granted under the 2003 plan and that we repurchase will be eligible for issuance under the 2003 plan.

The 2003 plan provides for the grant of incentive stock options and nonstatutory stock options. Our officers, employees, directors, consultants, independent directors and affiliates are eligible to receive options under the 2003 plan; however, incentive stock options may only be granted to our employees.

Our compensation committee administers the 2003 plan. Our board of directors, or a committee to which it has delegated its authority, may select the recipients of options and determine, subject to any limitations in the 2003 plan:

- the number of shares of common stock covered by options and the dates upon which those options become exercisable;
- the exercise prices of options;
- the duration of options; and
- the method of payment of the exercise price.

Option agreements issued pursuant to the 2003 plan provide that upon the occurrence of a change in control event (as defined in the option agreements under the 2003 plan), 50% of the unvested options outstanding as of the date of the change of control will become immediately exercisable unless the options are to be cancelled within 5 days of the change in control in which case 100% of the unvested options will be immediately exercisable. We have also entered into executive employment agreements with certain of our executive officers that provide that 100% of the unvested options outstanding will become immediately exercisable upon the occurrence of a change in control event in which the executive officer is terminated. See "Potential Payments Upon Termination or Change in Control" for a more detailed description of the vesting provisions of these agreements.

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Our compensation committee may amend, modify or terminate any outstanding award, only with the consent of the holder, unless the compensation committee or our board of directors determines that the amendment, modification or termination would not adversely affect the holder. Our board of directors may at any time suspend or terminate the 2003 plan, except that, to the extent determined by our board, no amendment requiring stockholder approval under any applicable legal, regulatory or listing requirement will become effective until the requisite stockholder approval is obtained.

### ***Management Incentive Plan***

For our fiscal year ending December 31, 2007, we adopted a management incentive plan for our executive and senior officers, including our senior vice presidents, vice presidents and controller, that provides an annual bonus payout in cash based on certain metrics set forth in the plan. In the first quarter of 2007, our compensation committee recommended and the board of directors approved the performance objectives for the 2007 Management Incentive Plan and the percentage of the bonus attributable to the achievement of corporate and individual performance objectives. For fiscal year 2007, the corporate performance objectives consist of the completion of certain milestones related to our VBLOC clinical trials, including our EMPOWER pivotal trial, expanding our management team and meeting financial budgetary goals. The individual performance objectives were set separately and specifically for each participating executive officer. For a more detailed description of our Management Incentive Plan, see the section entitled "Compensation Discussion and Analysis."

### ***401(k) Plan***

Our retirement plan, which we refer to as the 401(k) plan, is qualified under Section 401 of the Internal Revenue Code, and provides retirement benefits to all full-time employees. 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. Matching contributions may be made to the 401(k) plan at the discretion of our board. To date, we have not made any contributions to the 401(k) plan.

### **Indemnification of Officers and Directors**

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

Article 8 of our bylaws provides that we will indemnify each person who was or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she, or a person of whom he or she is the legal representative, is or was a director or officer of our company or is or was serving at the request of our company as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee or agent or in any other capacity while serving as a director, officer, employee or agent (all such persons are referred to as an indemnitee), shall be indemnified and held harmless by our company, against all expenses, liability and loss (including attorneys' fees, judgments, fines, penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if such indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our bylaws provide that we will indemnify any indemnitee seeking indemnity in connection with a

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proceeding (or part thereof) initiated by such person only if such proceeding (or part thereof) was authorized by our board of directors. We will indemnify the indemnitee for expenses incurred in defending any such proceeding in advance of its final disposition to the extent not prohibited by law. Such indemnification will only be made if the indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Expenses must be advanced to an indemnitee under certain circumstances.

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

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

At present, there is no pending litigation or proceeding involving any of our directors, officers or employees in which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons under our certificate of incorporation or bylaws or the indemnification agreements we have entered into with our directors and officers, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of October 25, 2007 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 25, 2007. 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 11,309,113 shares outstanding, on an as-converted basis, as of October 25, 2007. Percentage ownership calculations for beneficial ownership after this offering also include the 5,000,000 shares we are selling in this offering. 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.

MPM Capital, Bay City Capital, Aberdare Ventures, InterWest Partners, Onset Ventures and Charter Life Sciences, which are each principal stockholders, have indicated that they would like to purchase an aggregate of approximately 1,621,250 shares of common stock in this offering. Each of these entities, except Onset Ventures, is affiliated with a member of our board of directors as described in detail in the footnotes to the table below. Because these indications of interest are not binding agreements or commitments to purchase, these potential investors may elect not to purchase any shares in this offering, or our underwriters may elect not to sell any shares in this offering to any or all of their stockholders. Accordingly, the figures in the table below do not reflect the purchase of any shares in this offering by these potential investors. Assuming these purchases are completed in full, our executive officers and directors and their affiliates will together control approximately 68.8% of our outstanding common stock after this offering, based on 16,309,113 shares of common stock outstanding after this offering.

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Name and Address of Beneficial Owner	Beneficial Ownership Prior to Offering				Beneficial Ownership After Offering	
	Outstanding Shares Beneficially Owned	Right to Acquire Within 60 Days After October 25, 2007	Shares Beneficially Owned		Shares Beneficially Owned	
			Number	Percentage	Number	Percentage
<b>5% Stockholders:</b>						
MPM Capital(1)(2) 601 Gateway Blvd., Ste. 360 S. San Francisco, CA 94080	3,400,343	125,963	3,526,306	30.8%	3,526,306	21.5%
Bay City Capital(3)(4) 750 Battery St., Ste. 400 San Francisco, CA 94111	2,260,501	54,946	2,315,447	20.4	2,315,447	14.1
Aberdare Ventures(5)(6) One Embarcadero Ctr., Ste. 400 San Francisco, CA 94111	1,452,246	42,230	1,494,476	13.2	1,494,476	9.1
InterWest Partners(7)(8) 2710 Sand Hill Rd., Second Floor Menlo Park, CA 94025	1,359,261	—	1,359,261	12.0	1,359,261	8.3
Onset Ventures(9)(10) 2400 Sand Hill Rd., Ste. 150 Menlo Park, CA 94025	864,984	—	864,984	7.6	864,984	5.3
Charter Life Sciences(11)(12) 3130 Highland Ave., Ste. 3205 Cincinnati, OH 45219	622,544	16,484	639,028	5.6	639,028	3.9
<b>Executive Officers and Directors:</b>						
Mark B. Knudson, Ph.D.(13)	156,020	132,459	288,479	2.5	288,479	1.8
Greg S. Lea(14)	—	27,473	27,473	*	27,473	*
David C. Brooks(15)	—	15,027	15,027	*	15,027	*
Adrianus (Jos) Donders(16)	—	97,564	97,564	*	97,564	*
Russ Felkey(17)	17,353	29,453	46,806	*	46,806	*
Katherine S. Tweden(18)	6,318	63,288	69,606	*	69,606	*
Virginia M. Kirby	5,082	—	5,082	*	5,082	*
Richard R. Wilson(19)	60,212	14,920	75,132	*	75,132	*
Luke Evnin, Ph.D.(20)	3,400,343	125,963	3,526,306	30.8	3,526,306	21.5
Catherine Friedman(21)	—	11,447	11,447	*	11,447	*
Carl Goldfischer, M.D.(22)	2,260,501	54,946	2,315,447	20.4	2,315,447	14.1
Bobby I. Griffin(23)	123,569	52,657	176,226	1.6	176,226	1.1
Donald C. Harrison(24)	639,871	17,499	657,370	5.8	657,370	4.0
Paul H. Klingenstein(25)	1,510,337	43,914	1,554,251	13.7	1,554,251	9.5
Ellen Koskinas(26)	1,359,261	—	1,359,261	12.0	1,359,261	8.3
Nicholas L. Teti, Jr.(27)	—	11,447	11,447	*	11,447	*
<b>All executive officers and directors as a group (16 persons)(28)(29)</b>	<b>9,473,573</b>	<b>711,794</b>	<b>10,185,367</b>	<b>84.7</b>	<b>10,185,367</b>	<b>59.8</b>

\* Represents beneficial ownership of less than 1%.

- (1) Consists of 190,247 shares and warrants to purchase 7,049 shares held by MPM BioVentures III, L.P. (“BV3LP”); 2,829,602 shares and warrants to purchase 104,816 shares held by MPM BioVentures III-QP, L.P. (“BV3QP”); 239,110 shares and warrants to purchase 8,858 shares held by MPM BioVentures III

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GmbH & Co. Beteiligungs KG (“BV3KG”); 85,483 shares and warrants to purchase 3,168 shares held by MPM BioVentures III Parallel Fund L.P. (“BV3PF”); and 55,901 shares and warrants to purchase 2,072 shares held by MPM Asset Management Investors 2002 BV3 (“BV3 AM 2002”) (collectively, “MPM Capital”). MPM BioVentures III GP, L.P. (“BV3GP”) and MPM BioVentures III LLC (“BV3LLC”) are the direct and indirect general partners of BV3LP, BV3QP, BV2KG and BV3PF. Ansbert Gadicke, Nicholas Galakatos, Michael Steinmetz, Dennis Henner, Nicholas Simon III, Kurt Wheeler and Luke Evnin, one of our directors, are general partners of BV3LLC and BV3 AM 2002 and therefore hold shared voting and investment power over the shares held by BV3LP, BV3QP, BV3KG, BV3PF and BV3 AM 2002. Each of these general partners disclaims beneficial ownership of the shares owned by these entities except to the extent of their proportionate pecuniary interest therein.

- (2) MPM Capital (with which Luke Evnin, one of our directors, is affiliated) has indicated that it would like to purchase an aggregate of approximately 625,000 shares in this offering. If MPM Capital purchases all of the 625,000 shares of common stock for which it has indicated an interest in purchasing in this offering, the number of shares beneficially owned by MPM Capital after this offering will increase to 4,151,306, and the percentage of common stock beneficially owned by it after this offering will increase to approximately 25.3%.
- (3) Consists of 2,212,805 shares and warrants to purchase 53,786 shares held by Bay City Capital Fund IV, L.P.; 47,696 shares and warrants to purchase 1,160 shares held by Bay City Capital IV Co-Investment Fund IV, L.P. (collectively, the “Bay City Capital Funds”). Bay City Capital Management IV, L.P. is the general partner of the Bay City Capital Funds and Bay City Capital LLC (“BCC”) is a manager and member of Bay City Capital Management IV, L.P. BCC has sole voting and investment power over the shares held by the Bay City Capital Funds. BCC, BF4 GP Investors LLC, Fred Craves and Carl Goldfischer, one of our directors, are members of Bay City Capital Management IV, L.P. Mr. Craves and Dr. Goldfischer are also managing directors and members of BCC. Each of these individuals disclaim beneficial ownership with respect to the shares owned by the Bay City Capital Funds except to the extent of their pecuniary interest therein.
- (4) The Bay City Capital Funds (with which Carl Goldfischer, one of our directors, is affiliated) has indicated that it would like to purchase an aggregate of approximately 375,000 shares in this offering. If the Bay City Capital Funds purchase all of the 375,000 shares of common stock for which they have indicated an interest in purchasing in this offering, the number of shares beneficially owned by the Bay City Capital Funds after this offering will increase to 2,690,447, and the percentage of common stock beneficially owned by it after this offering will increase to approximately 16.4%.
- (5) Consists of 1,188,058 shares and warrants to purchase 41,293 shares held by Aberdare Ventures II, L.P.; 26,934 shares and warrants to purchase 937 shares held by Aberdare Ventures II (Bermuda), L.P.; 237,254 shares held by Aberdare II Annex Fund, L.P. (collectively, the “Aberdare Funds”). Aberdare GP II, LLC is the general partner of the Aberdare Funds and thereby has sole voting and investment power over the shares owned by the Aberdare Funds. Paul H. Klingenstein, one of our directors, is a managing partner of the Aberdare Funds and has shared voting and investment power over the shares held by these entities; however, Mr. Klingenstein disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. See footnote (25).
- (6) Aberdare Ventures (with which Paul H. Klingenstein, one of our directors, is affiliated) has indicated that it would like to purchase an aggregate of approximately 250,000 shares in this offering. If Aberdare Ventures purchases all of the 250,000 shares of common stock for which it has indicated an interest in purchasing in this offering, the number of shares beneficially owned by Aberdare Ventures after this offering will increase to 1,744,476, and the percentage of common stock beneficially owned by it after this offering will increase to approximately 10.7%.
- (7) Consists of 1,359,261 shares held by InterWest Partners IX, L.P. InterWest Management Partners IX, LLC is the general partner of InterWest Partners IX, L.P. and thereby has sole voting and investment power over the shares owned by InterWest Partners IX, L.P. Harvey B. Cash, Philip T. Gianos, W. Stephen Holmes, Gilbert H. Kliman, Arnold L. Oronsky, Thomas L. Rosch and Michael B. Sweeney are managing directors

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of InterWest Management Partners IX, LLC and Michael D. Boich, Bruce A. Cleveland, Christopher B. Ehrlich, Linda S. Grais, Nina Kjellson, Douglas A. Pepper, H. Ronald Nash, Khalad A. Nasr, Victor A. Westerlind and Ellen Koskinas, one of our directors, are venture members of InterWest Management Partners IX, LLC. Each of these managing directors and venture members of InterWest Management Partners IX, LLC have shared voting and investment power over the shares owned by InterWest Partners IX, L.P. and disclaim beneficial ownership over such shares except to the extent of their pro rata partnership interest therein.

- (8) InterWest Partners IX, L.P. (with which Ellen Koskinas, one of our directors, is affiliated) has indicated that it would like to purchase an aggregate of approximately 187,500 shares in this offering. If InterWest Partners IX, L.P. purchases all of the 187,500 shares of common stock for which it has indicated an interest in purchasing in this offering, the number of shares beneficially owned by InterWest Partners IX, L.P. after this offering will increase to 1,546,761, and the percentage of common stock beneficially owned by it after this offering will increase to approximately 9.5%.
- (9) F. Leslie Bottorf, Robert F. Kuhling, Jr., Susan A. Mason and Terry L. Opdendyk are managing directors of Onset V, L.P. and have shared voting and investment power over the shares owned by Onset V, L.P. and disclaim beneficial ownership over such shares, except to the extent of their pecuniary interest therein.
- (10) Onset V, L.P. has indicated that it would like to purchase an aggregate of approximately 93,750 shares in this offering. If Onset V, L.P. purchases all of the 93,750 shares of common stock for which it has indicated an interest in purchasing in this offering, the number of shares beneficially owned by Onset V, L.P. after this offering will increase to 958,734, and the percentage of common stock beneficially owned by it after this offering will increase to approximately 5.9%.
- (11) Consists of 622,544 shares and warrants to purchase 16,484 shares held by Charter Life Sciences. Donald C. Harrison, one of our directors, is a managing partner of Charter Life Sciences and has shared voting and investment power over the shares held by this entity; however, Dr. Harrison disclaims beneficial ownership of these shares except to the extent of his pecuniary interest therein. See footnote (24).
- (12) Charter Life Sciences (with which Donald C. Harrison, one of our directors, is affiliated) has indicated that it would like to purchase an aggregate of approximately 90,000 shares in this offering. If Charter Life Sciences purchases all of the 90,000 shares of common stock for which it has indicated an interest in purchasing in this offering, the number of shares beneficially owned by Charter Life Sciences after this offering will increase to 729,028, and the percentage of common stock beneficially owned by it after this offering will increase to approximately 4.5%.
- (13) Includes 128,442 shares and warrants to purchase 2,029 shares held by the Mark B. Knudson Revocable Trust u/a dtd 4/28/03; 19,286 shares held by the Knudson Family Limited Partnership; 8,292 shares and warrants to purchase 1,015 shares held by the Susan J. Knudson Revocable Trust u/a dtd 4/18/03. Also includes of options to purchase 129,415 shares that are currently exercisable or exercisable within 60 days of October 25, 2007 held by Dr. Knudson.
- (14) Consists of options to purchase 27,473 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.
- (15) Consists of options to purchase 15,027 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.
- (16) Consists of options to purchase 97,564 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.
- (17) Consists of options to purchase 29,453 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.
- (18) Consists of options to purchase 63,288 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.
- (19) Consists of warrants to purchase 2,283 shares and options to purchase 12,637 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.

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- (20) Consists of 3,400,343 shares and warrants to purchase 125,963 shares owned by MPM Capital Funds. See footnote (1). Dr. Evnin, one of our directors, also holds shared voting and investment power over the shares held by BV3LP, BV3QP, BV3KG, BV3PF and BV3 AM 2002. Dr. Evnin disclaims beneficial ownership of the shares owned by these entities except to the extent of his proportionate pecuniary interest therein. See also footnote (2).
- (21) Consists of options to purchase 11,447 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.
- (22) Consists of 2,260,501 shares and warrants to purchase 54,946 shares held by the Bay City Capital Funds. See footnote (3). Carl Goldfischer, one of our directors, also holds shared voting and investment power over the shares held by the Bay City Capital Funds. Dr. Goldfischer disclaims beneficial ownership of the shares owned by the Bay City Capital Funds except to the extent of his proportionate pecuniary interest therein. See also footnote (4).
- (23) Consists of options to purchase 52,657 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.
- (24) Consists of 17,327 shares and 1,015 warrants to purchase shares held by Donald C. Harrison. Also consists of 622,544 shares and warrants to purchase 16,484 shares held by Charter Life Sciences. See footnote (11). Dr. Harrison, one of our directors, also holds shared voting and investment power over the shares held by Charter Life Sciences. Dr. Harrison disclaims beneficial ownership of the shares owned by Charter Life Sciences except to the extent of his proportionate pecuniary interest therein. See also footnote (12). If all of these shares are purchased by Charter Life Sciences in this offering, the number of shares beneficially owned by Dr. Harrison will increase to 747,370, and the percentage of common stock beneficially owned by him after this offering will increase to 4.6%.
- (25) Consists of 58,091 shares and warrants to purchase 1,684 shares held by Paul H. Klingenstein. Also consists of 1,452,246 shares and warrants to purchase 42,230 shares held by the Aberdare Funds. See footnote (5). Mr. Klingenstein, one of our directors, also holds shared voting and investment power over the shares held by the Aberdare Funds. Mr. Klingenstein disclaims beneficial ownership of the shares owned by the Aberdare Funds except to the extent of his proportionate pecuniary interest therein. See also footnote (6). If all of these shares are purchased by the Aberdare Funds in this offering, the number of shares beneficially owned by Mr. Klingenstein will increase to 1,804,251, and the percentage of common stock beneficially owned by him after this offering will increase to 11.0%.
- (26) Consists of 1,359,261 shares held by InterWest Partners. See footnote (7). Ellen Koskinas, one of our directors, also holds shared voting and investment power over the shares held by InterWest Partners. Ms. Koskinas disclaims beneficial ownership of the shares owned by InterWest Partners except to the extent of her pro rata partnership interest therein. See also footnote (8).
- (27) Consists of options to purchase 11,447 shares that are currently exercisable or exercisable within 60 days of October 25, 2007.
- (28) Includes warrants to purchase 245,366 shares and 466,428 shares of common stock issuable upon exercise of options currently exercisable or exercisable within 60 days of October 25, 2007 held by all of the executive officers and directors named in the table above, excluding Virginia Kirby and Richard Wilson, who terminated their employment with us in 2006, and including Mark Stultz, Vice President of Marketing and Reimbursement and Dennis D. Kim, Vice President, Medical Affairs and Chief Medical Officer.
- (29) See footnotes (2), (4), (6), (8), (10) and (12). If all of these shares are purchased by these entities, which are affiliated with certain of our directors, the number of shares beneficially owned by all current executive officers and directors as a group will increase to 11,712,867, and the percentage of common stock beneficially owned by them after this offering will increase to 68.8%.

