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

**Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

ENTEROMEDICS INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Delaware
(State or other jurisdiction of
incorporation or organization)

48-1293684
(I.R.S. Employer
Identification Number)

3845
(Primary Standard Industrial
Classification Code Number)

**2800 Patton Road
St. Paul, Minnesota 55113
(651) 634-3071**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Dan W. Gladney
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St. Paul, Minnesota 55113
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of securities to be registered (1)	Proposed maximum aggregate offering price (1)	Amount of Registration Fee (2)
Class A Units consisting of:		
(i) shares of common stock, par value \$0.01 per share		
(ii) Warrants to purchase common stock		
Class B Units consisting of:		
(i) Series A Convertible Preferred Stock		
(ii) Common Stock issuable on conversion of Series A Convertible Preferred Stock		
(iii) Warrants to purchase common stock		
Total	\$5,750,000	\$579.03

- (1) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended (the "Act"). Pursuant to Rule 416 under the Act, the securities registered also include such indeterminate amounts and numbers of shares of common stock issuable to cover additional securities that may be offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions. Also includes the offering price of additional units that the underwriters have the option to purchase.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price of all securities being registered.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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

Subject to Completion dated September 20, 2016

PROSPECTUS



ENTEROMEDICS INC.

Class A Units consisting of shares of common stock and warrants and Class B Units consisting of Series A convertible preferred stock and warrants (and shares of common stock underlying shares of Series A convertible preferred stock and warrants)

We are offering Class A Units, with each Class A Unit consisting of two shares of common stock, par value \$0.01 per share and one warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants, the “Class A Units”) at a public offering price of \$ per Class A Unit. Each warrant included in the Class A Units entitles its holder to purchase one share of common stock at an exercise price of \$ per share.

We are also offering to those purchasers whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, Class B Units. Each Class B Unit will consist of one share of Series A Convertible Preferred Stock, par value \$0.01 per share (the “Series A Preferred Stock”), convertible at any time at the holder’s option into a number of shares of common stock equal to \$ divided by \$ (the “Conversion Price”) and warrants to purchase a number of shares of our common stock equal to \$ divided by the Conversion Price (together with the shares of common stock underlying such shares of Series A Preferred Stock and such warrants, the “Class B Units”) and, together with the Class A Units, the “Units”) at a public offering price of \$ per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase one share of common stock at an exercise price of \$ per share.

The Class A Units and Class B Units will not be certificated and the shares of common stock, Series A Preferred Stock and warrants comprising such units are immediately separable and will be issued separately in this offering.

Our common stock is listed on the Nasdaq Capital Market under the symbol “ETRM.” We intend to apply to list the warrants on the Nasdaq Capital Market under the symbol “ETRMW”. The last reported sale price of our common stock on the Nasdaq Capital Market on September 19, 2016 was \$0.14 per share.

Investing in the common stock and warrants involves risks. See “Risk Factors” beginning on page 11 of this prospectus.

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	<u>Per Class A Unit</u>	<u>Per Class B Unit (1)</u>	<u>Total</u>
Public offering price	\$	\$	\$
Underwriting discounts (2)	\$	\$	\$
Proceeds, before expenses, to EnteroMedics Inc.	\$	\$	\$

- (1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of \$ and (ii) a public offering price per warrant of \$ and (y) in respect of the Class B Units (i) a public offering price per share of Series A Preferred Stock of \$ and (ii) a public offering price per warrant of \$.
- (2) We refer you to “Underwriting” on page 46 for additional information regarding underwriting compensation.

Neither the United States Securities and Exchange Commission, or the SEC, nor any state securities commission has approved or disapproved of the common stock that may be offered under this prospectus, nor have any of these regulatory authorities determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriter has the option to purchase up to (i) additional shares of common stock, and/or (ii) additional warrants to purchase up to additional shares of common stock solely to cover over-allotments, if any, at the public offering price per share of common stock and the public offering price per warrant set forth above less the underwriting discounts and commissions. The over-allotment option may be used to purchase shares of common stock or warrants, or any combination thereof, as determined by the underwriter, but such purchases cannot exceed an aggregate of 15% of the number of shares of common stock (including the number of shares of common stock issuable upon conversion of shares of Series A Preferred Stock) and 15% of the warrants sold in the primary offering. The over-allotment option is exercisable for 45 days from the date of this prospectus.