## RELATED PARTY TRANSACTIONS

Since January 1, 2004, we have entered into the following transactions with our directors, director-nominees, officers and holders of more than five percent of our voting securities and affiliates of our directors, director-nominees, officers and five percent stockholders. All share and per share amounts pertaining to common stock have been retroactively adjusted to give effect to a 1-for-9.1 reverse stock split of our common stock and preferred stock effected November 8, 2007. As a result of the 1-for-9.1 reverse stock split, each share of outstanding Series B and Series C preferred stock is convertible into one share of our common stock.

### Registration Rights

We have granted registration rights to certain holders of our preferred stock and warrants to purchase our common and preferred stock, pursuant to the terms of an investor rights agreement. As of the date of this prospectus, the holders of preferred stock held an aggregate of 10,313,842 shares of preferred stock and warrants to purchase 249,724 shares of common and preferred stock. Upon the completion of this offering, all of the outstanding shares of our preferred stock, including shares issuable upon exercise of outstanding warrants to purchase common and preferred stock, will automatically convert into a total of 11,154,422 shares of our common stock. The holders of 10,997,940 of these common shares will have the right to require us to register these shares. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. The following related parties have registration rights:

<u>Name of Stockholder</u>	<u>Number of Registrable Shares</u>
<b>Directors and Officers</b>	
Mark B. Knudson, Ph.D.(1)	39,834
Bobby I. Griffin	123,569
Donald Harrison, M.D.	8,040
Paul H. Klingenstein(2)	59,775
<b>5% Stockholders</b>	
MPM Capital(3)	3,526,306
Bay City Capital(4)	2,315,447
Aberdare Ventures(5)	1,494,476
Charter Life Sciences, L.P.	639,028
Interwest Partners IX, L.P.	1,359,261
Onset V, L.P.	864,984
<b>Total:</b>	<b>10,430,720</b>

- (1) Consists of 30,527 registrable shares held by the Mark B. Knudson Revocable Trust and 9,307 registrable shares held by the Susan J. Knudson Revocable Trust.
- (2) Paul H. Klingenstein, a member of our board of directors, is also the managing partner of Aberdare Ventures.
- (3) Consists of 197,296 registrable shares held by MPM BioVentures III, L.P., 2,934,418 registrable shares held by MPM BioVentures III-QP, L.P., 247,968 registrable shares held by MPM BioVentures III GmbH & Co. Parallel-Beteiligungs KG, 88,651 registrable shares held by MPM BioVentures III Parallel Fund, L.P. and 57,973 registrable shares held by MPM Asset Management Investors 2002 BVIII LLC. Luke B. Evnin, a member of our board of directors, is a general partner of MPM Capital.
- (4) Consists of 2,266,591 registrable shares held by Bay City Capital Fund IV, L.P. and 48,856 registrable shares held by Bay City Capital Fund IV Co-Investment Fund, L.P. Carl Goldfischer, a member of our board of directors, is a managing director of Bay City Capital.
- (5) Consists of 1,229,351 registrable shares held by Aberdare Ventures II, L.P., 27,871 registrable shares held by Aberdare Ventures II (Bermuda), L.P. and 237,254 registrable shares held by Aberdare II Annex Fund, L.P.

**Securities Issued to Insiders**

The following summarizes purchases of our securities since January 1, 2004 by our executive officers, directors and holders of more than 5% of our common stock other than compensatory arrangements. All share and per share amounts pertaining to common stock have been retroactively adjusted to give effect to a 1-for-9.1 reverse stock split of our common stock and preferred stock effected November 8, 2007. As a result of the 1-for-9.1 reverse stock split, each share of outstanding Series B and Series C preferred stock is convertible into one share of our common stock.

**Series C Preferred Stock**

On July 6, 2006 and December 11, 2006, we entered into agreements with 25 individuals and entities, including Mark B. Knudson, Ph.D., MPM Capital, Bay City Capital, Aberdare Ventures, Charter Life Sciences, L.P., Interwest Partners IX, L.P., Onset V, L.P., Donald C. Harrison, M.D., Paul H. Klingenstein and Bobby I. Griffin to sell, in a private placement, an aggregate of 5,709,630 shares of our Series C preferred stock. The total aggregate offering price for these sales was \$46,206,019. All shares of Series C preferred stock will be automatically converted into 5,709,630 shares of our common stock upon the completion of this offering.

Of the 5,709,630 shares of Series C preferred stock sold pursuant to the Series C financing, 5,438,660 shares of Series C preferred stock were sold to the following related parties:

<b>Purchaser</b>	<b>Series C Shares</b>	<b>Purchase Price(1)</b>
<b>Directors and Executive Officers</b>		
Mark B. Knudson, Ph.D.(2)	9,498	\$ 76,871
Bobby I. Griffin	123,569	1,000,000
Donald C. Harrison, M.D.	1,899	15,374
Paul H. Klingenstein(3)	19,238	155,686
<b>5% Stockholders</b>		
MPM Capital(4)	1,347,977	10,908,699
Bay City Capital(5)	992,441	8,031,465
Aberdare Ventures(6)	477,667	3,865,595
Charter Life Sciences, L.P.	242,126	1,959,440
Interwest Partners IX, L.P.	1,359,261	11,000,001
Onset V, L.P.	864,984	7,000,000

- (1) Of the aggregate \$44,013,131 purchase price paid by related parties, an aggregate amount of \$5,215,849 was paid by converting all of the outstanding promissory notes, including accrued interest payable, that were convertible into our Series C preferred stock.
- (2) Consists of 6,332 shares held by the Mark B. Knudson Revocable Trust and 3,166 shares held by the Susan J. Knudson Revocable Trust.
- (3) Paul H. Klingenstein, a member of our board of directors, is also the managing partner of Aberdare Ventures.
- (4) Consists of 75,419 shares of Series C preferred stock held by MPM BioVentures III, L.P., 1,121,721 shares of Series C preferred stock held by MPM BioVentures III-QP, L.P., 94,789 shares of Series C preferred stock held by MPM BioVentures III GmbH & Co. Parallel-Beteiligungs KG, 33,888 shares of Series C Preferred held by MPM BioVentures III Parallel Fund, L.P. and 22,160 shares of Series C preferred stock held by MPM Asset Management Investors 2002 BVIII LLC. Luke B. Evnin, a member of our board of directors, is a general partner of MPM Capital.
- (5) Consists of 971,501 shares of Series C preferred stock held by Bay City Capital Fund IV, L.P. and 20,940 shares of Series C preferred stock held by Bay City Capital Fund IV Co-Investment Fund, L.P. Carl Goldfischer, a member of our board of directors, is a managing director of Bay City Capital.
- (6) Consists of 235,086 shares of Series C preferred stock held by Aberdare Ventures II, L.P., 5,327 shares of Series C preferred stock held by Aberdare Ventures II (Bermuda), L.P. and 237,254 shares of Series C preferred stock held by Aberdare II Annex Fund, L.P.

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### **Convertible Note Offering**

On December 12, 2005, we entered into a Convertible Note Purchase Agreement with 18 individuals and entities, including Mark B. Knudson, Ph.D., MPM Capital, Bay City Capital, Aberdare Ventures, Charter Life Sciences, L.P., Donald C. Harrison, M.D. and Paul H. Klingenstein to sell convertible promissory notes totaling \$5,250,003 (2005 Notes). The 2005 Notes were converted into 664,927 shares of our Series C Preferred Stock. Of the 664,927 shares of Series C Preferred issued upon conversion of the 2005 Notes, 644,518 shares were issued to the related parties below.

Of the \$5,250,003 of 2005 Notes that were sold pursuant to Convertible Note Purchase Agreement, \$5,088,857 of the 2005 Notes were sold to the following related parties:

<u>Purchaser</u>	<u>Note Purchase Price</u>	<u>Series C Shares</u>
<b>Directors and Executive Officers</b>		
Mark B. Knudson, Ph.D.(1)	\$ 75,000	9,498
Donald C. Harrison, M.D.	15,000	1,899
Paul H. Klingenstein(2)	45,819	5,803
<b>5% Stockholders</b>		
MPM Capital(3)	1,862,228	235,856
Bay City Capital(4)	1,494,178	189,241
Aberdare Ventures(5)	1,148,378	145,445
Charter Life Sciences, L.P.	448,254	56,776

- (1) Consists of \$50,000 of 2005 Notes purchased by the Mark B. Knudson Revocable Trust and \$25,000 of 2005 Notes purchased by the Susan J. Knudson Revocable Trust.
- (2) Paul H. Klingenstein, a member of our board of directors, is also the managing partner of Aberdare Ventures.
- (3) Consists of \$104,192 of 2005 Notes purchased by MPM BioVentures III, L.P., \$1,549,653 of 2005 Notes purchased by MPM BioVentures III-QP, L.P., \$130,952 of 2005 Notes purchased by MPM BioVentures III GmbH & Co. Parallel-Beteiligungs KG, \$46,816 of 2005 Notes purchased by MPM BioVentures III Parallel Fund, L.P. and \$30,615 of 2005 Notes purchased by MPM Asset Management Investors 2002 BVIII LLC. Luke B. Evnin, a member of our board of directors, is a general partner of MPM Capital.
- (4) Consists of \$1,462,651 of 2005 Notes purchased by Bay City Capital Fund IV, L.P. and \$31,527 of 2005 Notes purchased by Bay City Capital Fund IV Co-Investment Fund, L.P. Carl Goldfischer, a member of our board of directors, is a managing director of Bay City Capital.
- (5) Consists of \$1,122,923 of 2005 Notes purchased by Aberdare Ventures II, L.P. and \$25,455 of 2005 Notes purchased by Aberdare Ventures II (Bermuda), L.P.

### **Series B Preferred Stock and Common Stock Warrants**

On July 30, 2004, June 17, 2005 and December 12, 2005 we entered into agreements with 18 individuals and entities, including Mark B. Knudson, Ph.D., MPM Capital, Bay City Capital, Aberdare Ventures, Charter Life Sciences, L.P., Donald C. Harrison, M.D. and Paul H. Klingenstein to sell, in a private placement, an aggregate of 4,285,946 shares of our Series B preferred stock. The total aggregate offering price for these sales was \$16,899,654. All shares of Series B preferred stock will be automatically converted into 4,285,946 shares of our common stock upon the completion of this offering.

On December 12, 2005, in connection with the closing of our Series B preferred stock financing, we issued an aggregate of 170,336 warrants to purchase our common stock to 12 individuals and entities, including MPM Capital, Bay City Capital, Aberdare Ventures, Charter Life Sciences and Paul H. Klingenstein. The total aggregate offering price for these warrants was \$15,500.

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Of the 4,285,946 shares of Series B preferred stock and 170,336 warrants to purchase common stock sold pursuant to the Series B financing, 4,262,939 shares of Series B preferred stock and 170,292 warrants to purchase common stock were sold to the following related parties:

<u>Purchasers</u>	<u>Series B Shares</u>	<u>Purchase Price(1)</u>	<u>Common Warrants</u>
<b>Directors and Executive Officers</b>			
Mark B. Knudson, Ph.D.(2)	15,494	\$ 61,097	—
Donald C. Harrison, M.D.	5,126	20,216	—
Paul H. Klingenstein(3)	38,853	153,200	1,684
<b>5% Stockholders</b>			
MPM Capital(4)	1,580,409	6,231,611	54,948
Bay City Capital(5)	1,268,060	5,000,000	54,946
Aberdare Ventures(6)	974,579	3,842,800	42,230
Charter Life Sciences, L.P.	380,418	1,500,001	16,484

- (1) Of the aggregate \$16,808,925 purchase price paid by related parties, an aggregate amount of \$1,512,924 was paid by converting all of the outstanding promissory notes that were convertible into our Series B preferred stock.
- (2) Consists of 10,368 shares of Series B preferred stock held by the Mark B. Knudson Revocable Trust and 5,126 shares of Series B preferred stock held by the Susan J. Knudson Revocable Trust.
- (3) Paul H. Klingenstein, a member of our board of directors, is also the managing partner of Aberdare Ventures.
- (4) Consists of 88,423 shares of Series B preferred stock and 3,075 common stock warrants held by MPM BioVentures III, L.P., 1,315,139 shares of Series B preferred stock and 45,723 common stock warrants held by MPM BioVentures III-QP, L.P., 111,134 shares of Series B preferred stock and 3,864 common stock warrants held by MPM BioVentures III GmbH & Co. Parallel-Beteiligungs KG, 39,731 shares of Series B preferred stock and 1,382 common stock warrants held by MPM BioVentures III Parallel Fund, L.P. and 25,982 shares of Series B preferred stock and 904 common stock warrants held by MPM Asset Management Investors 2002 BVIII LLC. Luke B. Evnin, a member of our board of directors, is a general partner of MPM Capital.
- (5) Consists of 1,241,304 shares of Series B preferred stock and 53,786 common stock warrants held by Bay City Capital Fund IV, L.P. and 26,756 shares of Series B preferred stock and 1,160 common stock warrants held by Bay City Capital Fund IV Co-Investment Fund, L.P. Carl Goldfischer, a member of our board of directors, is a managing director of Bay City Capital.
- (6) Consists of 952,972 shares of Series B preferred stock and 41,293 common stock warrants held by Aberdare Ventures II, L.P. and 21,607 shares of Series B preferred stock and 937 common stock warrants held by Aberdare Ventures II (Bermuda), L.P.

### **Bridge Loan Financing**

On November 13, 2003, we entered into a bridge loan agreement with 12 individuals and entities, which was later amended on April 23, 2004 and June 30, 2004 (Bridge Financing). Pursuant to this bridge loan agreement, certain investors lent a total of \$1,564,843 to the company in 2003 and 2004 in exchange for convertible promissory notes bearing interest of 4% per annum (Bridge Notes). In connection with the bridge loan agreement, the company also issued warrants to purchase a total of 79,388 shares of Series B preferred stock. The Bridge Notes were converted into 405,690 shares of Series B Preferred. The Bridge Notes held by the related parties below were converted into 383,695 shares of Series B Preferred in connection with the Series B financing.

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Of the \$1,564,843 of Bridge Notes and 79,388 Series B Warrants sold pursuant to the Bridge Financing, \$1,479,852 of Bridge Notes and 75,074 Series B Warrants were sold to the following related parties:

<u>Name</u>	<u>Note Purchase Price</u>	<u>Series B Shares</u>	<u>Series B Warrants</u>
<b>Directors and Executive Officers</b>			
Mark B. Knudson, Ph.D.(1)	\$ 59,994	15,494	3,044
Donald C. Harrison, M.D.	19,998	5,126	1,015
<b>5% Stockholders</b>			
MPM Capital(2)	1,399,860	363,073	71,015

- (1) Consists of \$39,996 of Bridge Notes purchased by Mark B. Knudson and \$19,998 of Bridge Notes purchased by Susan J. Knudson.
- (2) Consists of \$78,322 of Bridge Notes and 3,974 Series B Warrants purchased by MPM BioVentures III, L.P., \$1,164,894 of Bridge Notes and 59,093 Series B Warrants purchased by MPM BioVentures III-QP, L.P., \$98,438 of Bridge Notes and 4,994 of Series B Warrants purchased by MPM BioVentures III GmbH & Co. Parallel-Beteiligungs KG, \$35,192 of Bridge Notes and 1,786 of Series B Warrants purchased by MPM BioVentures III Parallel Fund, L.P. and \$23,014 of Bridge Notes and 1,168 of Series B Warrants purchased by MPM Asset Management Investors 2002 BVIII LLC. Luke B. Evnin, a member of our board of directors, is a general partner of MPM Capital.

### ***Additional Security Issuances***

In addition to the transactions set forth above, we have also entered in the following transactions with our officers, directors and holders of more than five percent of our voting securities:

- On October 1, 2003, Dr. Knudson purchased 49,450 shares of restricted stock and Dr. Harrison purchased 8,104 shares of restricted stock for \$0.09 per share and we entered into a restricted stock agreement with each of Dr. Knudson and Dr. Harrison in connection with these purchases. The stock restriction agreements provide us with a right to repurchase the shares that lapses in increments of 1/48 each month.
- On April 23, 2004, we amended these restricted stock agreements to provide continued vesting for the holder as long as he or she is a director, officer or employee of the company or makes himself or herself available for advice and consultation following dissolution of Venturi II, LLC. We also entered into a consulting agreement with Dr. Harrison, which provided for continued vesting of his restricted stock pursuant to his restricted stock agreement if he performed certain services for us. Pursuant to his consulting agreement, Dr. Harrison has assisted us with the set up and design of our pre-clinical and clinical trials and continues to provide such services to us as needed. Our repurchase option for the stock held by Drs. Knudson and Harrison lapsed on April 30, 2007.

### **Consulting Agreements**

Effective January 2, 2003, we entered into a consulting agreement with Venturi Development, Inc., or VDI. The consulting agreement provided for VDI to receive compensation in the form of cash for services provided. Initially, VDI provided us with management support and advice on legal and contractual matters, especially with respect to our relationship with Mayo Clinic. However, after Dr. Knudson formally joined EnteroMedics in 2004, VDI no longer provided management services to us and its consulting role has been minimal. The consulting agreement with VDI was terminated effective as of June 30, 2007. The total cash payments were \$1,230,000 in 2004, \$46,000 in 2005, \$29,000 in 2006 and \$21,000 through the termination date in 2007. The majority of the consulting services provided by VDI were recorded as research and development and general and administrative. Mark B. Knudson, our President and Chief Executive Officer and the Chairman of our Board of Directors, is the President and Chief Executive Officer and a director of VDI.

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Effective September 21, 2006, we entered into a consulting agreement with Bobby I. Griffin, who is a member of our Board of Directors. The consulting agreement provides for the consultant to receive compensation, in the form of an option to purchase common stock for services provided. Mr. Griffin has assisted us with product development and has advised us with respect to the conduct of our clinical trials in connection with this agreement. Pursuant to this consulting agreement, Mr. Griffin received a one-time option grant to purchase 54,946 shares of common stock at \$1.91 per share that vest 25% on the first anniversary the date the consulting agreement was entered into and 1/36<sup>th</sup> per month each month thereafter for 36 months.

### **Participation in Initial Public Offering**

MPM Capital, Bay City Capital, Aberdare Ventures, InterWest Partners, Onset Ventures and Charter Life Sciences, which are each principal stockholders, have indicated an interest in purchasing an aggregate of approximately 1,621,250 shares of common stock in this offering. However, because these potential indications of interest are not binding agreements or commitments to purchase, any or all of these stockholders may elect not to purchase any shares in this offering, or our underwriters may elect not to sell any shares in this offering to any or all of these stockholders.

### **Sublease Agreement**

Effective September 2005, we entered into a sublease agreement for office and warehouse space with Restore Medical, Inc. Mark B. Knudson, our President and Chief Executive Officer and the Chairman of our Board of Directors, is the Chairman of the Board of Directors of Restore Medical, Inc. The lease expires on September 30, 2008. Under the terms of the sublease agreement, the monthly base rent ranges from \$11,476 to \$11,596. Rent expense recognized for the years ended December 31, 2006 and 2005 was \$127,766 and \$22,555, respectively. Rent expense recognized for the nine months ended September 30, 2007 was \$90,192. We also reimburse Restore Medical, Inc. for various facility and personnel related expenses, which for the years ended December 31, 2006 and 2005 were approximately \$128,000 and \$52,000, respectively. Facility and personnel related expense paid to Restore for the nine months ended September 30, 2007 was approximately \$242,000.

### **Indemnification Agreements**

We expect to enter into indemnification agreements with each of our directors and executive officers. Each indemnification agreement provides that we will indemnify the director or executive officer to the fullest extent permitted by law for claims arising in his or her capacity as our director, officer, employee or agent, provided that he or she acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe that his or her conduct was unlawful. If the claim is brought by us or on our behalf, we will not be obligated to indemnify the director or executive officer if he or she is found liable to us, unless the court determines that, despite the adjudication of liability, in view of all the circumstances of the case the director is fairly and reasonably entitled to indemnity. In the event that we do not assume the defense of a claim against our director or executive officer, we are required to advance his or her expenses in connection with his or her defense, provided that he or she undertakes to repay all amounts advanced if it is ultimately determined that he or she is not entitled to be indemnified by us.

### **Director and Executive Compensation**

Please see “Management—Director Compensation” and “—Executive Compensation” for information regarding the compensation of our non-employee directors and executive officers.

### **Review of Related Party Transactions**

Upon the closing of this offering and in accordance with its written charter, our Audit Committee will be responsible for reviewing all related party transactions as they are presented, and the approval of the Audit

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Committee will be required for all such transactions. The term “related party transactions” refers to transactions required to be disclosed in our filings with the SEC pursuant to Item 404 of Regulation S-K. In considering related party transactions, our Audit Committee is guided by its fiduciary duty to our stockholders. Our Audit Committee does not have any written or oral policies or procedures regarding the review, approval and ratification of transactions with related parties. Additionally, following this offering we will require each of our directors and executive officers to annually complete a directors’ and officers’ questionnaire that elicits information about related party transactions. Our Nominating and Governance Committee and board of directors will annually review all transactions and relationships disclosed in the director and officer questionnaires, and the Board makes a formal determination regarding each director’s independence.

## DESCRIPTION OF CAPITAL STOCK

### General

The following description of our capital stock 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 filed as exhibits to the registration statement of which this prospectus forms a part and to Delaware law. The descriptions of our common stock and preferred stock reflect changes to our capital structure that will occur prior to or upon the completion of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation and our amended and restated bylaws as our bylaws.

Upon consummation of this offering, our authorized capital stock will consist of 50,000,000 shares of common stock, par value \$0.01 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share, all of which preferred stock will be undesignated.

As of September 30, 2007, we had issued and outstanding:

- 614,891 shares of common stock, held by 29 holders of record;
- 318,266 shares of Series A convertible preferred stock, held by 7 holders of record;
- 4,285,946 shares of Series B convertible preferred stock, held by 19 holders of record; and
- 5,709,630 shares of Series C convertible preferred stock, held by 25 holders of record.

Upon the completion of this offering, all of the outstanding shares of our preferred stock will automatically convert into a total of 10,488,178 shares of our common stock and there will be no preferred stock outstanding. Approximately 16,309,113 shares of our common stock will be outstanding immediately after this offering, assuming no exercise by the underwriters of their over-allotment option. This number excludes 666,244 shares of common stock issuable upon the exercise of warrants outstanding as of September 30, 2007, on an as-converted basis and at a weighted average exercise price of \$4.71 per share; 2,078,771 shares of common stock issuable upon the exercise of options outstanding as of September 30, 2007, at a weighted average exercise price of \$3.67 per share; and 1,670,617 shares of common stock expected to be available for future issuance under our stock incentive plans upon completion of this offering.

### 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.

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

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

## Preferred Stock

Our certificate of incorporation provides that we may issue up to 5,000,000 shares of preferred stock in one or more series as may be determined by our board of directors. Our board has broad discretionary authority with respect to the rights of any new series of preferred stock and may establish the following with respect to the shares to be included in each series, without any vote or action of the stockholders:

- the number of shares;
- the designations, preferences and relative rights, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences; and
- any qualifications, limitations or restrictions.

We believe that the ability of our board of directors to issue one or more series of preferred stock will provide us with flexibility in structuring possible future financings and acquisitions, and in meeting other corporate needs that may arise. The authorized shares of preferred stock, as well as authorized and unissued shares of common stock, will be available for issuance without action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange or automated quotation system on which our securities may be listed or traded.

Our board of directors may authorize, without stockholder approval, the issuance of preferred stock with voting and conversion rights that could adversely affect the voting power and other rights of holders of common stock. Although our board has no current intention of doing so, it could issue a series of preferred stock that could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt of our company. Our board could also issue preferred stock having terms that could discourage an acquisition attempt through which an acquiror may be able to change the composition of our board, including a tender offer or other transaction that some, or a majority, of our stockholders might believe to be in their best interests or in which stockholders might receive a premium for their stock over the then-current market price. Any issuance of preferred stock therefore could have the effect of decreasing the market price of our common stock.

Our board of directors will make any determination to issue such shares based on its judgment as to the best interests of our company and stockholders. We have no current plan to issue any preferred stock after this offering.

## Registration Rights

We have granted the registration rights described below to the holders of our preferred stock and to certain holders of warrants to purchase our common stock and preferred stock, pursuant to the terms of an investor rights agreement. Upon the completion of this offering, all of the outstanding shares of our preferred stock, including shares that are issued upon exercise of outstanding warrants to purchase preferred stock, will automatically convert into a total of 10,984,086 shares of our common stock. The holders of 10,997,940 shares of common stock will have the right to require us to register these shares, together with other shares of common stock they hold, under the Securities Act under the circumstances set forth below. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. The following description of the terms of the registration rights agreement is intended as a summary only and is qualified in its entirety by reference to the investor rights agreement filed as an exhibit to the registration statement of which this prospectus forms a part.

*Demand Registration Rights.* Any time after six months after our initial public offering and on no more than one occasion during any twelve-month period, the holders of at least 50% of our registrable shares will have

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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 \$1,000,000 (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 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 commission will be paid by us. The investor rights agreement is governed by Delaware law.

### **Anti-takeover Effects of Provisions of Delaware Law and Our Certificate of Incorporation and Bylaws**

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

- before the stockholder became interested, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation

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outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or

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

Upon the closing of this offering, our certificate of incorporation and bylaws will 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

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was made. Although our bylaws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our bylaws may have the effect of precluding the consideration of some business at a meeting if the proper procedures are not followed or may discourage or defer a potential acquiror from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

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

### **Liability Limitations and Indemnification**

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

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

### **Transfer Agent and Registrar**

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

### **Listing**

Our common stock has been approved for quotation on the Nasdaq Global Market under the symbol "ETRM."

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to the offering made by this prospectus, there has been no market for our common stock, and we cannot assure you that a liquid trading market for our common stock will develop or be sustained after this offering. Future sales of substantial numbers of shares of our common stock, including shares issued upon exercise of options, in the public market after this offering, or the anticipation of those sales, could adversely affect market prices of our common stock prevailing from time to time and could impair our ability to raise capital through sales of our equity securities.

Upon completion of this offering, we will have outstanding 16,309,113 shares of common stock, after giving effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 10,488,178 shares of common stock prior to the completion of this offering.

The 5,000,000 shares sold in this offering will be freely tradable without restriction under the Securities Act unless purchased by our “affiliates,” as that term is defined in Rule 144 under the Securities Act. The remaining shares of common stock to be outstanding after this offering will be “restricted securities” under Rule 144. Substantially all of these restricted securities will be subject to the 180-day lock-up period, which may be extended in specified circumstances described below. Within 180 days of the date of this prospectus 416,031 shares will qualify for resale under Rule 144(k), 10,675,501 additional shares will qualify for resale under Rule 144, subject to volume limitations, and 11,537 additional shares will qualify for resale under Rule 701.

Restricted securities may be sold in the public market only if they have been registered or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act.

### Rule 144

In general, under Rule 144, beginning 90 days after the date of this prospectus, a person who has beneficially owned shares of our common stock for at least one year would be entitled to sell within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately \_\_\_\_\_ shares immediately after this offering; and
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales under Rule 144 are also subject to manner of sale provisions, notice requirements and the availability of current public information about us.

### Rule 144(k)

Subject to the lock-up agreements described below, shares of our common stock eligible for sale under Rule 144(k) may be sold immediately upon the completion of this offering. In general, under Rule 144(k), a person may sell shares of common stock acquired from us immediately upon completion of this offering, without regard to the manner or volume of sale or the availability of public information about us, if:

- the person is not our affiliate and has not been our affiliate at any time during the three months preceding such a sale; and
- the person has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate.

## **Rule 701**

In general, under Rule 701 of the Securities Act, any of our employees, consultants or advisors who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell those shares 90 days after the date of this prospectus in reliance on Rule 144, but without compliance with the holding period or certain other restrictions contained in Rule 144.

## **Lock-Up Agreements**

Each of our officers and directors, and substantially all of our other stockholders and holders of options to purchase our common stock, have agreed not to offer, sell, contract to sell or otherwise dispose of, or enter into any transaction that is designed to, or could be expected to, result in the disposition of any shares of our common stock or other securities convertible into or exchangeable or exercisable for shares of our common stock or derivatives of our common stock owned by these persons prior to this offering or common stock issuable upon exercise of options held by these persons for a period of 180 days after the date of this prospectus without the prior written consent of J.P. Morgan Securities Inc. and Morgan Stanley & Co. Incorporated.

J.P. Morgan Securities Inc. and Morgan Stanley & Co. Incorporated do not have any pre-established conditions to waiving the terms of the lock-up agreements. Any determination to release any shares subject to the lock-up agreements would be based on a number of factors at the time of determination, including but not necessarily limited to the market price of the common stock, the liquidity of the trading market for the common stock, general market conditions, the number of shares proposed to be sold and the timing, purpose and terms of the proposed sale.

The 180-day restricted period described above will be extended if:

- during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us occurs; or
- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

## **Registration Rights**

After this offering, holders of 10,997,940 shares of our common stock, including shares that are issuable upon the exercise of outstanding warrants, will have the right to require us to register these shares under the Securities Act under specific circumstances. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See “Description of Capital Stock—Registration Rights.”

## **Equity Plans**

As of September 30, 2007, we had outstanding options to purchase 2,078,771 shares of our common stock. Following this offering, we intend to file registration statements on Form S-8 under the Securities Act to register all of the shares of common stock issued or issuable under our 2003 plan.

**MATERIAL UNITED STATES FEDERAL TAX CONSEQUENCES FOR  
NON-UNITED STATES HOLDERS OF OUR COMMON STOCK**

The following is a general discussion of the material United States federal income and estate tax considerations applicable to non-United States holders with respect to their ownership and disposition of shares of our common stock purchased in this offering. This discussion is for general information only and is not tax advice. Accordingly, all prospective non-United States holders of our common stock should consult their own tax advisors with respect to the United States federal, state, local and non-United States tax consequences of the purchase, ownership and disposition of our common stock. In general, a non-United States holder means a beneficial owner of our common stock who is not for United States federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, partnership or any other organization taxable as a corporation or partnership for United States federal tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia; or
- an estate, the income of which is included in gross income for United States federal income tax purposes regardless of its source; or
- a trust if (a) a United States court is able to exercise primary supervision over the trust's administration and (b) one or more United States persons have the authority to control all of the trust's substantial decisions.

This discussion is based on current provisions of the United States Internal Revenue Code of 1986, as amended, existing and proposed United States Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences to non-United States holders described in this prospectus. We assume in this discussion that a non-United States holder holds shares of our common stock as a capital asset (generally, property held for investment).

This discussion does not address all aspects of United States federal income and estate taxation that may be relevant to a particular non-United States holder in light of that non-United States holder's individual circumstances, nor does it address any aspects of United States state or local or non-United States taxes. This discussion also does not consider any specific tax consequences that may be relevant to a non-United States holder in light of such holder's particular circumstances and does not address the special tax rules applicable to particular non-United States holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- partnerships or other pass-through entities;
- regulated investment companies or real estate investment trusts;
- pension plans;

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- owners of more than 5% of our common stock;
- “controlled foreign corporations” or “passive foreign investment companies”;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- owners that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain United States expatriates.

There can be no assurance that the Internal Revenue Service (“IRS”) will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, an opinion of counsel or ruling from the IRS with respect to the United States federal income or estate tax consequences to a non-United States holder of the purchase, ownership or disposition of our common stock. We urge prospective investors to consult with their own tax advisors regarding the United States federal, state and local and non-United States income and other tax considerations of purchasing, owning and disposing of shares of our common stock.

### **Distributions on Our Common Stock**

Any distributions on our common stock paid to non-United States holders of common stock generally will constitute dividends for United States federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under United States federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-United States holder’s investment, up to such holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “— Gain on Sale, Exchange or Other Disposition of Our Common Stock.” Dividends paid to a non-United States holder generally will be subject to withholding of United States federal income tax at a 30% rate or such lower rate as may be provided by an applicable income tax treaty between the United States and such holder’s country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-United States holder within the United States (and, if an applicable income tax treaty so provides, are also attributable to a permanent establishment or a fixed base maintained within the United States by such non-United States holder) are generally exempt from the 30% withholding tax if the non-United States holder satisfies applicable certification and disclosure requirements. However, such United States effectively connected income, net of specified deductions and credits, is taxed at the same graduated United States federal income tax rates applicable to United States persons. Any United States effectively connected income received by a non-United States holder that is a corporation may also, under certain circumstances, be subject to an additional branch profits tax at a 30% rate or such lower rate as may be provided by an applicable income tax treaty between the United States and such holder’s country of residence.

In order to claim the benefit of a tax treaty or to claim exemption from withholding because dividends paid on our common stock are effectively connected with the conduct of a trade or business in the United States, a non-United States holder must provide a properly executed IRS Form W-8BEN for treaty benefits or W-8ECI for effectively connected income, or such successor forms as the IRS designates, prior to the payment of dividends. These forms must be periodically updated. Non-United States holders may be eligible to obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

### **Gain on Sale, Exchange or Other Disposition of Our Common Stock**

In general, a non-United States holder will not be subject to any United States federal income tax or withholding tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- the gain is effectively connected with a United States trade or business (and, if an applicable income tax treaty so provides, is also attributable to a permanent establishment or a fixed base maintained within the United States by such non-United States holder), in which case the graduated United States federal income tax rates applicable to United States persons will apply, and, if the non-United States holder is a foreign corporation, the additional branch profits tax described above in “—Distributions on Our Common Stock” may also apply;
- the non-United States holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-United States holder will be subject to a 30% tax on the net gain derived from the disposition, which may be offset by United States-source capital losses of the non-United States holder, if any; or
- we are or have been, at any time during the five-year period preceding such disposition (or the non-United States holder's holding period, if shorter) a “United States real property holding corporation,” and our common stock has ceased to be traded on an established securities market prior to the beginning of the calendar year in which the disposition occurs.

We believe that we have not been and are not currently, and we do not anticipate becoming in the future, a “United States real property holding corporation” for United States federal income tax purposes.

### **United States Federal Estate Tax**

Shares of our common stock that are owned or treated as owned by an individual non-United States holder at the time of death are considered United States situs assets and will be included in the individual's gross estate for United States federal estate tax purposes. Such shares, therefore, may be subject to United States federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

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

Information reporting and backup withholding (currently at a 28% rate of tax) may apply to dividends paid with respect to our common stock and to proceeds from the sale or other disposition of our common stock. In certain circumstances, non-United States holders may avoid information reporting and backup withholding if they certify under penalties of perjury as to their status as non-United States holders or otherwise establish an exemption and certain other requirements are met. Non-United States holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules from a payment to a non-United States holder can be refunded or credited against the non-United States holder's United States federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

## UNDERWRITING

J.P. Morgan Securities Inc. and Morgan Stanley & Co. Incorporated are acting as joint book-running managers of this offering and, together with Cowen and Company, LLC and Leerink Swann LLC, are acting as the managing underwriters of this offering. Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters named below have severally agreed to purchase, and we have agreed to sell to them, the number of shares of common stock indicated in the table below:

<b>Underwriter</b>	<b>Number of Shares</b>
J.P. Morgan Securities Inc.	1,875,000
Morgan Stanley & Co. Incorporated	1,875,000
Cowen and Company, LLC	800,000
Leerink Swann LLC	450,000
<b>Total</b>	<b>5,000,000</b>

The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions, and part to certain dealers at a price that represents a concession not in excess of \$0.56 a share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

MPM Capital, Bay City Capital, Aberdare Ventures, InterWest Partners, Onset Ventures and Charter Life Sciences, which are each principal stockholders, have indicated an interest in purchasing an aggregate of approximately 1,621,250 shares of common stock in this offering. However, because these potential indications of interest are not binding agreements or commitments to purchase, any or all of these stockholders may elect not to purchase any shares in this offering, or our underwriters may elect not to sell any shares in this offering to any or all of these stockholders.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of 750,000 additional shares of common stock at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table. If the underwriters' over-allotment option is exercised in full, the total price to the public would be \$46,000,000, the total underwriters' discounts and commissions would be \$3,220,000 and the total proceeds to us would be \$42,780,000.

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The following table shows the per share and total underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' option.

Per Share	No Exercise		Full Exercise	
	\$	0.56	\$	0.56
Total	\$	2,800,000	\$	3,220,000

In addition, we estimate that the expenses of this offering other than underwriting discounts and commissions payable by us will be approximately \$1.5 million.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We, all of our directors and officers and holders of substantially all of our outstanding stockholders and holders of securities exercisable for or convertible into shares of common stock have agreed that, without the prior written consent of J.P. Morgan Securities Inc. and Morgan Stanley & Co. Incorporated, on behalf of the underwriters, we and they will not, during the period beginning on the date of this prospectus and ending 180 days thereafter:

- offer, pledge, sell, announce the intention to sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock;
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of common stock; or
- make any demand for or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise.

The restrictions described in the preceding paragraphs do not apply to:

- the sale by us of shares to the underwriters in connection with the offering;
- transactions by any person other than us relating to shares of common stock or other securities convertible or exchangeable into common stock acquired in open market transactions after the completion of the offering of the shares;
- the issuance by us of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;
- the grant of options or the issuance of shares of common stock by us to employees, officers, directors, advisors or consultants pursuant to equity incentive plans and the issuance by us of any shares of common stock upon the exercise of such options; or
- the transfer of shares of common stock or any security convertible or exchangeable into shares of common stock as a bona fide gift, as a distribution to general or limited partners, stockholders, members or affiliates of our stockholders, or by will or intestate succession to a member of the immediate family of our stockholders, or to a trust for the benefit of such immediate family member.

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With respect to the last bullet, it shall be a condition to the transfer or distribution that the transferee provide prior written notice of such transfer or distribution to J.P. Morgan Securities Inc. and Morgan Stanley & Co. Incorporated, execute a copy of the lock-up agreement, that no filing by any donee or transferee with the SEC shall be required or shall be made voluntarily in connection with such transfer or distribution, other than a filing on Form 5, and no such transfer or distribution may include a disposition for value.

The 180-day restricted period described in the preceding paragraph will be extended if:

- during the last 17 days of the 180-day restricted period we issue an earnings release or material news or a material event relating to us occurs; or
- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

In order to facilitate this offering of common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or by purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. In addition, to stabilize the price of the common stock, the underwriters may bid for and purchase shares of common stock in the open market. Finally, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the common stock in the offering, if the syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

Our common stock has been approved for quotation on the Nasdaq Global Market under the symbol “ETRM.”

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

Prior to this offering, there has been no public market for the shares of common stock. The initial public offering price was determined by negotiations between us and the representatives of the underwriters. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general; sales, earnings and other financial operating information in recent periods; and the price-earnings ratios, price-sales ratios and market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. Once our shares of common stock begin trading in the public market, we cannot be certain that an active trading market for the shares will develop, and it is possible that after the offering the shares will not trade in the market above their initial offering price. A prospectus in electronic format may be made available on the web sites maintained by one or more of the underwriters, and one or more

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of the underwriters may distribute prospectuses electronically. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters that make Internet distributions on the same basis as other allocations.