The underwriter expects to deliver the securities to purchasers on , 2016.

Ladenburg Thalmann

, 2016

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

Registered Trademarks and Trademark Applications: In the United States we have registered trademarks for VBLOC®, ENTEROMEDICS® and MAESTRO®, each registered with the United States Patent and Trademark Office, and trademark applications for VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN. In addition, some or all of the marks VBLOC, ENTEROMEDICS, MAESTRO, MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS, VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, India, Kuwait, Mexico, Saudi Arabia, Switzerland and the United Arab Emirates. This prospectus contains other trade names and trademarks and service marks of EnteroMedics and of other companies.

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

PROSPECTUS SUMMARY

This summary highlights selected information contained in greater detail elsewhere in this prospectus or incorporated by reference into this prospectus. This summary may not contain all of the information that you should consider before investing in the common stock and warrants. You should carefully read the entire prospectus, including "Risk Factors" beginning on page 11 and the financial statements and related notes and other documents incorporated by reference into this prospectus, before making an investment decision.

Our Business

We are a medical device company focused on the design and development of devices that use neuroblocking technology to treat obesity, metabolic diseases 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 U.S. Food and Drug Administration ("FDA") approval to sell our product in the United States and have regulatory approval to sell our product in the European Economic Area and other countries that recognize the European CE Mark.

Our Product

The vBloc Rechargeable System, our initial product, uses vBloc Therapy to limit the expansion of the stomach, help control hunger sensations between meals, reduce the frequency and intensity of stomach contractions and produce a feeling of early and prolonged fullness. We believe the vBloc Rechargeable System offers obese patients a minimally-invasive treatment that can result in significant, durable and sustained weight loss. We believe that our vBloc Rechargeable System allows bariatric surgeons to offer a new option to obese patients who are concerned about the risks and complications associated with currently available anatomy-altering, restrictive or malabsorptive surgical procedures.

The vBloc Rechargeable System



Our vBloc Rechargeable 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 and connected to a neuroregulator, which is subcutaneously implanted. The vBloc Rechargeable System is powered by an internal rechargeable battery. The vBloc Rechargeable System is implanted by a bariatric surgeon using a procedure that is typically performed within 60-90 minutes. The physician activates the vBloc Rechargeable System after implantation. vBloc Therapy is then delivered intermittently each day as scheduled (recommended during the patient's waking hours) through the neuroregulator. The scheduled

delivery of the intermittent pulses blocking the vagus nerve is customized for each patient's weight loss and overall treatment objectives. 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.

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc Rechargeable System, for the treatment of adult patients with obesity who meet certain specifications for Body Mass Index ("BMI") with a related health condition such as high blood pressure or high cholesterol levels, and who have tried to lose weight in a supervised weight management program and failed within the past five years. Additionally, we obtained European CE Mark approval for our vBloc Rechargeable System in 2011 for the treatment of obesity. The CE Mark approval for our vBloc Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. To date, we have relied on, and anticipate that we will continue to rely on, third-party manufacturers and suppliers for the production of the vBloc Rechargeable System.

Our Market

The Obesity and Metabolic Disease Epidemic. Obesity is a disease that has been increasing at an alarming rate with significant medical repercussions and associated economic costs. Since 1980, the worldwide obesity rate has more than doubled, with about 13% of the world's adult population now being obese. The World Health Organization ("WHO") currently estimates that as many as 600 million people worldwide are estimated to be obese and more than 1.9 billion adults are estimated to be overweight. Being overweight or obese is also the fifth leading risk for global deaths, with approximately 3.4 million adults dying each year as a result.

According to the WHO, there are over 70 progressive obesity-related diseases and disorders associated with obesity, which are also known as comorbidities, including Type 2 diabetes, hypertension, infertility and certain cancers. Worldwide, 44% of the diabetes burden, 23% of the heart disease burden and between 7% and 41% of certain cancer burdens are attributable to overweight and obesity.

We believe that this 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 effective treatments.