Each underwriter has represented that (i) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) received by it in connection with the issue or sale of any common stock in circumstances in which Section 21(1) of the FSMA does not apply to us and (ii) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a “Relevant Member State”), each underwriter has represented and agreed that with effect from and including the date on which the European Union Prospectus Directive (the “EU Prospectus Directive”) is implemented in that Relevant Member State (the “Relevant Implementation Date”) it has not made and will not make an offer of common stock to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the EU Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of shares to the public in that 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 EU Prospectus Directive) subject to obtaining the prior consent of the book-running managers for any such offer; or
- in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of shares to the public” in relation to any shares 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 or subscribe the shares, as the same may be varied in that Member State by any measure implementing the EU Prospectus Directive in that Member State and the expression EU Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

## LEGAL MATTERS

Dorsey & Whitney LLP will pass upon the validity of the shares of common stock offered by this prospectus. Latham & Watkins LLP, Costa Mesa, California is acting as counsel for the underwriters.

## EXPERTS

The financial statements included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their reports appearing herein, and are included in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

Gemini Valuation Services, LLC has consented to reference in this prospectus of its report setting forth the appraisal of our securities, and to the use in this prospectus of its name and any statements contained in such reports.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus does not contain all of the information included in the registration statement, portions of which are omitted as permitted by the rules and regulations of the SEC. For further information pertaining to us and the common stock to be sold in this offering, you should refer to the registration statement and its exhibits. 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 filed as an exhibit to the registration statement or such other document, each such statement being qualified in all respects by such reference. On the completion of this offering, we will be subject to the informational requirements of the Securities Exchange Act and will be required to file annual, quarterly and current reports, proxy statements and other information with the SEC. We anticipate making these documents publicly available, free of charge, on our website at [www.enteromedics.com](http://www.enteromedics.com) as soon as reasonably practicable after filing such documents with the SEC.

You can read the registration statement and our future filings with the SEC 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 facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section 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 facilities.

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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
EnteroMedics Inc.  
St. Paul, Minnesota

We have audited the accompanying consolidated balance sheets of EnteroMedics Inc. and subsidiary (a development stage company) (the "Company"), as of December 31, 2006 and 2005, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2006. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of EnteroMedics Inc. and Subsidiary at December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, effective January 1, 2006, the Company adopted the provisions of Financial Accounting Standards Board Statement No. 123(R), "Share-Based Payment."

/s/ DELOITTE & TOUCHE LLP  
Minneapolis, MN  
May 21, 2007 (November 8, 2007, as to the third paragraph of Note 18)

**EnteroMedics Inc.**  
**(A development stage company)**

**Consolidated Balance Sheets**

	<u>December 31,</u>		<u>September 30,</u>	<u>Pro Forma</u>
	<u>2006</u>	<u>2005</u>	<u>2007</u>	<u>at</u> <u>September 30,</u> <u>2007</u> <u>(Note 2)</u>
	<u>(Unaudited)</u>			
<b>ASSETS</b>				
Current assets:				
Cash and cash equivalents (Note 2)	\$ 17,536,472	\$ 10,718,501	\$ 15,884,602	
Short-term investments available for sale	5,755,000	—	5,195,000	
Short-term investments held to maturity	11,440,540	—	1,484,442	
Interest receivable	109,401	—	57,525	
Other receivables	46,120	21,601	13,499	
Prepaid expenses and other current assets	67,646	141,636	244,905	
Total current assets	34,955,179	10,881,738	22,879,973	
Property and equipment, net	1,102,327	642,548	1,470,473	
Other assets	6,395	36,564	307,784	
Total assets	<u>\$ 36,063,901</u>	<u>\$ 11,560,850</u>	<u>\$ 24,658,230</u>	
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>				
Current liabilities:				
Current portion of notes payable	\$ 2,651,336	\$ 998,055	\$ 4,401,577	
Accounts payable	678,762	316,850	238,410	
Accrued expenses	1,704,231	914,473	1,885,994	
Accrued interest payable	—	12,658	—	
Total current liabilities	5,034,329	2,242,036	6,525,981	
Convertible notes payable	—	5,250,003	—	
Notes payable, less current portion (net discounts of \$90,075, \$33,586 and \$471,061 at December 31, 2006 and 2005 and September 30, 2007 (unaudited), respectively)	1,726,959	2,094,259	5,129,747	
Convertible preferred stock warrant liability	728,841	—	—	
Total liabilities	<u>7,490,129</u>	<u>9,586,298</u>	<u>11,655,728</u>	
Stockholders' equity:				
Series C convertible preferred stock, \$0.01 par value 6,043,957 shares authorized; 5,709,630 shares issued and outstanding at December 31, 2006 and September 30, 2007 (unaudited) (liquidation value of \$46,206,014); no shares issued and outstanding pro forma (unaudited)	57,096	—	57,096	\$ —
Series B convertible preferred stock, \$0.01 par value 4,515,285 shares authorized; 4,285,946 shares issued and outstanding at December 31, 2006 and 2005 and September 30, 2007 (unaudited) (liquidation value of \$16,899,652); no shares issued and outstanding pro forma (unaudited)	42,859	42,859	42,859	—
Series A convertible preferred stock, \$0.01 par value 318,270 shares authorized; 318,266 shares issued and outstanding at December 31, 2006 and 2005 and September 30, 2007 (unaudited) (liquidation value of \$2,087,616); no shares issued and outstanding pro forma (unaudited)	3,183	3,183	3,183	—
Common stock, \$0.01 par value 14,505,945 shares authorized; 579,759, 480,101 and 614,891 shares issued and outstanding at December 31, 2006 and 2005 and September 30, 2007 (unaudited), respectively; 11,309,113 shares issued and outstanding pro forma (unaudited)	5,798	4,801	6,149	113,091
Additional paid-in capital	63,389,371	19,178,815	67,628,026	69,272,574
Deferred compensation	(66,479)	(87,527)	(47,542)	(47,542)
Deficit accumulated during development stage	(34,858,056)	(17,167,579)	(54,687,269)	(56,335,621)
Total stockholders' equity	<u>\$ 28,573,772</u>	<u>\$ 1,974,552</u>	<u>\$ 13,002,502</u>	<u>\$ 13,002,502</u>
Total liabilities and stockholders' equity	<u>\$ 36,063,901</u>	<u>\$ 11,560,850</u>	<u>\$ 24,658,230</u>	

See accompanying notes to consolidated financial statements.

**EnteroMedics Inc.**  
**(A development stage company)**  
**Consolidated Statements Of Operations**

	Years Ended December 31,			Nine Months Ended September 30,		Period From December 19, 2002 (Inception) to September 30, 2007
	2006	2005	2004	2007	2006	(Unaudited)
				(Unaudited)		(Unaudited)
<b>Operating expenses:</b>						
Research and development	\$ 14,361,226	\$ 8,832,722	\$ 1,754,537	\$ 13,894,118	\$ 9,933,440	\$ 41,195,731
Selling, general and administrative	3,760,590	2,319,561	1,491,254	5,462,648	2,614,715	13,168,909
Total operating expenses	18,121,816	11,152,283	3,245,791	19,356,766	12,548,155	54,364,640
Other income (expense):						
Interest income	1,135,855	109,884	34,857	1,089,448	658,996	2,370,044
Interest expense	(710,108)	(181,151)	(237,818)	(1,185,799)	(559,252)	(2,330,528)
Change in value of the convertible preferred stock warrant liability	6,597	—	—	(361,504)	—	(354,907)
Other, net	(1,005)	8,359	—	(14,592)	(17,341)	(7,238)
Net loss	<u>\$ (17,690,477)</u>	<u>\$ (11,215,191)</u>	<u>\$ (3,448,752)</u>	<u>\$ (19,829,213)</u>	<u>\$ (12,465,752)</u>	<u>\$ (54,687,269)</u>
Net loss per share—basic and diluted	<u>\$ (34.19)</u>	<u>\$ (28.82)</u>	<u>\$ (24.36)</u>	<u>\$ (33.01)</u>	<u>\$ (24.74)</u>	
Shares used to compute basic and diluted net loss per share	<u>517,462</u>	<u>389,101</u>	<u>141,564</u>	<u>600,639</u>	<u>503,946</u>	
Pro forma basic and diluted net loss per share (unaudited)	<u>\$ (2.20)</u>			<u>\$ (1.76)</u>		
Shares used to compute pro forma basic and diluted net loss per share (unaudited)	<u>8,042,585</u>			<u>11,088,817</u>		

See accompanying notes to consolidated financial statements.

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**EnteroMedics Inc.**  
**(A development stage company)**

**Consolidated Statements of Stockholders' Equity (Deficit)**  
**Period from December 19, 2002 (Inception) to September 30, 2007**

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
Common stock issued at inception of Alpha Medical, Inc. on December 19, 2002 at \$0.09 per share for cash	—	\$ —	—	\$ —	—	\$ —
Common stock issued at inception of Beta Medical, Inc. on December 19, 2002 at \$0.09 per share for cash	—	—	—	—	—	—
Alpha Medical, Inc. Series A convertible preferred stock issued on December 31, 2002 at \$9.10 per share for cash	—	—	—	—	33,150	332
Beta Medical, Inc. Series A convertible preferred stock issued on December 31, 2002 at \$9.10 per share for cash	—	—	—	—	33,150	332
Net loss for the period ended December 31, 2002	—	—	—	—	—	—
Alpha Medical, Inc. Series A convertible preferred stock issued on October 1, 2003 at \$9.10 per share for cash	—	—	—	—	38,461	384
Beta Medical, Inc. Series A convertible preferred stock issued on October 1, 2003 at \$9.10 per share for cash	—	—	—	—	93,406	934
Cancellation of Alpha Medical, Inc. Series A convertible preferred stock and common stock upon merger with Beta Medical, Inc. effective October 1, 2003 (Note 1)	—	—	—	—	(71,613)	(716)
Issuance of Series A convertible preferred stock upon merger of Alpha Medical, Inc. and Beta Medical, Inc. effective October 1, 2003 (Note 1)	—	—	—	—	65,934	659
Common stock issued in October 2003 at \$0.09 per share for cash	—	—	—	—	—	—
Warrants issued for the purchase of 23,516 shares of Series B convertible preferred stock for cash at \$0.00455 per share in connection with the November 13, 2003 convertible bridge notes	—	—	—	—	—	—
Net loss for the year ended December 31, 2003	—	—	—	—	—	—
<b>Balance, December 31, 2003 (unaudited)</b>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>192,488</u>	<u>\$ 1,925</u>

See accompanying notes to consolidated financial statements.

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Common Stock		Additional Paid- In Capital	Deferred Compensation	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
Shares	Amount				
109,890	\$ 1,099	8,901	\$ —	\$ —	\$ 10,000
109,890	1,099	8,901	—	—	10,000
—	—	301,342	—	—	301,674
—	—	301,342	—	—	301,674
—	—	—	—	(603,348)	(603,348)
—	—	349,616	—	—	350,000
—	—	849,066	—	—	850,000
(109,890)	(1,099)	(659,859)	—	—	(661,674)
—	—	661,015	—	—	661,674
115,376	1,154	9,346	—	—	10,500
—	—	107	—	—	107
—	—	—	—	(1,900,288)	(1,900,288)
<u>225,266</u>	<u>\$ 2,253</u>	<u>\$1,829,777</u>	<u>\$ —</u>	<u>\$ (2,503,636)</u>	<u>\$ (669,681)</u>

**EnteroMedics Inc.**  
**(A development stage company)**  
**Consolidated Statements of Stockholders' Equity**  
**(Deficit) (Continued)**  
**Period from December 19, 2002 (Inception) to September 30, 2007**

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
<b>Balance, December 31, 2003</b>	—	\$ —	—	\$ —	192,488	\$ 1,925
Warrants issued for the purchase of 6,484 shares of Series B convertible preferred stock for cash at \$0.00455 per share in connection with the April 23, 2004 convertible bridge notes	—	—	—	—	—	—
Exercise of 125,778 Series A convertible preferred stock warrants on April 23, 2004 for cash at \$1.4919359 per share	—	—	—	—	125,778	1,258
Warrants issued for the purchase of 4,396 shares of Series B convertible preferred stock for cash at \$0.00455 per share in connection with the June 30, 2004 convertible bridge notes	—	—	—	—	—	—
Fair value of warrants related to convertible bridge notes	—	—	—	—	—	—
Series B convertible preferred stock issued upon conversion of \$1,564,843 of convertible bridge notes and \$34,809 of accrued interest payable on July 30, 2004 at \$3.9430 per share	—	—	405,690	4,057	—	—
Series B convertible preferred stock issued on July 30, 2004 for cash at \$3.9430 per share, net of financing costs of \$94,776	—	—	1,914,767	19,148	—	—
Warrants issued for the purchase of 45,333 shares of Series B convertible preferred stock on December 1, 2004 valued at \$1.0747 per warrant for debt commitment	—	—	—	—	—	—
Issuance of 22,912 common stock options to nonemployees in 2004 valued at \$0.1574 per option	—	—	—	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
<b>Balance, December 31, 2004</b>	<u>—</u>	<u>\$ —</u>	<u>2,320,457</u>	<u>\$ 23,205</u>	<u>318,266</u>	<u>\$ 3,183</u>

See accompanying notes to consolidated financial statements.

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<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Deferred Compensation</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity (Deficit)</u>
<u>Shares</u>	<u>Amount</u>				
225,266	\$ 2,253	\$1,829,777	\$ —	\$ (2,503,636)	\$ (669,681)
—	—	30	—	—	30
—	—	186,394	—	—	187,652
—	—	20	—	—	20
—	—	153,722	—	—	153,722
—	—	1,595,595	—	—	1,599,652
—	—	7,436,077	—	—	7,455,225
—	—	48,720	—	—	48,720
—	—	3,610	(3,610)	—	—
—	—	—	830	—	830
—	—	—	—	(3,448,752)	(3,448,752)
<u>225,266</u>	<u>\$ 2,253</u>	<u>\$11,253,945</u>	<u>\$ (2,780)</u>	<u>\$ (5,952,388)</u>	<u>\$ 5,327,418</u>

**EnteroMedics Inc.**  
**(A development stage company)**  
**Consolidated Statements of Stockholders' Equity**  
**(Deficit) (Continued)**  
**Period from December 19, 2002 (Inception) to September 30, 2007**

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
<b>Balance, December 31, 2004</b>	—	\$ —	2,320,457	\$ 23,205	318,266	\$ 3,183
Series B convertible preferred stock issued on June 17, 2005 for cash at \$3.9430 per share, net of financing costs of \$5,218	—	—	760,834	7,608	—	—
Warrants issued for the purchase of 69,744 shares of Series B convertible preferred stock in September 2005 valued at \$1.0702 per warrant for debt commitment and funding	—	—	—	—	—	—
Warrants issued for the purchase of 170,336 shares of common stock on December 12, 2005 for cash at \$0.09 per warrant	—	—	—	—	—	—
Series B convertible preferred stock issued on December 12, 2005 at \$3.9430 per share, net of financing costs of \$11,085	—	—	1,204,655	12,046	—	—
Common stock issued to non-employees in 2005 valued at \$0.46 per share	—	—	—	—	—	—
Issuance of 46,543 common stock options to non-employees in 2005 valued at \$0.1565 per option	—	—	—	—	—	—
Exercise of 29,561 common stock options in 2005 for cash at \$0.46 per share	—	—	—	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
<b>Balance, December 31, 2005</b>	—	\$ —	4,285,946	\$ 42,859	318,266	\$ 3,183

See accompanying notes to consolidated financial statements.

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<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Deferred Compensation</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity (Deficit)</u>
<u>Shares</u>	<u>Amount</u>				
225,266	\$ 2,253	\$ 11,253,945	\$ (2,780)	\$ (5,952,388)	\$ 5,327,418
—	—	2,987,174	—	—	2,994,782
—	—	74,636	—	—	74,636
—	—	15,500	—	—	15,500
—	—	4,726,870	—	—	4,738,916
225,274	2,252	100,248	(102,500)	—	—
—	—	7,288	(7,288)	—	—
29,561	—	—	—	—	—
—	296	13,154	—	—	13,450
—	—	—	25,041	—	25,041
—	—	—	—	(11,215,191)	(11,215,191)
<u>480,101</u>	<u>\$ 4,801</u>	<u>\$ 19,178,815</u>	<u>\$ (87,527)</u>	<u>\$ (17,167,579)</u>	<u>\$ 1,974,552</u>

**EnteroMedics Inc.**  
**(A development stage company)**

**Consolidated Statements of Stockholders' Equity**  
**(Deficit) (Continued)**

**Period from December 19, 2002 (Inception) to September 30, 2007**

	Series C Convertible Preferred Stock		Series B Convertible Preferred Stock		Series A Convertible Preferred Stock	
	Shares	Amount	Shares	Amount	Shares	Amount
<b>Balance, December 31, 2005</b>	—	\$ —	4,285,946	\$ 42,859	318,266	\$ 3,183
Warrants issued for the purchase of 34,872 shares of Series B convertible preferred stock in March 2006 valued at \$2.9257 per warrant for debt funding	—	—	—	—	—	—
Series C convertible preferred stock issued upon conversion of \$5,250,003 of convertible bridge notes and \$131,013 of accrued interest payable on July 6, 2006 at \$8.0926 per share	664,919	6,649	—	—	—	—
Series C convertible preferred stock issued on July 6, 2006 for cash at \$8.0926 per share, net of financing costs of \$2,222,342	4,921,142	49,211	—	—	—	—
Warrants issued for the purchase of 147,635 shares of Series C convertible preferred stock on July 6, 2006 valued at \$4.9813 per warrant for equity financing	—	—	—	—	—	—
Series C convertible preferred stock issued on December 11, 2006 for cash at \$8.0926 per share	123,569	1,236	—	—	—	—
Series C convertible preferred stock warrants reclassified to convertible preferred stock warrant liability on December 11, 2006	—	—	—	—	—	—
Common stock issued to nonemployees in 2006 valued at \$0.46 per share	—	—	—	—	—	—
Common stock issued to nonemployees in 2006 valued at \$1.91 per share	—	—	—	—	—	—
Employee stock-based compensation expense	—	—	—	—	—	—
Non-employee stock-based compensation expense	—	—	—	—	—	—
Exercise of 87,022 common stock options in 2006 for cash at \$0.46 per share	—	—	—	—	—	—
Amortization of deferred compensation	—	—	—	—	—	—
Net loss	—	—	—	—	—	—
<b>Balance, December 31, 2006</b>	<u>5,709,630</u>	<u>57,096</u>	<u>4,285,946</u>	<u>42,859</u>	<u>318,266</u>	<u>3,183</u>
Employee stock-based compensation expense (Unaudited)	—	—	—	—	—	—
Non-employee stock-based compensation expense (Unaudited)	—	—	—	—	—	—
Warrants issued for the purchase of 33,982 shares of Series C convertible preferred stock in May 2007 valued at \$8.2783 per warrant for debt funding (Unaudited)	—	—	—	—	—	—
Warrants issued for the purchase of 67,963 shares of Series C convertible preferred stock in May 2007 valued at \$8.0926 per warrant for debt facility commitment (Unaudited)	—	—	—	—	—	—
Warrants issued for the purchase of 16,991 shares of Series C convertible preferred stock in August 2007 valued at \$11.6377 per warrant for debt facility funding (Unaudited)	—	—	—	—	—	—
Series C convertible preferred stock warrants reclassified from convertible preferred stock warrant liability (Unaudited)	—	—	—	—	—	—
Exercise of 35,132 common stock options in 2007 for cash at \$0.60 per share (Unaudited)	—	—	—	—	—	—
Amortization of deferred compensation (Unaudited)	—	—	—	—	—	—
Net loss (Unaudited)	—	—	—	—	—	—
<b>Balance, September 30, 2007 (Unaudited)</b>	<u>5,709,630</u>	<u>\$ 57,096</u>	<u>4,285,946</u>	<u>\$ 42,859</u>	<u>318,266</u>	<u>\$ 3,183</u>

See accompanying notes to consolidated financial statements.

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<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Deferred Compensation</u>	<u>Deficit Accumulated During the Development Stage</u>	<u>Total Stockholders' Equity (Deficit)</u>
<u>Shares</u>	<u>Amount</u>				
480,101	\$ 4,801	\$19,178,815	\$ (87,527)	\$ (17,167,579)	\$ 1,974,552
—	—	102,022	—	—	102,022
—	—	5,374,367	—	—	5,381,016
—	—	37,553,450	—	—	37,602,661
—	—	735,438	—	—	735,438
—	—	998,764	—	—	1,000,000
—	—	(735,438)	—	—	(735,438)
9,889	100	4,400	(4,500)	—	—
2,747	27	5,223	(5,250)	—	—
—	—	47,479	—	—	47,479
—	—	86,125	—	—	86,125
87,022	870	38,726	—	—	39,596
—	—	—	30,798	—	30,798
—	—	—	—	(17,690,477)	(17,690,477)
579,759	5,798	63,389,371	(66,479)	(34,858,056)	28,573,772
—	—	633,064	—	—	633,064
—	—	1,465,146	—	—	1,465,146
—	—	281,321	—	—	281,321
—	—	550,212	—	—	550,212
—	—	197,731	—	—	197,731
—	—	1,090,345	—	—	1,090,345
35,132	351	20,836	—	—	21,187
—	—	—	18,937	—	18,937
—	—	—	—	(19,829,213)	(19,829,213)
<u>614,891</u>	<u>\$6,149</u>	<u>\$67,628,026</u>	<u>\$ (47,542)</u>	<u>\$ (54,687,269)</u>	<u>\$ 13,002,502</u>

**EnteroMedics Inc.**  
**(A development stage company)**  
**Consolidated Statements of Cash Flows**

	<u>Years Ended December 31,</u>			<u>Nine Months Ended</u>		<u>Period from</u>
				<u>September 30,</u>		<u>December 19,</u>
	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2007</u>		<u>2002</u>
				<u>(Unaudited)</u>		<u>(Inception) to</u>
				<u>(Unaudited)</u>		<u>September 30,</u>
				<u>(Unaudited)</u>		<u>2007</u>
				<u>(Unaudited)</u>		<u>(Unaudited)</u>
<b>Cash flows from operating activities:</b>						
Net loss	\$ (17,690,477)	\$ (11,215,191)	\$ (3,448,752)	\$ (19,829,213)	\$ (12,465,752)	\$ (54,687,269)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation	175,194	58,407	5,085	283,316	114,465	523,171
Loss on sale of equipment	—	—	2,361	—	—	2,361
Employee stock-based compensation	47,479	—	—	633,064	23,320	680,543
Nonemployee stock-based compensation	116,923	25,041	830	1,484,083	90,710	1,626,877
Amortization of commitment fees, debt issuance costs and original issue discount	77,097	84,824	208,716	623,268	63,164	1,003,851
Amortization of short-term investment discount	(156,442)	—	—	(112,046)	(69,354)	(268,488)
Change in carrying value of warrant liability	(6,597)	—	—	361,504	—	354,907
Change in operating assets and liabilities:						
Interest receivable	(109,401)	—	—	51,876	(135,911)	(57,525)
Other receivables	(24,519)	(9,570)	(11,999)	32,621	13,235	(13,499)
Prepaid expenses and other current assets	73,990	(88,625)	(36,051)	(177,259)	(16,831)	(244,905)
Other assets	(1,395)	(5,000)	—	(276,379)	(1,395)	(282,774)
Accounts payable	361,912	159,311	134,714	(440,352)	41,739	238,410
Accrued expenses	789,758	700,055	10,769	181,763	363,410	1,885,994
Accrued interest payable	118,355	12,658	29,103	—	118,355	165,822
Net cash used in operating activities	<u>(16,228,123)</u>	<u>(10,278,090)</u>	<u>(3,105,224)</u>	<u>(17,183,754)</u>	<u>(11,860,845)</u>	<u>(49,072,524)</u>
<b>Cash flows from investing activities:</b>						
Purchases of short-term investments available for sale	(5,755,000)	—	—	—	(5,770,000)	(5,755,000)
Maturities of short-term investments available for sale	—	—	—	560,000	—	560,000
Purchases of short-term investments held to maturity	(14,284,098)	—	—	(4,331,856)	(14,284,098)	(18,615,954)
Maturities of short-term investments held to maturity	3,000,000	—	—	14,400,000	—	17,400,000
Purchases of property and equipment	(634,973)	(449,811)	(241,664)	(651,462)	(417,597)	(1,996,005)
Net cash (used in) provided by investing activities	<u>(17,674,071)</u>	<u>(449,811)</u>	<u>(241,664)</u>	<u>9,976,682</u>	<u>(20,471,695)</u>	<u>(8,406,959)</u>
<b>Cash flows from financing activities:</b>						
Proceeds from stock options exercised	39,596	13,450	—	21,187	36,408	74,233
Proceeds from warrants issued	—	15,500	50	—	—	15,657
Proceeds from warrants exercised	—	—	187,652	—	—	187,652
Proceeds from sale of common stock	—	—	—	—	—	30,500
Proceeds from sale of Series A convertible preferred stock	—	—	—	—	—	1,803,348

See accompanying notes to consolidated financial statements.

**EnteroMedics Inc.**  
**(A development stage company)**  
**Consolidated Statements of Cash Flows (Continued)**

	Years Ended December 31,			Nine Months Ended September 30,		Period from December 19, 2002 (Inception) to September 30, 2007
	2006	2005	2004	2007	2006	(Unaudited)
				(Unaudited)		(Unaudited)
Proceeds from sale of Series B convertible preferred stock	—	7,750,001	7,550,001	—	—	15,300,002
Series B convertible preferred stock financing costs	—	(16,303)	(94,776)	—	—	(111,079)
Proceeds from sale of Series C convertible preferred stock	40,825,003	—	—	—	39,825,002	40,825,003
Series C convertible preferred stock financing costs	(1,486,904)	—	—	—	(1,477,773)	(1,486,904)
Proceeds from convertible notes payable	—	5,250,003	494,950	—	—	6,814,846
Proceeds from notes payable	2,620,221	3,125,900	—	7,500,000	2,620,221	13,331,121
Repayments on notes payable	(1,277,751)	—	(85,000)	(1,965,985)	(654,690)	(3,328,736)
Debt issuance costs	—	(23,748)	(37,971)	—	—	(91,558)
Net cash provided by financing activities	40,720,165	16,114,803	8,014,906	5,555,202	40,349,168	73,364,085
Net increase (decrease) in cash and cash equivalents	6,817,971	5,386,902	4,668,018	(1,651,870)	8,016,628	15,884,602
<b>Cash and cash equivalents:</b>						
Beginning of year	10,718,501	5,331,599	663,581	17,536,472	10,718,501	—
End of year	<u>\$ 17,536,472</u>	<u>\$ 10,718,501</u>	<u>\$ 5,331,599</u>	<u>\$ 15,884,602</u>	<u>\$ 18,735,129</u>	<u>\$ 15,884,602</u>
<b>Supplemental disclosure:</b>						
Interest paid	\$ 514,655	\$ 83,669	\$ —	\$ 562,531	\$ 377,734	\$ 1,160,855
<b>Noncash investing and financing activities:</b>						
Cancellation of Alpha Medical, Inc. Series A convertible preferred stock and common stock	\$ —	\$ —	\$ —	\$ —	\$ —	\$ (661,674)
Issuance of Beta Medical, Inc. Series A convertible preferred stock in exchange for Alpha Medical, Inc. Series A convertible preferred stock and common stock	—	—	—	—	—	661,674
Value of warrants issued with debt	102,022	37,318	153,722	479,052	102,022	772,114
Value of warrants issued for debt commitment	—	37,318	48,720	550,212	—	636,250
Value of warrants issued with Series C financing	735,438	—	—	—	735,438	735,438
Conversion of notes payable to Series B convertible preferred shares	—	—	1,564,843	—	—	1,564,843
Conversion of interest payable to Series B convertible preferred shares	—	—	34,809	—	—	34,809
Conversion of notes payable to Series C convertible preferred shares	5,250,003	—	—	—	5,250,003	5,250,003
Conversion of interest payable to Series C convertible preferred shares	131,013	—	—	—	131,013	131,013
Value of options issued for deferred compensation	—	7,288	3,610	—	—	10,898
Common stock issued for deferred compensation	9,750	102,500	—	—	4,500	112,250

See accompanying notes to consolidated financial statements.

**EnteroMedics Inc.**  
**(A development stage company)**  
**Notes to Consolidated Financial Statements**

**(1) Formation and Business of the Company**

EnteroMedics Inc. (EnteroMedics or the Company) is developing implantable systems to treat obesity and other gastrointestinal disorders. The Company was incorporated in the state of Minnesota on December 19, 2002, originally as two separate legal entities, Alpha Medical, Inc. (Alpha) and Beta Medical, Inc. (Beta), both of which were owned 100% by a common stockholder. Effective October 1, 2003, the two entities were combined and changed its name to EnteroMedics Inc. The Company changed its state of incorporation to Delaware on July 22, 2004. The Company is in the development stage and since inception has devoted substantially all of its resources to recruiting personnel, developing its product technology, obtaining patents to protect its intellectual property and raising capital, and has not derived revenues from its primary business activity. Accordingly, the Company is in the development stage, as defined by Statement of Financial Accounting Standards No. 7, *Accounting and Reporting by Development Stage Enterprises*. The Company is headquartered in St. Paul, Minnesota.

Pursuant to Statement of Financial Accounting Standards No. 141, *Business Combinations*, the term business combinations excludes transfer of net assets or exchange of equity interest between entities under common control. The merger of Alpha into Beta was a merger between entities under common control and, therefore, related assets and liabilities were recorded at their carrying amount at the date of merger and prior period statements of operations, stockholders' equity and cash flows are shown as previously reported. At the time of the merger, each share of common stock and Series A convertible preferred stock of Alpha was converted into Series A convertible preferred stock of Beta, the surviving entity, at a rate of 0.363267812 per share. Alpha had 109,890 shares of common stock and 71,613 shares of Series A convertible preferred stock outstanding, which were converted into 65,934 shares of Beta Series A convertible preferred stock.

EnteroMedics Europe Srl (EnteroMedics Europe), a wholly-owned subsidiary of the Company, was formed in January 2006. EnteroMedics Europe is a Switzerland entity established as a means to conduct clinical trials in Switzerland. Upon establishment there were 20 shares of EnteroMedics Europe issued and outstanding with a par value of 1,000 Swiss Francs. EnteroMedics purchased 100% of the shares and then issued one share to a fiduciary agent. The one share is the property of EnteroMedics and is held by the fiduciary in a fiduciary capacity under terms of the Fiduciary Agreement. Pursuant to Statement of Financial Accounting Standards No. 52, *Foreign Currency Translation*, the functional currency of EnteroMedics Europe has been determined to be the U.S. Dollar.

Since inception, EnteroMedics has incurred losses through September 30, 2007 totaling approximately \$54.7 million and has not generated positive cash flows from operations. The Company expects such losses to continue into the foreseeable future as it continues to develop and commercialize its technologies. The Company may need to obtain additional financing and there can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. If adequate funds are not available, the Company may have to delay development or commercialization of products or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to commercialize.

**(2) Summary of Significant Accounting Policies**

***Unaudited Interim Financial Information***

The accompanying consolidated balance sheet as of September 30, 2007, the consolidated statements of operations and cash flows for nine months ended September 30, 2007 and 2006 and for the period from December 19, 2002 (inception) to September 30, 2007 and the consolidated statements of stockholders' equity (deficit) for the nine months ended September 30, 2007 are unaudited. The unaudited interim financial statements

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's financial position and results of operations and cash flows for the nine months ended September 30, 2007 and 2006 and for the period from inception to September 30, 2007. The financial data and other information disclosed in these notes to the consolidated financial statements related to the nine-month periods are unaudited. The results of the nine months ended September 30, 2007 are not necessarily indicative of the results to be expected for the year ending December 31, 2007 or for any other interim period or for any other future year.

***Unaudited Pro Forma Presentation***

The unaudited pro forma consolidated balance sheet data presented as of September 30, 2007 reflects the conversion of all outstanding shares of convertible preferred stock as of that date into 10,488,178 shares of common stock, which will occur upon closing of the proposed initial public offering, as if the conversion had occurred on September 30, 2007. It also includes 206,044 shares issued to the Mayo Foundation discussed at Note 16. Upon issuance of these shares related to an initial public offering, the Company will record a one-time stock-based compensation expense at the then current fair value with an off-setting increase to common stock and additional paid-in capital. For purposes of pro forma presentation, the Company assumed a one-time stock-based compensation expense of \$1,648,352, which amount was computed using the initial public offering price of \$8.00 per share.

On November 13, 2007, pursuant to Article IV, Section 4(b)(ii) of the Company's Fourth Amended and Restated Certificate of Incorporation, the holders of more than 63% of the outstanding shares of Series B and Series C Preferred Stock consented to the automatic conversion of all outstanding shares of the Company's preferred stock effective as of immediately prior to closing of an initial public offering of the Company's common stock in which the public offering price is equal to or greater than \$8.00 per share. The unaudited pro forma information assumes a public offering price of at least \$8.00 per share and reflects the automatic conversion of all the outstanding shares of Series A convertible preferred stock, par value of \$0.01 per share, Series B convertible preferred stock, par value of \$0.01 per share, and Series C convertible preferred stock, par value of \$0.01 per share, as defined in the amended and restated certificate of incorporation approved by the Company's board of directors and stockholders on October 3, 2007, discussed at Note 18. Upon closing of the proposed initial public offering, the Company's authorized capital stock will consist of 50,000,000 shares of common stock, par value \$0.01 per share, and 5,000,000 shares of preferred stock, par value \$0.01 per share.

***Basis of Presentation***

The Company has prepared the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America. The Company's fiscal year ends on December 31.

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

***Principles of Consolidation***

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany transactions and accounts have been eliminated in consolidation.

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

***Concentration of Credit Risk and Other Risks and Uncertainties***

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. Cash and cash equivalents are deposited in demand and money market accounts at two financial institutions. At times, such deposits may be in excess of insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Most of the products developed by the Company will require clearance from the U.S. Food and Drug Administration (FDA) or corresponding foreign regulatory agencies prior to commercial sales. There can be no assurance the Company's products will receive the necessary clearances. If the Company is denied clearance or clearance is delayed, it will have a material adverse impact on the Company.

The medical device industry is characterized by frequent and extensive litigation and administrative proceedings over patent and other intellectual property rights. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often difficult to predict, and the outcome may be uncertain until the court has entered final judgment and all appeals are exhausted. The Company's competitors may assert that its products or the use of the Company's products are covered by U.S. or foreign patents held by them.

***Fair Value of Financial Instruments***

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. The fair values of investments in debt and equity securities are disclosed in Note 3. The fair value of the Company's long-term debt is \$4,612,710 as of December 31, 2006 based on borrowing rates available to the Company.

***Cash and Cash Equivalents***

The Company considers highly liquid investments with maturities of 90 days or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates market value. The Company's cash equivalents are primarily in money market funds and commercial paper. The Company deposits its cash and cash equivalents in high-quality credit institutions. Under terms of the Company's notes payable agreements (see Note 6), in the event of default, the lender has the right to enforce account control agreements and restrict the Company's access to their cash and investment accounts.

***Short-Term Investments***

The Company considers all investments with maturities greater than three months and less than one year at the time of purchase as short-term investments and classifies them as either available for sale or held to maturity.

Available-for-sale securities are carried at fair value based on quoted market prices, with the unrealized gains and losses included in other comprehensive income within stockholders' equity (deficit) in the consolidated balance sheets. Realized gains and losses and declines in value judged to be other than temporary on available-for-sale securities are included in interest and other income. Interest and dividends on securities classified as available for sale are included in interest income. The cost of securities sold is based on the specific identification method.

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

Short-term investments in debt securities which the Company has the positive intent and ability to hold to maturity are reported at cost, adjusted for premiums and discounts that are recognized in interest income, using the interest method, over the period to maturity. Unrealized losses on held-to-maturity securities reflecting a decline in value determined to be other than temporary are charged to income.

***Property and Equipment, Net***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation of property and equipment is computed using the straight-line method over their estimated useful lives of three to seven years. Leasehold improvements are amortized on a straight-line basis over the lesser of their useful life or the term of the lease. Upon retirement or sale, the cost and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is reflected in the consolidated statements of operations. Repairs and maintenance are expensed as incurred.

***Impairment of Long-Lived Assets***

The Company evaluates its long-lived assets for indicators of possible impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the asset over the asset's fair value or estimates of future discounted cash flows. The Company has not identified any such impairment losses to date.

***Income Taxes***

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The Company has provided a full valuation allowance against the gross deferred tax assets as of December 31, 2006 and 2005 (see Note 12). The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the Consolidated Statements of Operations.

***Research and Development Expenses***

Research and development expenses are charged to expense as incurred. Research and development expenses include, but are not limited to, product development, clinical and regulatory expenses, payroll and other personnel expenses, materials, supplies, and consulting costs.

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

***Patent Costs***

Costs associated with the submission of a patent application are expensed as incurred given the uncertainty of the patents resulting in probable future economic benefits to the Company. Patent-related legal expenses included in general and administrative costs were \$274,665, \$214,300 and \$129,272 for the years ended December 31, 2006, 2005 and 2004, respectively, and \$943,235 for the period from December 19, 2002 (inception) to September 30, 2007 (unaudited). Patent-related legal expenses included in general and administrative costs for the nine months ended September 30, 2007 and 2006 were \$312,011 (unaudited) and \$183,111 (unaudited), respectively.

***Derivative Instruments***

The Company accounts for the Series C preferred stock warrants as derivatives under Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related Emerging Issues Task Force (EITF) interpretations and Securities and Exchange Commission (SEC) rules, which require that the warrants be classified as a liability and measured at fair value with changes in fair value recognized currently in earnings, when there are not enough authorized shares to be issued upon exercise of the warrants. The Company has recorded changes in fair value as interest expense in the consolidated statements of operations.

***Stock-Based Compensation***

Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*, and related interpretations, and followed the minimum value disclosure provisions of Statement of Financial Accounting Standards No. 123 (SFAS 123), *Accounting for Stock-Based Compensation*. Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the Company's stock and the exercise price. Employee stock-based compensation determined under APB 25 is recognized over the option vesting period.

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

Effective January 1, 2006, the Company adopted the fair value provisions of Statement of Financial Accounting Standards No. 123R (SFAS 123R), *Share-Based Payment*, which supersedes its previous accounting under APB 25. SFAS 123R requires the recognition of compensation expense, using a fair-value-based method, for costs related to all share-based payments including stock options. SFAS 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The Company adopted SFAS 123R using the prospective transition method, which requires that for nonpublic entities that used the minimum value method for either pro forma or financial statement recognition purposes, SFAS 123R shall be applied to option grants or modifications to existing options after the required effective date. For options granted prior to the new SFAS 123R effective date and for which the requisite service period has not been performed as of January 1, 2006, the Company will continue to apply the intrinsic value provisions of APB 25 on the remaining unvested awards. All option grants valued after January 1, 2006 will be expensed on a straight-line basis over the vesting period.

The Company accounts for stock-based compensation arrangements with nonemployees in accordance with the Emerging Issues Task Force Abstract No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. The Company records the expense of such services based on the estimated fair value of the equity instrument using the Black-Scholes pricing model. The value of the equity instrument is charged to earnings over the term of the service agreement.