The United States Market. Obesity has been identified by the U.S. Surgeon General as the fastest growing cause of disease and death in the United States. Currently, the Center for Disease Control (the "CDC") estimates that 35.7% of U.S. adults (or approximately 73,000,000 people) are obese, having a BMI of 30 or higher. BMI is calculated by dividing a person's weight in kilograms by the square of their height in meters. It is estimated that if obesity rates stay consistent, 51% of the U.S. population will be obese by 2030. According to data from the U.S. Department of Health and Human Services, almost 80% of adults with a BMI above 30 have a co-morbidity, and almost 40% have two or more of these comorbidities. According to The Obesity Society and the CDC, obesity is associated with many significant weight-related comorbidities including Type 2 diabetes, high blood-pressure, sleep apnea, certain cancers, high cholesterol, coronary artery disease, osteoarthritis and stroke. According to the American Cancer Society, 572,000 Americans die of cancer each year, about one-third of which are linked to excess body weight, poor nutrition and/or physical inactivity. Over 75% of hypertension cases are directly linked to obesity, and approximately two-thirds of U.S. adults with Type 2 diabetes are overweight or have obesity. Currently, medical costs associated with obesity in the U.S. are estimated to be up to \$210 billion per year and nearly 21% of medical costs in the U.S. can be attributed to obesity. Researchers estimate that if obesity trends continue, obesity related medical costs could rise by another \$44-\$66 billion each year in the U.S.

by 2030. The medical costs paid by third-party payors for people who are obese were \$2,741 per year, or 42% higher than those of people who are normal weight and the average cost to employers is \$6,627 to \$8,067 per year per obese employee (BMI of 35 to 40 and higher).

Current Treatment Options and Their Limitations. We believe existing options for the treatment of obesity have seen limited adoption to date due to patient concerns 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 but carry significant safety risks and may present troublesome side effects and compliance issues.
- *Bariatric surgery.* In more severe cases of obesity, patients may pursue more aggressive surgical treatment options such as gastric balloon, gastric banding, sleeve gastrectomy and gastric bypass. These procedures promote weight loss by surgically restricting the stomach's capacity and outlet size. While largely effective, these procedures generally result in major lifestyle changes including dietary restrictions and food intolerances and they may present substantial side effects and carry short- and long-term safety and side effect risks that have limited their adoption.

Market Opportunity Given the limitations of behavioral modification, pharmaceutical therapy and bariatric surgical approaches, we believe there is a substantial need for a patient-friendly, safer, effective and durable solution that:

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

Our Technology

vBloc Therapy is designed to block the gastrointestinal effects of the vagus nerve 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 controls hunger sensations between meals, limits the expansion of the stomach and reduces the frequency and intensity of stomach contractions, leading to earlier fullness. In addition, vBloc Therapy reduces the absorption of calories by decreasing the secretion of digestive enzymes. The resulting physiologic effects of vBloc Therapy produce a feeling of early and prolonged fullness following smaller meal portions. By intermittently blocking the vagus nerve and allowing it to return to full function between therapeutic episodes, our therapy limits the body's natural tendency to circumvent the therapy, which can result in long-term weight loss.

We have designed our vBloc Rechargeable System to address a significant market opportunity that we believe exists for a patient-friendly, safe, effective, less-invasive and durable therapy that is intended to address the underlying causes of hunger and obesity. Our vBloc Rechargeable System offers each of the following benefits, which we believe could lead to the adoption of vBloc Therapy as the surgical therapy of choice for obesity and its comorbidities:

- **Preserves Normal Anatomy.** The vBloc Rechargeable System is designed to deliver therapy that blocks the neural signals that influence a patient's hunger and sense of fullness without altering digestive system anatomy. Accordingly, patients should experience fewer and less severe side effects compared to treatments that incorporate anatomical alterations.
- **Allows Continued Ingestion and Digestion of Foods Found in a Typical, Healthy Diet.** Because our therapy leaves the digestive anatomy unaltered, patients are able to maintain a more consistent nutritional balance compared to existing surgical approaches, thus allowing them to effect positive changes in their eating behavior in a non-forced and potentially more consistent way.
- **May be Implanted on an Outpatient Basis and Adjusted Non-Invasively.** The vBloc Rechargeable System is designed to be laparoscopically implanted within a 60-90 minute procedure, 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 ReCharge and EMPOWER clinical trials to demonstrate the safety of the vBloc Rechargeable System. In our clinical trials to date, including the ReCharge and EMPOWER trials, we have not observed any mortality related to our device or any unanticipated adverse device effects. We have also not observed any long-term problematic clinical side effects in any patients, including in those patients who have been using vBloc Therapy for more than one year.
- **Targets Multiple Factors that Contribute to Hunger and Obesity.** We designed vBloc Therapy to target the digestive, metabolic and information transmission functions of the vagus nerve and to affect the perception of hunger and fullness, which together contribute to obesity and its metabolic consequences.