***Net Loss Per Share***

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. The Company's potential dilutive shares, which include outstanding common stock options, unvested common shares subject to repurchase, convertible preferred stock and warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be to reduce a net loss per share.

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

The pro forma basic and diluted net loss per share calculations for the year ended December 31, 2006 and the nine months ended September 30, 2007 assume the conversion of all outstanding shares of convertible preferred stock into shares of common stock, using the as-if converted method, as of January 1, 2006, or the date of issuance, if later are as follows:

	Year ended December 31,			Nine Months Ended September 30,	
	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2007</u>	<u>2006</u>
				(Unaudited)	
Numerator:					
Net loss	\$(17,690,477)	\$(11,215,191)	\$(3,448,752)	\$(19,829,213)	\$(12,465,752)
Denominator for historical and basic and diluted net loss per share:					
Weighted-average common shares outstanding	543,442	443,927	225,266	603,954	533,550
Weighted-average unvested common shares subject to repurchase	(25,980)	(54,826)	(83,702)	(3,315)	(29,604)
Denominator for net loss per common share—basic and diluted	<u>517,462</u>	<u>389,101</u>	<u>141,564</u>	<u>600,639</u>	<u>503,946</u>
Net loss per share—basic and diluted	<u>\$ (34.19)</u>	<u>\$ (28.82)</u>	<u>\$ (24.36)</u>	<u>\$ (33.01)</u>	<u>\$ (24.74)</u>
Net loss	\$(17,690,477)			\$(19,829,213)	
Pro forma adjustment to reverse the mark-to-market adjustments to the convertible preferred stock warrants	(6,597)			361,504	
Net loss used to compute pro forma net loss per share	<u>\$(17,697,074)</u>			<u>\$(19,467,709)</u>	
Shares used above	517,462			600,639	
Pro forma adjustment to reflect assumed weighted-average effect of conversion of convertible preferred stock to common stock shares used to compute pro forma basic and diluted net loss per share	7,525,123			10,488,178	
Denominator for pro forma basic and diluted net loss per share	<u>8,042,585</u>			<u>11,088,817</u>	
Pro forma net loss per share—basic and diluted	<u>\$ (2.20)</u>			<u>\$ (1.76)</u>	

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	December 31,			September 30,	
	2006	2005	2004	2007 (Unaudited)	2006
Convertible preferred stock	10,313,842	4,604,212	2,638,723	10,313,842	10,190,273
Stock options outstanding	1,261,869	772,424	340,952	2,078,771	1,218,427
Warrants to purchase convertible preferred stock	376,972	194,465	124,721	495,908	376,972
Warrants to purchase common stock	170,336	170,336	—	170,336	170,336

**Recently Issued Accounting Standards**

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes — an interpretation of FASB Statement No. 109*, which clarifies the accounting for uncertainty in tax positions. FIN 48 requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of the Company's 2007 fiscal year, with the cumulative effect, if any, of the change in accounting principle recorded as an adjustment to opening retained earnings. The adoption of FIN 48 had no impact on the Company's consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. Earlier adoption is permitted, provided the company has not yet issued financial statements, including for interim periods, for that fiscal year. The Company is currently evaluating the impact of SFAS 157.

In September 2006, the United States Securities and Exchange Commission issued Staff Accounting Bulletin No. 108 (SAB 108), *Considering the Effects of Prior Year Misstatements When Quantifying Misstatements in Current Year Financial Statements*, which provides interpretive guidance on how registrants should quantify financial statement misstatements. Under SAB 108, registrants are required to consider both a "rollover" method which focuses primarily on the income statement impact of misstatements and the "iron curtain" method which focuses primarily on the balance sheet impact of misstatements. SAB 108 was effective for 2006 and had no impact on the Company's consolidated financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities — Including an amendment of FASB Statement No. 115*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The amendment to SFAS 115 applies to all entities with investments in available-for-sale or trading securities. The statement is effective for fiscal years beginning after November 15, 2007. The Company has not yet determined the effect SFAS 159 will have on its consolidated financial statements.

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

**(3) Short-term Investments**

The amortized cost and fair value of short-term investments available for sale, with gross unrealized gains and losses, were as follows:

**As of September 30, 2007 (unaudited)**

	Cost	Gross Unrealized		Fair value
		Gains	Losses	
State and municipal tax-exempt bonds	\$1,000,000	\$ —	\$ —	\$1,000,000
Corporate debt	4,195,000	—	—	4,195,000
Total investment securities available for sale	<u>\$5,195,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$5,195,000</u>

**As of December 31, 2006**

	Cost	Gross Unrealized		Fair value
		Gains	Losses	
State and municipal tax-exempt bonds	\$1,000,000	\$ —	\$ —	\$1,000,000
Corporate debt	4,755,000	—	—	4,755,000
Total investment securities available for sale	<u>\$5,755,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$5,755,000</u>

Short-term investments available for sale at September 30, 2007 (unaudited) and December 31, 2006 consist solely of variable rate demand notes with a seven-day put option and interest rates that reset on a weekly basis. There were no short-term investments available for sale as of December 31, 2005.

The amortized cost and fair value of short-term investments held to maturity, with gross unrealized gains and losses, were as follows:

**As of September 30, 2007 (unaudited)**

	Cost	Gross Unrealized		Fair value
		Gains	Losses	
Commercial paper	\$1,484,442	\$ 259	\$ 325	\$1,484,376
Total investment securities held to maturity	<u>\$1,484,442</u>	<u>\$ 259</u>	<u>\$ 325</u>	<u>\$1,484,376</u>

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

As of December 31, 2006

	Cost	Gross unrealized		Fair value
		Gains	Losses	
Corporate debt	\$ 6,998,355	\$ 1,572	\$ (606)	\$ 6,999,321
U.S. Treasury and agencies	2,945,510	2,289	—	2,947,799
Commercial paper	1,496,675	—	—	1,496,675
Total investment securities held to maturity	<u>\$ 11,440,540</u>	<u>\$ 3,861</u>	<u>\$ (606)</u>	<u>\$ 11,443,795</u>

There were no short-term investments held to maturity as of December 31, 2005.

**(4) Property and Equipment**

Property and equipment consist of the following as of:

	September 30,	December 31,	
	2007 (Unaudited)	2006	2005
Furniture and equipment	\$ 1,273,353	\$ 943,159	\$ 359,900
Computer hardware and software	418,338	255,609	170,265
Leasehold improvements	299,894	142,821	176,451
	1,991,585	1,341,589	706,616
Less accumulated depreciation and amortization	(521,112)	(239,262)	(64,068)
Property and equipment, net	<u>\$ 1,470,473</u>	<u>\$ 1,102,327</u>	<u>\$ 642,548</u>

Depreciation expense included in general and administrative costs was \$175,194, \$58,407 and \$5,085 for the years ended December 31, 2006, 2005 and 2004, respectively, and \$523,171 for the period from December 19, 2002 (inception) to September 30, 2007 (unaudited). Depreciation expense included in general and administrative costs for the nine months ended September 30, 2007 and 2006 was \$283,316 (unaudited) and \$114,465 (unaudited), respectively.

**(5) Accrued Expenses**

Accrued expenses consist of the following as of:

	September 30,	December 31,	
	2007 (Unaudited)	2006	2005
Professional service related expenses	\$ 844,557	\$ 694,953	\$ 414,824
Payroll related expenses	723,865	601,733	345,200
Other expenses	317,572	407,545	154,449
Accrued expenses	<u>\$ 1,885,994</u>	<u>\$ 1,704,231</u>	<u>\$ 914,473</u>

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

**(6) Notes payable**

Notes payable consists of the following as of:

	September 30, 2007 (Unaudited)	December 31,	
		2006	2005
Equipment loan dated June 7, 2005	\$ 70,843	\$ 128,170	\$ 199,450
Equipment loan dated June 7, 2005	15,436	29,607	46,710
Growth capital loan dated September 30, 2005 (net discounts of \$7,464 (unaudited), \$18,659 and \$33,586 at September 30, 2007 and December 31, 2006 and 2005, respectively)	749,455	1,637,427	2,466,414
Equipment loan dated December 30, 2005	186,169	278,763	337,023
Equipment loan dated December 30, 2005	23,043	35,219	42,717
Growth capital loan dated March 31, 2006 (net discounts of \$8,162 (unaudited) and \$14,283 at September 30, 2007 and December 31, 2006, respectively)	265,556	431,136	—
Growth capital loan dated March 31, 2006 (net discounts of \$32,647 (unaudited) and \$57,133 at September 30, 2007 and December 31, 2006, respectively)	1,062,223	1,724,543	—
Equipment loan dated April 28, 2006	68,182	94,867	—
Equipment loan dated April 28, 2006	13,205	18,563	—
Growth capital loan dated May 22, 2007 (net discounts of \$116,512 (unaudited) at September 30, 2007)	2,383,488	—	—
Growth capital loan dated May 22, 2007 (net discounts of \$116,512 (unaudited) at September 30, 2007)	2,383,488	—	—
Growth capital loan dated August 31, 2007 (net discounts of \$94,882 (unaudited) at September 30, 2007)	1,155,118	—	—
Growth capital loan dated August 31, 2007 (net discounts of \$94,882 (unaudited) at September 30, 2007)	1,155,118	—	—
Total debt	9,531,324	4,378,295	3,092,314
Less current portion	4,401,577	(2,651,336)	(998,055)
Total long-term debt	<u>\$ 5,129,747</u>	<u>\$ 1,726,959</u>	<u>\$ 2,094,259</u>

The Company entered into a loan agreement on December 1, 2004 that provided for equipment loans and growth capital loans up to an aggregate original principal amount of \$250,000 and \$3,000,000, respectively, through June 30, 2005. In conjunction with this loan agreement, the Company issued detachable warrants to acquire 45,333 shares of Series B convertible preferred stock (Series B) at \$3.9430 per share. The warrants have a seven and a half year life. The fair value of the warrants at the time of issuance was determined to be \$48,720 and was recorded as interest expense over the term of the commitment. \$41,760 and \$6,960 was recorded in 2005 and 2004, respectively. This fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 60%, dividend rate of 0%, risk-free interest rate of 4.38% and the seven and a half year warrant life.

The above December 1, 2004 loan agreement was amended on September 29, 2005. The amendment provided for additional lender commitments for equipment loans and growth capital loans to the Company up to

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**Notes to Consolidated Financial Statements — (Continued)**

an aggregate original principal amount of \$500,000 and \$2,000,000, respectively. The termination date of the original growth capital loan commitment was amended to September 30, 2005 and the termination date for the additional equipment loans and growth capital loans was March 31, 2006 (see below). In conjunction with the amendment, the Company issued detachable warrants to acquire 34,872 shares of Series B stock at \$3.9430 per share or shares of Series C convertible preferred stock (Series C) having an aggregate exercise price of \$137,500. On June 21, 2006, prior to the close of the Series C stock financing round, the lender informed the Company of its intent to have the warrants be for Series B stock. The warrants have a seven and a half year life. The fair value of the warrants at the time of issuance was determined to be \$37,318 and was recorded as interest expense over the term of the commitment. \$18,659 was recorded in both 2006 and 2005. This fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 55%, dividend rate of 0%, risk-free interest rate of 4.29% and the seven and a half year warrant life.

The aggregate amount funded by the lender as noted above was \$5,746,121 and \$3,125,900 as of December 31, 2006 and 2005, respectively. The Company entered into two separate equipment loans (aggregate of \$120,221) during 2006 and four separate equipment loans (aggregate of \$625,900) during 2005 with the below terms:

1. *Equipment Loan Dated June 7, 2005*—Face amount of \$199,450 payable in 30 equal principal and interest installments beginning January 1, 2006 through May 2008 with a final payment of \$17,283 on June 1, 2008 at an annual percentage rate of 8.023%. Interest only payments for the first six months of the loan are at an annual percentage rate of 10%.
2. *Equipment Loan Dated June 7, 2005*—Face amount of \$46,710 payable in 30 equal principal and interest installments beginning January 1, 2006 through June 1, 2008 at an annual percentage rate of 11.461%. Interest only payments for the first six months of the loan are at an annual percentage rate of 10%.
3. *Equipment Loan Dated December 30, 2005*—Face amount of \$337,023 payable in 30 equal principal and interest installments beginning July 1, 2006 through November 2008 with a final payment of \$29,384 on December 1, 2008 at an annual percentage rate of 9.273%. Interest only payments for the first six months of the loan are at an annual percentage rate of 10%.
4. *Equipment Loan Dated December 30, 2005*—Face amount of \$42,717 payable in 30 equal principal and interest installments beginning July 1, 2006 through December 1, 2008 at an annual percentage rate of 12.71%. Interest only payments for the first six months of the loan are at an annual percentage rate of 10%.
5. *Equipment Loan Dated April 28, 2006*—Face amount of \$100,537 payable in 30 equal principal and interest installments beginning November 1, 2006 through March 2009 with a final payment of \$8,787 on April 1, 2009 at an annual percentage rate of 9.773%. Interest only payments for the first six months of the loan are at an annual percentage rate of 10%.
6. *Equipment Loan Dated April 28, 2006*—Face amount of \$19,684 payable in 30 equal principal and interest installments beginning November 1, 2006 through April 1, 2009 at an annual percentage rate of 13.21%. Interest only payments for the first six months of the loan are at an annual percentage rate of 10%.

The Company entered into a growth capital loan on September 30, 2005 with a face amount of \$2,500,000 payable in 23 equal principal and interest installments beginning April 1, 2006 through February 2008 with a final payment of \$237,825 on March 1, 2008 at an annual percentage rate of 8.486%, an effective rate of 10.12%.

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**Notes to Consolidated Financial Statements — (Continued)**

Interest only payments for the first six months of the loan are at an annual percentage rate of 10.999%. In conjunction with the funding of the growth capital loan, the Company issued detachable warrants to acquire 34,872 shares of Series B stock at \$3.9430 per share or shares of Series C stock having an aggregate exercise price of \$137,500. On June 21, 2006, prior to the close of the Series C stock financing round, the lender informed the Company of its intent to have the warrants be for Series B stock. The warrants have a seven and a half year life. The fair value of the warrants at the time of issuance was determined to be \$37,318 and is recorded as interest expense over the term of the loan. \$14,927 and \$3,732 was recorded in 2006 and 2005, respectively. Interest expense for the nine months ended September 30, 2007 and 2006 was \$11,195 (unaudited) and \$11,195 (unaudited), respectively. This fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 55%, dividend rate of 0%, risk-free interest rate of 4.33% and the seven and a half year warrant life.

The Company entered into two separate growth capital loans on March 31, 2006 with a combined face amount of \$2,500,000 payable in 23 equal principal and interest installments beginning October 1, 2006 through August 2008 with a final payment of \$238,875 on September 1, 2008 at an annual percentage rate of 9.49%, an effective rate of 14.07%. Interest only payments for the first six months of the loan are at an annual percentage rate of 10.999%. In conjunction with the funding of the growth capital loan, the Company issued detachable warrants to acquire 34,872 shares of Series B stock at \$3.9430 per share or shares of Series C stock having an aggregate exercise price of \$137,500. On June 21, 2006, prior to the close of the Series C stock financing round, the lender informed the Company of its intent to have the warrants be for Series B stock. The warrants have a seven year life. The fair value of the warrants at the time of issuance was determined to be \$102,022 and is recorded as interest expense over the term of the loan. \$30,606 was recorded in 2006. Interest expense for the nine months ended September 30, 2007 and 2006 was \$30,607 (unaudited) and \$20,404 (unaudited), respectively. This fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 54%, dividend rate of 0%, risk-free interest rate of 4.85% and the seven year warrant life.

On May 17, 2007 the Company entered into a \$15.0 million debt facility with the same lender of the other notes payable. The initial commitment under the debt facility is for \$10.0 million and allows for two \$5.0 million draw periods, the first of which was required upon closing. The loan agreement was amended to provide for two draw periods on the second \$5.0 million that is available to the Company under the terms of the original agreement. As amended, \$2.5 million was available to the Company through August 31, 2007 and the remaining \$2.5 million is available to the Company through October 31, 2007. Upon closing of the initial commitment, the Company issued 67,963 Series C stock warrants with an exercise price of \$8.0926 per share and a seven year life. The fair value of the warrants at the time of issuance was determined to be \$550,212 and is being recorded as interest expense. \$525,202 (unaudited) was recorded as interest expense for the nine months ended September 30, 2007. The fair value of the warrants was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 55.5%, dividend rate of 0%, risk-free interest rate of 4.76% and the seven year warrant life.

Under the terms of the May 17, 2007 debt facility, the Company completed the initial \$5.0 million draw by entering into two separate growth capital loans on May 22, 2007 with a combined face amount of \$5,000,000 payable in 29 equal principal and interest installments beginning December 1, 2007 through April 1, 2010 with a final payment of \$343,050 on May 1, 2010 at an annual percentage rate of 10.25%. Interest only payments for the first six months of the loan are at an annual percentage rate of 12.48%. In conjunction with the funding of the growth capital loan, the Company issued detachable warrants to acquire 33,982 shares of Series C stock at an exercise price of \$8.0926 per share. The warrants have a seven year life. The fair value of the warrants at the time of issuance was determined to be \$281,321 and is recorded as interest expense over the term of the loan. \$48,296

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**Notes to Consolidated Financial Statements — (Continued)**

(unaudited) was recorded as interest expense for the nine months ended September 30, 2007. This fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 55.5%, dividend rate of 0%, risk-free interest rate of 4.83% and the seven year warrant life.

The debt facility agreement entered into on May 17, 2007 was amended on August 28, 2007 to provide for two draw periods on the second \$5.0 million that is available under the terms of the original agreement. As amended, \$2.5 million was available to the Company through August 31, 2007 and the remaining \$2.5 million was available to the Company through October 31, 2007. On August 31, 2007, the Company completed the \$2.5 million draw available through that date by entering into two separate growth capital loans with a combined face amount of \$2.5 million payable in 29 equal principal and interest installments beginning March 1, 2008 through July 1, 2010 with a final payment of \$171,525 on August 1, 2010 at an annual percentage rate of 10.25%. Interest only payments for the first six months of the loan are at an annual percentage rate of 12.48%. In conjunction with the funding of the growth capital loan, the Company issued detachable warrants to acquire 16,991 shares of Series C stock at an exercise price of \$8.0926 per share. The warrants have a seven year life. The fair value of the warrants at the time of issuance was determined to be \$197,731 and is recorded as interest expense over the term of the loan. \$7,968 (unaudited) was recorded as interest expense for the nine months ended September 30, 2007. The fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 52.6%, dividend rate of 0%, risk-free interest rate of 4.54% and a seven year life. See Note 18 regarding a subsequent draw.

The final \$5.0 million commitment available to the Company under the terms of the debt facility is subject to the Company closing a next round of financing and would be available to be drawn on by the Company through 2008. The Company is not required to pay any additional equity consideration for this portion of the facility unless it is utilized.

Each of the above loans is collateralized by a first security priority lien on all of the Company's assets, excluding intellectual property. In the event we have less than four remaining months of liquidity, we are required to grant a temporary lien on our intellectual property. The number of remaining months of liquidity is calculated by dividing cash and cash equivalents as of the end of any particular month by the sum of our total operating expenses for each of the immediately preceding four months.

The Company also entered into account control agreements for each cash and investment account held by the Company. The lender has the right to enforce the account control agreements in the event of default. If enforced, the lender has the ability to withdraw funds from the accounts and restrict the Company's access to the funds.

The Company was in compliance with all covenants related to the notes payable at September 30, 2007 (unaudited) and December 31, 2006, and has not incurred any events of default as described in the terms of the notes payable agreements.

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**Notes to Consolidated Financial Statements — (Continued)**

Scheduled debt principal payments are as follows as of September 30, 2007 (unaudited):

<b>Years Ending December 31:</b>	
2007	\$ 827,727
2008	4,341,151
2009	2,997,717
2010	1,835,790
	<u>10,002,385</u>
Less: Original issue discount	(471,061)
Notes payable, net	<u>\$ 9,531,324</u>

Scheduled debt principal payments are as follows as of December 31, 2006:

<b>Years Ending December 31:</b>	
2007	\$ 2,651,336
2008	1,794,877
2009	22,157
	<u>4,468,370</u>
Less: Original issue discount	(90,075)
Notes payable, net	<u>\$ 4,378,295</u>

**(7) Convertible notes payable**

On December 12, 2005, the Company issued convertible notes payable, to various investors, including some officers of the Company, with an original aggregate face amount of \$5,250,003. The convertible notes payable accrued interest at a fixed rate per annum equal to 4.34%. Accrued interest payable on the convertible notes payable was \$12,658 as of December 31, 2005.

Accrued interest and principal were due in full at the earliest to occur of (i) the maturity date (December 12, 2008), (ii) an equity conversion event, or (iii) an acquisition conversion event. On July 6, 2006, the Company completed an equity conversion event when it closed a Series C convertible preferred stock financing. As a result, the outstanding principal balance of \$5,250,003 and the accrued interest payable balance of \$131,013 were automatically converted into 664,919 shares of Series C convertible preferred stock at \$8.0926 per share.

See Note 9 for details of the Series C convertible preferred stock financing.

**(8) Convertible Bridge Notes**

*November 13, 2003 Convertible Bridge Note*

On November 13, 2003, the Company entered into a 4% Bridge Loan Agreement with various investors, including some officers of the Company. The Company received aggregate proceeds in the amount of \$1,069,893. Accrued interest and principal was convertible contingent upon subsequent financing. The due date was May 31, 2004 provided a definitive term sheet for an equity sale had been executed by the Company on or

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before April 30, 2004. In consideration for entering into the Bridge Loan Agreement, the Company issued Series B stock warrants with an exercise price equal to the price paid per share at the next equity financing. The number of warrants to be issued were defined as the committed capital balance multiplied by 0.2 and divided by the price paid per share at the next equity financing. In closing the November 13, 2003 Bridge Loan Agreement, the price paid per share at the next equity financing was estimated to be \$9.10, resulting in 23,516 warrants. The Company received cash consideration for the 23,516 warrants at a rate of \$0.00455 per share or an aggregate amount of \$107, which was recorded as additional paid-in capital during 2003. Upon closing the Series B equity financing on July 30, 2004, the price paid per share was set at \$3.9430 resulting in a total of 54,278 seven-year warrants being issued.

The fair value of the warrants at the time of issuance was determined to be \$103,320 and was recorded as additional paid-in capital and interest expense in 2004. The fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 66%, dividend rate of 0%, risk-free interest rate of 4.27%, and the maximum seven-year warrant life.

*April 23, 2004 Convertible Bridge Note*

On April 23, 2004, the Company amended the November 13, 2003 Bridge Loan Agreement to provide for additional capital. The terms and investors of the November 13, 2003 Bridge Loan Agreement remained the same with the only changes being to the amount of capital being committed and the number of warrants being issued as additional consideration. The Company received additional aggregate proceeds in the amount of \$294,970 for a combined outstanding total of \$1,364,863. In consideration for entering into the Amended Bridge Loan Agreement, the Company issued additional Series B stock warrants with an exercise price equal to the price paid per share at the next equity financing. The number of warrants to be issued were defined as the committed capital balance multiplied by 0.2 and divided by the price paid per share at the next equity financing. In closing the Amended Bridge Loan Agreement, the price paid per share at the next equity financing was estimated to be \$9.10, resulting in 6,484 additional warrants. The Company received cash consideration for the 6,484 warrants at a rate of \$0.00455 per share or an aggregate amount of \$30, which was recorded as additional paid-in capital during 2004. Upon closing the Series B equity financing on July 30, 2004, the price paid per share was set at \$3.9430 resulting in a total of 14,967 seven-year warrants being issued.

The fair value of the warrants at the time of issuance was determined to be \$30,038 and was recorded as additional paid-in capital and interest expense in 2004. The fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 65%, dividend rate of 0%, risk-free interest rate of 4.45%, and the maximum seven-year warrant life.

*June 30, 2004 Convertible Bridge Note*

On June 30, 2004, the Company amended the November 13, 2003 Bridge Loan Agreement for a second time to provide for additional capital. The terms and investors of the November 13, 2003 Bridge Loan Agreement remained the same with the only changes being to the amount of capital being committed and the number of warrants being issued as additional consideration and a due date of July 31, 2004. The Company received additional aggregate proceeds in the amount of \$199,980 for a combined outstanding total of \$1,564,843. In consideration for entering into the Second Amended Bridge Loan Agreement, the Company issued additional Series B stock warrants with an exercise price equal to the price paid per share at the next equity financing. The number of warrants to be issued were defined as the committed capital balance multiplied by 0.2 and divided by

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the price paid per share at the next equity financing. In closing the Second Amended Bridge Loan Agreement, the price paid per share at the next equity financing was estimated to be \$9.10, resulting in 4,396 additional warrants. The Company received cash consideration for the 4,396 warrants at a rate of \$0.00455 per share or an aggregate amount of \$20, which was recorded as additional paid-in capital during 2004. Upon closing the Series B equity financing on July 30, 2004, the price paid per share was set at \$3.9430 resulting in a total of 10,143 seven-year warrants being issued.

The fair value of the warrants at the time of issuance was determined to be \$20,364 and was recorded as additional paid-in capital and interest expense in 2004. The fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 65%, dividend rate of 0%, risk-free interest rate of 4.62%, and the maximum seven-year warrant life.

See Note 10 for the conversion of the above convertible notes payable to Series B convertible preferred stock.

A total of 79,388 warrants to purchase Series B convertible preferred stock were issued as a result of the three convertible bridge loans.

**(9) Series C Convertible Preferred Stock Financing**

On July 6, 2006, the Company closed the Series C convertible preferred stock (Series C) financing. The Company sold 4,921,142 shares of Series C stock for \$8.0926 per share, or total gross proceeds of \$39,825,003. In addition, \$5,250,003 of Convertible Notes Payable principal and \$131,013 of accrued interest payable were converted into 664,919 shares of Series C stock. The Company incurred \$2,222,342 in costs, which were recorded as a reduction to additional paid-in capital. Included in the Series C financing costs was \$735,438 of value related to 147,635 Series C warrants issued to the private placement underwriter. The fair value of the warrants was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 55%, dividend rate of 0%, risk-free interest rate of 5.18%, and the maximum seven-year warrant life. The fair value of the warrants was recorded in additional paid-in capital.

On December 11, 2006, the Company sold an additional 123,569 shares of Series C stock for \$8.0926 per share, or total gross proceeds of \$1,000,000.

As of the closing date of the additional sale of 123,569 shares of Series C stock, the Company had insufficient authorized and unissued Series C stock available to share settle the Series C warrants which requires the instrument to be accounted for under Statement of Financial Accounting Standards No. 133 and classified as a liability in accordance with EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. The fair market value of the warrant as of December 31, 2006 was \$728,841. The change in fair value is recorded separately in the consolidated statements of operations.

On May 14, 2007 the Company filed an amended certificate of incorporation to increase the number of authorized shares of Series C stock to 6,043,956. As a result of the amendment, the Company had sufficient authorized and unissued shares of Series C stock available to share settle the Series C warrants. The fair market value of the warrants on May 14, 2007 was determined to be \$1,090,345. The change in fair value from December 31, 2006 to the amendment date of \$361,504 was recorded as expense and the convertible preferred stock liability was reclassified to additional paid-in capital.

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**Notes to Consolidated Financial Statements — (Continued)**

**(10) Series B Convertible Preferred Stock Financing**

On July 30, 2004, the Company closed the first tranche of the Series B convertible preferred stock (Series B) financing. The Company sold 1,914,767 shares of Series B stock for \$3.9430 per share, or total gross proceeds of \$7,550,001. In addition, \$1,564,843 of Convertible Bridge Loan principal and \$34,809 of accrued interest were converted into 405,690 shares of Series B stock. The Company incurred \$94,776 in costs, which were recorded as a reduction to additional paid-in capital.

During 2005, the Company closed the final two tranches of the Series B convertible preferred stock financing. On June 17, 2005, the Company sold 760,834 shares of Series B stock for \$3.9430 per share, or total gross proceeds of \$3,000,000. On December 12, 2005, the Company sold 1,204,655 shares of Series B stock for \$3.9430 per share, or total gross proceeds of \$4,750,001. The Company incurred a total of \$16,303 in costs related to the 2005 closings, which were recorded as a reduction to additional paid-in capital.

The Company also issued 170,336 common stock warrants on December 12, 2005 to various Series B stockholders at a price of \$0.09 per share. The warrants have an exercise price of \$0.46 and terminate in five years. The fair value of the warrants at the time of issuance was determined to be \$15,500 and was recorded as additional paid-in capital. The fair value was calculated using a Black-Scholes valuation model and the following assumptions: volatility of 49%, dividend rate of 0%, risk-free interest rate of 4.55%, and the maximum five-year warrant life.

**(11) Convertible Preferred Stock**

The Company has 318,266 shares of Series A convertible preferred stock (Series A) and 4,285,946 shares of Series B convertible preferred stock outstanding as of September 30, 2007 (unaudited) and December 31, 2006 and 2005, and 5,709,630 shares of Series C convertible preferred stock outstanding as of September 30, 2007 (unaudited) and December 31, 2006. The following are preferred stock terms in accordance with the certificate of incorporation:

*Redemption Rights*

No class of preferred stock has any redemption rights.

*Liquidation Preferences*

The stockholders of Series C and Series B convertible preferred stock share senior liquidation rights on a *pari passu* basis of \$8.0926 and \$3.9430 per share, respectively, prior to Series A's liquidation preference of \$6.5593 per share. After all of the above liquidation preferences have been paid, any remaining liquidation proceeds are paid to common stockholders and all classes of preferred stock on an as-if converted basis.

A liquidation of the Company includes the sale, lease, exchange, exclusive licensing or other disposition of all or substantially all of the Company's assets or intellectual property; the merger, business combination, reorganization, or consolidation of the Company with another entity gaining more than 50% ownership; or a liquidation, dissolution or winding up of the Company.

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**Notes to Consolidated Financial Statements — (Continued)**

*Dividends*

Series C and Series B stockholders are entitled to a noncumulative dividend on a *pari passu* basis prior to the payment of dividends on Series A and common stock. The Series C and Series B dividend rates are \$0.6470 per annum and \$0.3158 per annum, respectively. After payment of the combined Series C and Series B dividends and prior to the payment of dividends to common stockholders, Series A stockholders are entitled to a non-cumulative dividend of \$0.5251 per annum. After all preferred stock dividend preferences have been paid, the common stockholders participate with preferred stockholders on an as-if converted basis.

*Anti-dilution Rights*

If the Company issues equity or convertible instruments that are not subject to defined carve out provisions, below the then applicable conversion price for each preferred stock series, the conversion price to common stock will be adjusted on a weighted average basis.

*Conversion Rights*

All classes of preferred stock are convertible into common stock at the option of the holder. As noted above, the conversion price of all outstanding preferred stock issuances is subject to weighted average anti-dilution protection. At September 30, 2007 (unaudited) and December 31, 2006, Series A, Series B and Series C shares are convertible into 492,602, 4,285,946 and 5,709,630 shares of common stock based on the terms of the agreement, respectively.

All classes of preferred stock are mandatorily convertible upon (a) a qualified initial public offering whereby the public offering price is not less than \$24.02 per share (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations or the like) and results in gross proceeds to the Company of at least \$30 million in the aggregate after deducting underwriting commissions and discounts or (b) the date specified by written consent or agreement of the holders of at least 63% of the then outstanding shares of Series B and Series C preferred stock voting together as a single class on an as-converted basis, as defined in the certificate of incorporation. See Note 18 for subsequent amendment to the conversion rights.

*Voting Rights*

Preferred stockholders have the same voting rights as common stockholders. Preferred stockholders have one vote for each share of common stock deemed held, as determined by the then current conversion price. As a result of the preferred stockholders' board of directors' representation and voting rights, they effectively control the affairs of the Company, including its liquidation.

*Registration Rights*

Holders of preferred stock and certain holders of warrants have been granted registration rights pursuant to the terms of an investor rights agreement. These holders of preferred stock and warrants will automatically convert to common shares in a public offering and they have the right to require registration of those common shares.

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**Notes to Consolidated Financial Statements — (Continued)**

**(12) Income Taxes**

The Company has incurred net operating losses (NOLs) since inception. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying consolidated financial statements.

The income tax expense benefit differed from the amount computed by applying the U.S. federal income tax rate of 34% to income before income taxes as a result of the following:

	<u>2006</u>	<u>2005</u>	<u>2004</u>
Computed 'expected' tax benefit	34.0%	34.0%	34.0%
Other permanent adjustments	-0.4%	-0.4%	-2.4%
Federal research and development credit	2.3%	3.5%	2.9%
State income taxes, net of federal benefit	6.0%	7.0%	6.6%
Effect of foreign operations	-1.5%	0.0%	0.0%
Change in federal valuation allowance	-40.4%	-44.1%	-41.1%
	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

The tax effect of temporary differences that give rise to significant portions of the deferred tax assets as of December 31 is presented below:

	<u>2006</u>	<u>2005</u>
<b>Deferred tax assets (liabilities):</b>		
Start-up costs	\$ 5,505,000	\$ 2,315,000
Reserves and accruals	157,000	38,000
Property and equipment	16,000	1,000
Research and development credit	1,107,000	692,000
Net operating loss carry forwards	7,784,000	4,444,000
Total gross deferred tax assets	<u>14,569,000</u>	<u>7,490,000</u>
Valuation allowance	<u>(14,569,000)</u>	<u>(7,490,000)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible.

Based on the level of historical taxable losses and projections of future taxable income (losses) over the periods in which the deferred tax assets are deductible, management currently believes that it is more likely than not that the Company will not realize the benefits of these deductible differences. Accordingly, the Company has provided a valuation allowance against the gross deferred tax assets as of December 31, 2006 and 2005.

As of December 31, 2006, the Company has U.S. federal net operating loss carry forwards of approximately \$17,856,000. The federal net operating loss carry forwards expire in the years 2022 through 2026.

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**Notes to Consolidated Financial Statements — (Continued)**

Federal tax laws impose significant restrictions on the utilization of net operating loss carry forwards and research and development credits in the event of a change in ownership of the Company, as defined by the Internal Revenue Code Section 382. The Company's net operating loss carry forwards and research and development credits may be subject to the above limitations.

In July 2006 the FASB issued Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes*. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with Statement of Financial Accounting Standards No. 109 (SFAS 109), *Accounting for Income Taxes*. This interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition of tax benefits, classification on the balance sheet, interest and penalties, accounting in interim periods, disclosure, and transition. The Company adopted FIN 48 effective January 1, 2007. At the date of adoption of FIN 48, the Company had no unrecognized tax benefits and expected no significant changes in unrecognized tax benefits in the next 12 months. The adoption of this statement did not result in a cumulative accounting adjustment and did not impact the financial position, results of operations or cash flows. In accordance with FIN 48, paragraph 19, the Company has decided to classify any interest and penalties as a component of tax expense. To date, there have been no interest or penalties charged to us in relation to the underpayment of income taxes.

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**Notes to Consolidated Financial Statements — (Continued)**

**(13) Stock Options**

The Company has adopted the EnteroMedics Inc. 2003 Stock Incentive Plan (the Plan) that includes both incentive stock options and nonqualified stock options to be granted to employees, officers, consultants, independent contractors, directors and affiliates of the Company. At September 30, 2007 (unaudited) and December 31, 2006, according to the Plan, 2,387,348 shares and 1,728,007 shares, respectively, have been authorized and reserved. The board of directors establishes the terms and conditions of all stock option grants, subject to the Plan and applicable provisions of the Internal Revenue Code. Incentive stock options must be granted at an exercise price not less than the fair market value of the common stock on the grant date. The options granted to participants owning more than 10% of the Company's outstanding voting stock must be granted at an exercise price not less than 110% of fair market value of the common stock on the grant date. The options expire on the date determined by the board of directors, but may not extend more than 10 years from the grant date, while incentive stock options granted to participants owning more than 10% of the Company's outstanding voting stock expire five years from the grant date. The vesting period for employees is generally over four years. The vesting period for non-employees is determined based on the services being provided.

Stock option activity is as follows:

	Shares Available For Grant	Outstanding Options		Aggregate Intrinsic Value
		Number of Shares	Weighted- Average Exercise Price	
Shares reserved at Plan inception	42,858	—	\$ —	
<b>Balance, December 31, 2003 (unaudited)</b>	42,858	—	—	
Shares reserved	439,561	—	—	
Options granted	(344,796)	344,796	0.46	
Options exercised	—	—	—	
Options cancelled	3,847	(3,847)	0.46	
<b>Balance, December 31, 2004</b>	141,470	340,949	0.46	
Shares reserved	678,891	—	—	
Options granted	(504,285)	504,285	0.46	
Options exercised	—	(29,561)	0.46	
Options cancelled	43,255	(43,255)	0.46	
<b>Balance, December 31, 2005</b>	359,331	772,418	0.46	
Shares reserved	566,697	—	—	
Options granted	(679,911)	679,911	1.15	
Options exercised	—	(87,022)	0.46	
Options cancelled	103,436	(103,436)	0.46	
<b>Balance, December 31, 2006</b>	349,553	1,261,871	0.83	\$ 1,362,935
Shares reserved (unaudited)	659,341	—	—	
Options granted (unaudited)	(889,650)	889,650	7.58	
Options exercised (unaudited)	—	(35,132)	0.60	
Options cancelled (unaudited)	37,618	(37,618)	3.88	
<b>Balance, September 30, 2007 (unaudited)</b>	156,862	2,078,771	\$ 3.67	\$24,157,413

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

During the 15-month period ended September 30, 2007, the Company granted stock options with exercise prices as follows:

<u>Grants Made During Quarter Ended</u>	<u>Number of Options Granted</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted- Average Fair Value per Share</u>	<u>Weighted- Average Intrinsic Value per Share</u>
September 30, 2006	275,278	\$ 1.91	\$ 1.91	\$ —
December 31, 2006	50,455	1.91	1.91	—
March 31, 2007	498,958	5.19	5.19	—
June 30, 2007	240,113	8.03	8.03	—
September 30, 2007	150,579	14.76	14.76	—

The Company received valuations from Gemini Valuation Services, LLC, an unrelated valuation specialist, to help support the valuation of the common stock as of April 20, 2006, July 6, 2006, January 31, 2007, February 28, 2007, April 30, 2007, May 21, 2007, June 7, 2007, July 31, 2007 and August 31, 2007. These valuations were contemporaneous with those dates with the exception of the April 20, 2006 valuation which was retrospective.