vBloc Therapy, delivered via our vBloc Rechargeable System, is intended to offer patients an effective, safe, outpatient solution that minimizes complications. It enables patients to lose weight and maintain long-term weight loss while enjoying a normal, healthy diet. We also believe that the vBloc Rechargeable System will appeal to physicians based on the inherent physiological approach of vBloc Therapy and its favorable safety profile.

Our Commercialization Strategy

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

Commercialize Our Products Using a Geography Focused Direct-to-Patient Marketing Effort Within the United States. We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc Rechargeable System. We have begun a controlled commercial launch at select bariatric centers of excellence in the United States and had our first commercial sales in 2015. During 2015, we started the process of building a sales force and a controlled expansion of our operations and hired three new executives in January 2016 to oversee this expansion. The direct sales force is supported by field technical managers who provide training,

technical and other support services to our customers. Throughout 2015 our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven bariatric centers of excellence that met our certification criteria, which led to the training and certification of over 50 centers and 75 surgeons in implanting and administering vBloc Therapy. We continue to build on these efforts in 2016 through geography and self-pay patient focused direct-to-patient marketing and key opinion leader and center specific partnering.

Our direct sales force is initially targeting outcome-focused, aftercare-based centers in key self-pay markets and will promote the vBloc Rechargeable System to physicians and patients who have concerns with current bariatric surgical procedures. We are calling on physicians, weight-management specialists, nurses and others involved in the obesity management process who influence patient adoption.

Account management and patient registration processes used during the clinical trial are being transitioned to a commercial registration structure. Centers responsible for implanting our product will be expanded and trained to perform patient selection, implant the vBloc Rechargeable System and manage appropriate follow-up procedures.

Our sales representatives are supported by field clinical experts who are responsible for training, technical support, and other support services at various implant centers. Our sales representatives implement consumer marketing programs and provide surgical centers and implanting surgeons with educational patient materials.

We market directly to patients but sell our product to select surgical centers throughout the United States that have patients that would like to use the vBloc Rechargeable System to treat obesity and its comorbidities. The surgical centers then sell our product to the patients and implant and administer vBloc Therapy. In 2015 and 2016, the patients that purchased the vBloc Rechargeable System paid for the therapy themselves and did not receive reimbursement from an insurance provider, and we expect that most of our sales will come from self-pay patients in the remainder of 2016 and 2017. We are working to obtain coverage for our product from the U.S. Centers for Medicare and Medicaid Services (“CMS”), major insurance carriers, local coverage entities and self-insured plans, including Integrated Delivery Networks (“IDNs”). We received coverage from one significant IDN in the northeast in 2016 and are in active discussions with other IDNs throughout the country.

Identify Appropriate Coding, Obtain Coverage and Payment for the vBloc Rechargeable System. While payors are not our direct customers, their coverage and reimbursement policies influence patient and physician selection of obesity treatment. We are employing a focused campaign to obtain payor support for vBloc Therapy. We plan to seek specific and appropriate coding, coverage and payment for our vBloc Rechargeable System from CMS and from private insurers. We plan to establish a market price for the vBloc Rechargeable System in the United States that is comparable to other active implantable devices such as implantable cardioverter defibrillators, neurostimulation devices for chronic pain and depression, and cochlear implant systems.

CMS issued a national coverage determination for several specific types of bariatric surgery in 2006, which we view as positive potential precedent and guidance factors that CMS might use in deciding to cover our therapy. 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 have begun to actively work with major insurance carriers, local coverage entities and self-insured plans, as well as CMS, beginning the process to obtain coverage for procedures using our product. Initial coverage for vBloc will likely occur in self-contained healthcare systems that operate as IDNs, as these systems are able to evaluate risk-benefit ratios in a closed environment. For example, we recently announced coverage for its employees from the Winthrop Hospital System in New York, a significant IDN in the northeast. Other similar arrangements are in active discussion.

Drive the Adoption and Endorsement of vBloc Therapy Through Obesity Therapy Experts and Patient Ambassadors. Our Clinical Development strategy is to collaborate closely with regulatory bodies, obesity therapy experts and others involved in the obesity management process, patients and their advocates and

scientific experts. We have established credible and open relationships with obesity therapy experts and have identified vBloc Therapy patient ambassadors and we believe these individuals will be important in promoting patient awareness and gaining widespread adoption of the vBloc Rechargeable System.

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, diabetes, hypertension 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 metabolic and gastrointestinal disorders in addition to obesity.

Concentrate Our Resources on the U.S. Market. We intend to devote our near-term efforts toward mounting a successful system launch in the United States. We intend to explore select international markets to commercialize the vBloc Rechargeable System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates.

Clinical Experience

We have conducted a series of clinical trials to date, which have shown that vBloc Therapy offers physicians a programmable method to selectively and reversibly block the vagus nerve resulting in clinically and statistically significant excess weight loss. To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in our human clinical trials. We have also not observed any long-term problematic clinical side effects in any patients. In addition, data from our trials outside the United States demonstrate that vBloc Therapy may hold promise in improving obesity-related comorbidities such as diabetes and hypertension. We are conducting, or plan to conduct, further studies in each of these comorbidities to assess vBloc Therapy's potential in addressing multiple indications.

Our 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. We own numerous U.S. and foreign patents, and have numerous patent applications pending, most of which pertain to treating gastrointestinal disorders and we believe provide us with broad intellectual property protection covering electrically-induced vagal blocking and methods for treating obesity. Assuming timely payment of maintenance fees as they become due, many of these patents will expire in 2023. We have also received or applied for patents in Europe, Australia, China, India and Japan. 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 the Mayo Foundation for Medical Education and Research for three issued U.S. patents, which are unrelated to our vBloc Therapy.

Risks Associated with Our Business

Our business is subject to numerous risks discussed more fully in the section entitled "*Risk Factors*" immediately following this prospectus summary. We are a medical device company with a limited operating history upon which you can evaluate our business. We received FDA approval to sell our product in the United States on January 14, 2015. We have also completed the regulatory process required to sell our product in the European Economic Area and other countries that recognize the European CE Mark, but did not recognize any revenue

from commercial sales of our product in 2014 or 2013. We completed the first commercial sale of our product outside of the United States in 2012. We recently commenced commercial operations in the United States, and made our first commercial sales in the United States in the second quarter of 2015. The success of our business will depend on our ability to establish a sales force, make sales and control costs, as well as our ability to obtain additional regulatory approvals needed to market new versions of our vBloc Rechargeable System and any other products we may develop in the future, all of which we may be unable to do. Additionally, if third-party payors do not cover and reimburse the cost of our vBloc Rechargeable System and the related surgery and facility costs, or such coverage is limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our vBloc Rechargeable System will be impaired and our future revenue, if any, will be adversely affected. If we are unable to successfully market our vBloc Rechargeable System for its indicated use or are unable to obtain adequate third-party coverage and reimbursement, we may never 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.

Our Corporate Information

We were incorporated in Minnesota in December 2002 as two separate legal entities, Alpha Medical, Inc. and Beta Medical, Inc., both of which were owned 100% by a common stockholder. In 2003, the two entities were combined and we changed our name to EnteroMedics Inc. 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. The information on, or that may be accessed through, our website is not a part of, or incorporated by reference, in this prospectus supplement. As used in this prospectus, references to “we,” “our,” “us” and “EnteroMedics” refer to EnteroMedics Inc. and its subsidiary unless the context requires otherwise.