The options outstanding, vested and currently exercisable by exercise price at September 30, 2007 (unaudited):

<u>Outstanding Options and Expected to Vest</u>				<u>Options Exercisable and Vested</u>		
<u>Exercise Price</u>	<u>Number of Shares Outstanding</u>	<u>Weighted-Average Remaining Contractual Life (Years)</u>	<u>Aggregate Intrinsic Value</u>	<u>Number of Options</u>	<u>Weighted-Average Exercise Price</u>	<u>Aggregate Intrinsic Value</u>
\$0.46	894,411	7.8	\$13,265,920	557,728	\$ 0.46	\$ 8,272,777
\$1.91	321,886	9.0	4,305,703	77,941	\$ 1.91	1,042,618
\$5.19	471,782	9.4	4,765,230	1,099	\$ 5.19	11,101
\$7.46	102,750	9.6	804,100	31,595	\$ 7.46	247,261
\$8.46	137,363	9.7	937,500	27,473	\$ 8.46	187,503
\$14.74	144,617	9.9	78,960	6,594	\$ 14.74	3,600
\$15.29	5,962	10.0	—	—	\$ 15.29	—
	<u>2,078,771</u>		<u>\$24,157,413</u>	<u>702,430</u>	\$ 1.39	<u>\$ 9,764,860</u>

The options outstanding, vested and currently exercisable by exercise price at December 31, 2006:

<u>Outstanding Options and Expected to Vest</u>				<u>Options Exercisable and Vested</u>		
<u>Exercise Price</u>	<u>Number of Shares Outstanding</u>	<u>Weighted- Average Remaining Contractual Life (Years)</u>	<u>Aggregate Intrinsic Value</u>	<u>Number of Options</u>	<u>Weighted- Average Exercise Price</u>	<u>Aggregate Intrinsic Value</u>
\$ 0.46	936,138	8.6	\$1,362,935	381,859	\$ 0.46	\$555,987
\$ 1.91	325,733	9.8	—	550	\$ 1.91	—
	<u>1,261,871</u>		<u>\$1,362,935</u>	<u>382,409</u>	\$ 0.46	<u>\$555,987</u>

**EnteroMedics Inc.**  
**(A development stage company)**

**Notes to Consolidated Financial Statements — (Continued)**

**Stock-Based Compensation for Non-employees**

Stock-based compensation expenses related to stock options granted to nonemployees is recognized on an accelerated basis as the stock options are earned. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The fair value of the stock options granted is calculated at each reporting date, using the Black-Scholes option-pricing model, until the award vests or there is a substantial disincentive for the non-employee not to perform the required services. The fair value for the years ended December 31, 2006, 2005 and 2004, and for the nine months ended September 30, 2007 (unaudited) was calculated using the following assumptions:

	Nine Months Ended September 30, 2007	Years Ended December 31,		
		2006	2005	2004
Risk-free interest rates	4.58%–5.03%	4.48%–5.14%	4.14%–4.56%	4.22%–4.47%
Expected life	10 years	10 years	10 years	10 years
Expected dividends	0%	0%	0%	0%
Expected volatility	60.75%–63.25%	62.83%–66.57%	62.67%–69.60%	64.50%–73.75%

Stock-based compensation expense charged to operations on options granted to nonemployees for the years ended December 31, 2006, 2005 and 2004 was \$90,840, \$5,354 and \$830, respectively, and \$1,562,170 for the period from December 19, 2002 (inception) to September 30, 2007 (unaudited). Stock-based compensation expense charged to operations on options granted to non-employees for the nine months ended September 30, 2007 and 2006 was \$1,465,146 (unaudited) and \$70,272 (unaudited), respectively.

**Employee Stock-Based Awards Granted on or Subsequent to January 1, 2006**

On January 1, 2006, the Company adopted the fair value recognition provisions of SFAS 123R, using the prospective transition method. Under this transition method, beginning January 1, 2006, compensation cost recognized includes: (a) compensation cost for all stock-based awards granted prior to, but not yet vested as of December 31, 2005, based on the intrinsic value method in accordance with the provisions of APB 25, and (b) compensation cost for all stock-based payments granted or modified subsequent to December 31, 2005, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R.

As a result of adopting SFAS 123R on January 1, 2006, the Company's net loss for the nine months ended September 30, 2007 and for the year ended December 31, 2006 was \$633,064 (unaudited) and \$47,479, respectively, higher than if it had continued to account for employee stock-based compensation under APB 25.

Under SFAS 123R, compensation cost for employee stock-based awards is based on the estimated grant-date fair value and is recognized over the vesting period of the applicable award on a straight-line basis. For the period from January 1, 2006 to September 30, 2007, the Company issued employee stock-based awards in the form of stock options. The weighted average estimated fair value of the employee stock options granted for the nine months ended September 30, 2007 (unaudited) and for the year ended December 31, 2006 was \$4.51 and \$0.683 per share, respectively.

The Company uses the Black-Scholes pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant is affected by our stock price

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**Notes to Consolidated Financial Statements — (Continued)**

as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rates and expected dividends. The estimated grant-date fair values of the employee stock options were calculated using the Black-Scholes valuation model, based on the following assumptions for the nine months ended September 30, 2007 (unaudited) and for the year ended December 31, 2006:

	<u>Nine Months Ended September 30, 2007</u>	<u>Year Ended December 31, 2006</u>
Risk-free interest rates	4.48%–4.79%	4.39%–5.04%
Expected life	6 years–6.5 years	5 years–6.25 years
Expected dividends	0%	0%
Expected volatility	55.25%–58.63%	55.17%–62.86%

*Expected Life.* The expected life is based on the “simplified” method described in the SEC Staff Accounting Bulletin, Topic 14: *Share-Based Payment*.

*Volatility.* Since the Company is a private entity with no historical data regarding the volatility of its common stock, the expected volatility used for 2006 and 2007 is based on volatility of similar entities, referred to as “guideline” companies. In evaluating similarity, the Company considered factors such as industry, stage of life cycle and size.

*Risk-Free Interest Rate.* The risk-free rate is based on U.S. Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

*Dividend Yield.* The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation model.

*Forfeitures.* SFAS No. 123R also requires the Company to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. If the Company’s actual forfeiture rate is materially different from its estimate, the stock-based compensation expense could be significantly different from what the Company has recorded in the current period.

As of September 30, 2007 (unaudited) and December 31, 2006, there was \$3,412,395 and \$358,474, respectively, of total unrecognized compensation costs related to non-vested stock option awards granted after January 1, 2006, which are expected to be recognized over a weighted-average period of 3.73 years and 3.61 years, respectively.

The weighted-average grant-date fair value of stock options granted to employees for the nine months ended September 30, 2007 (unaudited) and for the year ended December 31, 2006 was \$4.51 and \$0.68, respectively, per share. The aggregate intrinsic value of stock options (the amount by which the market price of the stock on the date of exercise exceeded the exercise price of the option) exercised during the nine months ended September 30, 2007 (unaudited) and for the years ended December 31, 2006 and 2005, was \$191,054, \$13,198 and \$0, respectively.

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**Notes to Consolidated Financial Statements — (Continued)**

**(14) Warrants**

Stock warrant activity is as follows:

	Common Shares	Price(1)	Series A Preferred Shares	Price(1)	Series B Preferred Shares	Price(1)	Series C Preferred Shares	Price(1)
<b>Balance as of:</b>								
December 31, 2002 (unaudited)	—		—		—		—	
Granted	—		125,778	\$ 0.91	23,516	\$ 3.9430	—	
Exercised	—		—		—		—	
Cancelled	—		—		—		—	
December 31, 2003 (unaudited)	—		125,778	\$ 0.91	23,516	\$ 3.9430	—	
Granted	—		—		101,205	\$ 3.9430	—	
Exercised	—		(125,778)	\$ 1.46	—		—	
Cancelled	—		—		—		—	
December 31, 2004	—		—		124,721	\$ 3.9430	—	
Granted	170,336	\$ 0.46	—		69,744	\$ 3.9430	—	
Exercised	—		—		—		—	
Cancelled	—		—		—		—	
December 31, 2005	170,336	\$ 0.46	—		194,465	\$ 3.9430	—	
Granted	—		—		34,872	\$ 3.9430	147,635	\$ 8.0926
Exercised	—		—		—		—	
Cancelled	—		—		—		—	
December 31, 2006	170,336	\$ 0.46	—		229,337	\$ 3.9430	147,635	\$ 8.0926
Granted (unaudited)	—		—		—		118,936	\$ 8.0926
Exercised (unaudited)	—		—		—		—	
Cancelled (unaudited)	—		—		—		—	
September 30, 2007 (unaudited)	<u>170,336</u>	<u>\$ 0.46</u>	<u>—</u>		<u>229,337</u>	<u>\$ 3.9430</u>	<u>266,571</u>	<u>\$ 8.0926</u>

(1) Represents weighted-average exercise price per share.

At September 30, 2007 and December 31, 2006, the weighted-average remaining contractual life of outstanding warrants was 4.91 (unaudited) and 5.22 years, respectively.

The aggregate number of common shares that could be issued if all warrants were exercised and converted to common stock at the option of the holder would be 666,244.

See Notes 6 and 8 for discussions relating to the Series B stock warrants issued during 2003, 2004, 2005 and 2006 and Notes 6 and 9 for discussion related to the Series C stock warrants issued during 2006 and 2007.

On November 13, 2003 the Company granted Venturi II, LLC (Venturi), sole Series A stockholder, 125,778 shares of Series A stock warrants with an initial exercise price of \$0.91 and a term of 10 years. The warrants

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**Notes to Consolidated Financial Statements — (Continued)**

were granted as part of Venturi's dissolution plans and were granted with the understanding that they would be exercised as soon as practicable. As the warrants were granted as part of a dissolution plan, no charge related to the warrant grant was required in 2003.

The 125,778 warrants granted to Venturi were exercised on April 23, 2004 at a price of \$1.4919359 per share resulting in gross proceeds of \$187,652. Once exercised, Venturi owned 104,396 shares of EnteroMedics common stock and 318,266 shares of EnteroMedics Series A convertible preferred stock. Venturi dissolved on April 22, 2004 and transferred its ownership in EnteroMedics common stock and Series A convertible preferred stock to Venturi investors who held Class A Units and Class B Units, respectively, on a pro rata basis.

**(15) Related Party Transactions**

The Company shares space with Restore Medical, Inc. (Restore), a related party who has directors and stockholders that are officers of the Company. The Company reimburses Restore for various facility expenses, including property taxes, common area maintenance charges, payroll for the use of personnel, and shipping charges. In 2006 and 2005, the Company also reimbursed Restore for rent expense related to the sublease agreement discussed in Note 16. Total expenses recorded were approximately \$256,000, \$75,000 and \$55,000 for the years ended December 31, 2006, 2005 and 2004, respectively, and approximately \$701,000 for the period from December 19, 2002 (inception) to September 30, 2007 (unaudited). Total expenses recorded for the nine months ended September 30, 2007 and September 30, 2006 were approximately \$332,000 (unaudited) and \$188,000 (unaudited), respectively. The majority of expenses are included in general and administrative costs on the consolidated statements of operations. Included in accounts payable and accrued expenses is a total of \$34,859 (unaudited), \$66,076 and \$12,603 due to Restore as of September 30, 2007 and December 31, 2006 and 2005, respectively.

The Company obtains consulting services from Venturi Development Inc. (VDI), whose stockholders and officers are investors in the Company. The consultants receive cash compensation for services provided. Total expenses recorded, including consulting expenses, were approximately \$29,000, \$46,000 and \$1,230,000 for the years ended December 31, 2006, 2005 and 2004, respectively, and approximately \$2,650,000 for the period from December 19, 2002 (inception) to December 31, 2006. Total expenses recorded, including consulting expenses, for the nine months ended September 30, 2007 and September 30, 2006 were approximately \$29,000 (unaudited) and \$29,000 (unaudited), respectively. Expenses paid to VDI are primarily included in research and development and general and administrative expense on the consolidated statements of operations. On September 30, 2007 and December 31, 2006 and 2005, the Company had an outstanding payable balance to VDI of \$0 (unaudited), \$0 and \$5,380, respectively.

Effective September 21, 2006, the Company entered into a consulting agreement with Bobby I. Griffin, who is a member of the board of directors. The consulting agreement provides for the consultant to receive compensation in the form of an option to purchase common stock for services provided. Pursuant to this consulting agreement, Mr. Griffin received a one-time option grant to purchase 54,946 shares of common stock at \$1.91 per share that vests 25% on the first anniversary of the date the consulting agreement was entered into and 1/36th per month each month thereafter for 36 months. The consulting agreement is for one year and does not provide for the forfeiture of any vested or unvested options if after one year Mr. Griffin stops performing services as a consultant. The Company is accounting for this transaction under the guidance of Emerging Issues Task Force Abstract No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*. Under EITF 96-18, options are recorded at their fair value on the measurement date. The Company remeasures the fair value of the options granted at each reporting period until performance under the consulting agreement is completed and the measurement date is reached. The

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**Notes to Consolidated Financial Statements — (Continued)**

Company is expensing the fair value of the options granted over the requisite service period which is the term of the consulting agreement, or one year. Total expense recorded was approximately \$5,000 for the year ended December 31, 2006, and approximately \$783,000 for the period from December 19, 2002 (inception) to September 30, 2007 (unaudited). Total expenses recorded for the nine months ended September 30, 2007 were approximately \$778,000 (unaudited). All of the expenses are included in general and administrative costs on the consolidated statements of operations.

**(16) Commitments and Contingencies**

In September 2005, the Company entered into a three-year noncancelable operating sublease agreement for office/warehouse space with Restore. The lease expires on September 30, 2008 with monthly base rent ranging from \$7,518 to \$7,676. Effective January 1, 2007, the sublease was amended to include additional square footage. Under the amended sublease agreement, the monthly base rent ranges from \$11,476 to \$11,596. Rent expense recognized for the years ended December 31, 2006 and 2005 was \$127,766 and \$22,555, respectively. Rent expense recognized for the nine months ended September 30, 2007 and 2006 was \$90,192 (unaudited) and \$67,664 (unaudited), respectively. The Company also reimburses Restore for various facility and personnel related expenses discussed in Note 15. Prior to entering into the sublease agreement with Restore, the Company assumed VDI's sublease agreement with Integ Inc. (Integ) and paid Integ directly for rent and other facility charges in the amount of \$32,370 and \$41,648 for the years ended December 31, 2005 and 2004, respectively, and \$111,953 for the period from December 19, 2002 (inception) to December 31, 2005. Facility related expenses are included as general and administrative costs on the consolidated statements of operations.

The following is a schedule of total future minimum lease payments due as of September 30, 2007 (unaudited):

<b>Periods ending December 31:</b>	
2007	34,788
2008	<u>104,364</u>
	<u>\$ 139,152</u>

The following is a schedule of total future minimum lease payments due as of December 31, 2006:

<b>Years ending December 31:</b>	
2007	138,076
2008	<u>104,364</u>
	<u>\$ 242,440</u>

The Company is exposed to product liability claims that are inherent in the testing, production, marketing and sale of medical devices. Management believes any losses that may occur from these matters are adequately covered by insurance, and the ultimate outcome of these matters will not have a material effect on the Company's financial position or results of operations.

In 2005, EnteroMedics entered into an exclusive collaborative obesity device research and development agreement with the Mayo Foundation for Medical Education and Research (Mayo Foundation), Rochester, Minnesota. Through this agreement, EnteroMedics will collaborate with a group of physicians and researchers at Mayo Clinic in the field of obesity. Under the terms of this five-year agreement, EnteroMedics and this group of

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**Notes to Consolidated Financial Statements — (Continued)**

Mayo specialists will collectively work toward the development of new and innovative medical devices for the treatment of obesity. The agreement also includes 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.

Under this agreement, the Company issued 219,780 shares of common stock to the Mayo Foundation in 2005 and recorded \$100,000 as deferred compensation, which is being amortized over the term of the five-year agreement. Unamortized deferred compensation related to the agreement was \$46,667 (unaudited), \$61,667 and \$81,667 at September 30, 2007 and December 31, 2006 and 2005, respectively. EnteroMedics may also be obligated to issue up to 206,044 shares of common stock as consideration if future Mayo patents are issued or if the FDA approves a product patented by the Mayo or jointly patented by the Mayo and EnteroMedics. Should the Company complete an initial public offering (IPO) prior to the achievement of the previously discussed milestones, the 206,044 shares of common stock become immediately issuable to the Mayo Foundation. Upon issuance of these shares related to an IPO, the Company will record a one-time stock-based compensation expense at the then current fair value.

The Company may also be obligated to pay the Mayo Foundation, contingent upon the occurrence of certain future events, earned royalty payments, including a minimum annual royalty as defined by the agreement, for the commercial sale of products developed and patented by the Mayo Foundation, jointly patented by the Company and the Mayo Foundation, or a product where the Mayo Foundation provided know-how as defined by the agreement. If no products are patented, the minimum royalty is not due. The Mayo Foundation receives an annual \$250,000 retainer fee which commenced in 2005 and continues through January 2009. The annual retainer fee paid to the Mayo Foundation is recorded on the statement of operations as research and development expense.

**(17) Retirement Plan**

The Company has a 401(k) profit-sharing plan that provides retirement benefits to employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations. The Company's matching is at the discretion of the Company's board of directors. For the nine months ended September 30, 2007 (unaudited) and the years ended December 31, 2006, 2005 and 2004 and for the period from December 19, 2002 (inception) to September 30, 2007 (unaudited), the Company did not provide any matching of employees' contributions.

**(18) Subsequent Events (Unaudited)**

On May 24, 2007, the Company's board of directors approved the filing of a registration statement with the Securities and Exchange Commission for an initial public offering (IPO) of the Company's common stock as well as an amendment to Section 4(a) of the Company's 2003 Stock Incentive Plan (the "Plan"), subject to stockholder approval, to become effective upon the effectiveness of the offering. The amendment to the Plan provides 3,901,100 shares of the Company's common stock to be reserved for issuance upon the exercise of stock options or other awards that may be granted pursuant to the Plan.

On October 3, 2007, the Company's board of directors and stockholders approved an amendment to the Company's Amended and Restated Certificate of Incorporation to provide for the mandatory conversion of all shares of preferred stock into common stock utilizing the quotient obtained by dividing the original purchase price per share of \$6.5593, \$3.9430 and \$8.0926 by \$4.2379, \$3.9430 and \$8.0926 per share, respectively, upon a qualified public offering whereby the public offering price is greater than the quotient obtained by dividing

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**Notes to Consolidated Financial Statements — (Continued)**

\$180 million by the number of shares of total fully-diluted common stock as of the time of closing of the public offering (without taking into account the securities offered or sold in the public offering) and aggregate gross proceeds to the Company of at least \$30 million after deducting underwriting commissions and discounts. On November 13, 2007, pursuant to Article IV, Section 4(b)(ii) of the Company's Fourth Amended and Restated Certificate of Incorporation, the holders of more than 63% of the outstanding shares of Series B and Series C Preferred Stock consented to the automatic conversion of all outstanding shares of the Company's preferred stock effective as of immediately prior to closing of an initial public offering of the Company's common stock in which the public offering price is equal to or greater than \$8.00 per share.

On October 3, 2007, the Company's Board of Directors and stockholders approved a 1-for-9.1 reverse split of the Company's common stock and preferred stock which became effective upon the filing of an amendment and restatement of the Company's Amended and Restated Certificate of Incorporation on November 8, 2007. All share and per share amounts have been retroactively adjusted to reflect the stock split for all periods presented.

On October 31, 2007, we completed the \$2.5 million draw that was available to us through that date by entering into two separate growth capital loans with a combined face amount of \$2.5 million. The amount is payable in 29 equal principal and interest installments beginning March 1, 2008 through July 1, 2010 with a final payment of \$171,525 on August 1, 2010 at an annual percentage rate of 10.25%. Interest only payments for the first four months of the loan are at an annual percentage rate of 12.48%. In conjunction with the funding of the growth capital loan, the Company issued detachable warrants to acquire 16,991 shares of Series C stock at an exercise price of \$8.0926 per share. The warrants have a seven year life.

Through and including December 9, 2007 (25 days after the date of this prospectus), all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the obligation of dealers to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

**5,000,000 Shares**



**Common Stock**

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**PROSPECTUS**

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**JPMorgan**

**Morgan Stanley**

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**Cowen and Company**

**Leerink Swann**

November 14, 2007

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