Recent Developments

In May 2016, we received written notices from the Nasdaq Stock Market (“Nasdaq”) stating that we were not in compliance with the following two Nasdaq listing requirements: (1) the requirement that we have a minimum of \$2.5 million stockholders’ equity (the “Stockholders’ Equity Requirement”) and (2) the \$1.00 minimum bid price stock price requirement (the “Minimum Bid Requirement”). We have received an extension until November 14, 2016 from Nasdaq to regain compliance with the Stockholders’ Equity Requirement. The extension was granted based on a plan we submitted to Nasdaq to regain compliance with the Stockholders’ Equity Requirement through a combination of note conversions and accelerated principal amortizations and infusions of equity capital prior to the deadline. In connection with the plan submitted to Nasdaq, we entered into an amendment to the securities purchase agreement with the holders of our outstanding convertible notes to facilitate conversions and allow us to incentivize further conversions of our outstanding convertible notes into equity. Since entering into the amendment, we have experienced a significant increase in accelerated principal amortizations and conversions at the election of the holders. Through June 30, 2016, \$3.2 million of aggregate principal amount of the Notes was converted or accelerated by the holders into approximately 6.1 million shares of our common stock. Through _____, 2016, \$ _____ million of aggregate principal amount of our outstanding convertible notes has been converted or accelerated by the holders into approximately _____ million shares of our common stock and there is \$ _____ million of aggregate principal amount of the convertible notes outstanding as of _____, 2016.

Additionally, we have 180 calendar days from the May 9, 2016 notice date to regain compliance with the Minimum Bid Requirement. In the event we do not regain compliance with this requirement, we may be granted an additional 180 calendar days to regain compliance with the Minimum Bid Requirement if we (i) meet the continued listing requirement for market value of publicly held shares and all of the other applicable

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requirements for initial listing on Nasdaq other than the Minimum Bid Requirement, and (ii) provide written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. On September 19, 2016, we provided notice of our intention to call a special meeting of our stockholders on October 19, 2016 to obtain stockholder approval for a reverse stock split.

The Offering

Issuer	EnteroMedics Inc.
Class A Units Offered	We are offering Class A Units. Each Class A Unit consists of two shares of common stock and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants).
Offering Price per Class A Unit	\$ combined price for each Class A Unit.
Class B Units Offered	We are also offering to those purchasers, whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of the number of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, Class B Units. Each Class B Unit will consist of one share of Series A Preferred Stock, par value \$0.01 per share, convertible into a number of shares of common stock equal to \$ divided by the Conversion Price and warrants to purchase a number of shares of our common stock equal to the \$ divided by the Conversion Price (together with the shares of common stock underlying such shares of Series A Preferred Stock and such warrants).
Offering Price per Class B Unit	\$ combined price for each Class B Unit.
Description of warrants	The warrants will be exercisable beginning on the closing date and expire on the fifth anniversary of the closing date and have an initial exercise price per share equal to \$ per share, subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock.
Description of Series A Preferred Stock	Each share of Series A Preferred Stock is convertible at any time at the holder's option into a number of shares of common stock equal to \$ divided by the Conversion Price. Notwithstanding the foregoing, we shall not effect any conversion of Series A Preferred Stock, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of shares of Series A Preferred Stock (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of our common stock in excess of 4.99% (or, at the election of the purchaser, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise. For additional information, see "Description of Securities—Preferred Capital Stock" on page 42 of this prospectus.

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Shares of common stock underlying the warrants	shares.
Shares of common stock outstanding before this offering	57,129,000 shares as of August 31, 2016.
Shares of common stock to be outstanding after this offering	shares.
Shares of Series A Preferred Stock outstanding before this offering	None.
Shares of Series A Preferred Stock to be outstanding after this offering	shares.
Over-allotment option	We have granted the underwriter an option to purchase additional shares of common stock equal to 15% of the shares (including shares of common stock underlying the Series A Preferred Stock) in the offering and/or additional warrants equal to 15% of the warrants in the offering at public offering price per share of common stock and the public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commission. This option is exercisable, in whole or in part, for a period of 45 days from the date of this prospectus.
Market for the Common Stock	Our common stock is listed on the Nasdaq Capital Market under the symbol “ETRM”.
Proposed Nasdaq Capital Market listing symbols for warrants	We intend to apply to list the warrants on the Nasdaq Capital Market under the symbol “ETRMW”.
No listing of Series A Preferred Stock	We do not intend to apply for listing of the Series A Preferred Stock on any securities exchange or trading system.
Risk Factors	See “Risk Factors” beginning on page 11 and other information included in this prospectus for a discussion of factors that you should consider carefully before deciding to invest this offering.

RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully read and consider the risks described below, as well as the other information in this prospectus and other information incorporated by reference herein, before deciding to invest in our securities. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations or cash flows. In that case, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Business and Industry

We are a medical device company with a limited history of operations, limited history of sales in the United States and a limited history of sales in countries outside of the United States, and we cannot assure you that we will ever generate substantial revenue or be profitable.

We are a medical device company with a limited operating history upon which you can evaluate our business. We received U.S. Food and Drug Administration (“FDA”) approval to sell our product in the United States on January 14, 2015 and we have had commercial sales within the United States in 2015 and 2016. We have also completed the regulatory process required to sell our product in the European Economic Area and other countries that recognize the European CE Mark, and have not generated revenue from commercial sales outside of the United States since 2012 and then only on a limited basis in Australia and the Middle East. We have been engaged in research and development and clinical trials since our inception in 2002 and have invested substantially all of our time and resources in developing our vBloc Therapy, which we have begun to commercialize in the form of our vBloc Rechargeable System. The success of our business will depend on our ability to establish a sales force, make sales and control costs, as well as our ability to obtain additional regulatory approvals needed to market new versions of our vBloc Rechargeable System and any other products we may develop in the future, all of which we may be unable to do. If we are unable to successfully market our vBloc Rechargeable System for its indicated use, we may never become profitable and may have to cease operations as a result. 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 losses for the foreseeable future.

We have incurred losses in each year since our formation in 2002. Our net loss applicable to common stockholders for the fiscal years ended December 31, 2015, 2014 and 2013 was \$25.5 million, \$26.1 million and \$25.8 million, respectively. We have funded our operations to date principally from the sale of securities and 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. Although we recently received the regulatory approval required to sell our vBloc Rechargeable System in the United States and have the approvals required for sales in the European Economic Area and other countries that recognize the European CE Mark, we have only generated limited revenue from commercial sales in the United States and have not generated revenue from commercial sales outside of the United States since 2012 and then only on a limited basis in Australia and the Middle East. We expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our general and administrative expenses to increase as we continue to add the infrastructure necessary to support our initial commercial sales, operate as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur significant 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.

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on the commercialization of our product and on research and development, including conducting current and future clinical trials for our vBloc Rechargeable System and subsequent versions of our product. Cash used in operations was \$12.5 million for the six months ended June 30, 2016 and \$22.6 million, \$19.4 million and \$18.4 million for the fiscal years ended December 31, 2015, 2014 and 2013, respectively. We expect that our cash used in operations will continue to be significant in the upcoming years, and that we will need to raise additional capital to commercialize our vBloc Rechargeable System in the United States, the European Economic Area, other countries that recognize the European CE Mark and other international markets, to explore other indications for our product, to continue our research and development programs, and to fund our ongoing operations.

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

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our vBloc Rechargeable System and any products that we may develop;
- the rate of market acceptance of our vBloc Rechargeable 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 vBloc Rechargeable System or our future products;
- the scope, rate of progress, results and cost of any clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to these types of transactions.

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

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

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

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

We face significant uncertainty in the industry due to government healthcare reform.

The Patient Protection and Affordable Care Act, as amended, (the “Affordable Care Act”) as well as other healthcare reform may have a significant impact on our business. The impact of the Affordable Care Act on the health care industry is extensive and includes, among other things, the federal government assuming a larger role in the health care system, expanding healthcare coverage of United States citizens and mandating basic healthcare benefits. The Affordable Care Act contains many provisions designed to generate the revenues necessary to fund the coverage expansions and to reduce costs of Medicare and Medicaid, including imposing a 2.3% excise tax on domestic sales of many medical devices by manufacturers that began in 2013. Although a moratorium was placed on the medical device excise tax in 2016 and 2017, if it is reinstated, it may adversely affect our sales and the cost of goods sold. In addition, any healthcare reforms enacted in the future may, like the Affordable Care Act, be phased in over a number of years but, if enacted, could reduce our revenue, increase our costs, or require us to revise the ways in which we conduct business or put us at risk for loss of business. In addition, our results of operations, financial position and cash flows could be materially adversely affected by changes under the Affordable Care Act and changes under any federal or state legislation adopted in the future.

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

Our operations are directly, or indirectly through 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 sales, marketing and education programs.

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

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act, known as “qui tam” actions, can be brought by any individual on behalf of the government and such

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

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

The health care industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. The obesity treatment market in which we operate has grown significantly in recent years and is expected to continue to expand as technology continues to evolve and awareness of the need to treat the obesity epidemic grows. Although we are not aware of any competitors in the neuroblocking market, we face potential competition from pharmaceutical and surgical obesity treatments. Many of our competitors in the obesity treatment field have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly if they pursue competing solutions through collaborative arrangements with large and established companies, such as Allergan, Apollo Endosurgery, Boston Scientific, LivaNova PLC, 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.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions, or data corruption could significantly disrupt our operations and adversely affect our business and operating results.

We currently rely on information technology and telephone networks and systems, including the Internet, to process and transmit sensitive electronic information and will rely on such systems to manage or support a variety of business processes and activities, including sales, billing, customer service, procurement and supply chain, manufacturing, and distribution. We use enterprise information technology systems to record, process, and summarize financial information and results of operations for internal reporting purposes and to comply with regulatory financial reporting, legal, and tax requirements.

Our information technology systems, some of which are managed by third-parties, may be susceptible to damage, disruptions or shutdowns due to computer viruses, attacks by computer hackers, failures during the process of upgrading or replacing software, databases or components thereof, power outages, hardware failures, telecommunication failures, user errors or catastrophic events. We are not aware of any breaches of our information technology infrastructure. Despite the precautionary measures we have taken to prevent breakdowns in our information technology and telephone systems, if our systems suffer severe damage, disruption or shutdown and we are unable to effectively resolve the issues in a timely manner, our business and operating results may suffer.

Risks Associated with Development and Commercialization of the vBloc Rechargeable System

Our efforts to commercialize our vBloc Rechargeable System may not succeed or may encounter delays which could significantly harm our ability to generate revenue.

Our ability to generate revenue will depend upon the successful commercialization of our vBloc Rechargeable System. Our efforts to commercialize this product may not succeed for a number of reasons, including:

- our vBloc Rechargeable System may not be accepted in the marketplace by physicians, patients and third-party payors;
- the price of our vBloc Rechargeable System, associated costs of the surgical procedure and treatment and the availability of sufficient third-party reimbursement for the system implantation and follow-up procedures;
- appropriate reimbursement and/or coding options may not exist to enable billing for the system implantation and follow-up procedures;
- we may not be able to sell our vBloc Rechargeable System at a price that allows us to meet the revenue targets necessary to generate enough 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 vBloc Rechargeable System;
- we, or the investigators of our product, may not be able to have information on the outcome of the trials published in medical journals;
- the availability and perceived advantages and disadvantages of alternative treatments;
- any rapid technological change may make our product obsolete;
- we may not be able to have our vBloc Rechargeable 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 vBloc Rechargeable System or to develop sales and marketing capabilities for our vBloc Rechargeable System; and
- we may be sued for infringement of intellectual property rights and could be enjoined from manufacturing or selling our products.

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

After we received FDA approval on January 14, 2015, we began the commercialization process for our vBloc Rechargeable System in the United States, and had our first commercial sales within the United States in 2015.

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Previously, in 2012, we commenced commercial sales of our vBloc Rechargeable System in Australia and the Middle East, but have not generated revenue from commercial sales outside of the United States since 2012 as we focused our resources on the U.S. regulatory approval process and commercialization of our product in the United States and we do not know when, or if, we will have the resources to commercialize our vBloc Rechargeable System internationally. If we are not successful in the commercialization of our vBloc Rechargeable System for the treatment of obesity we may not generate enough revenue to offset our expenses and may be forced to cease operations as a result.

We have not received, and may never receive, approval from the regulatory bodies of any foreign country other than the European Economic Area to market our vBloc Rechargeable System for the treatment of obesity.

We do not have the necessary regulatory approvals to market our vBloc Rechargeable System in any foreign market other than the European Economic Area for which we received CE Mark approval for our vBloc Rechargeable System in March 2011 for the treatment of obesity and other countries which accept these regulatory approvals. Additionally, the vBloc Rechargeable System was previously listed on the Australian Register of Therapeutic Goods (the “ARTG”). The CE Mark approval for our vBloc Rechargeable System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. We have not generated revenue from commercial sales outside of the United States since 2012 as we focused our resources on the U.S. regulatory approval process and commercialization of our product in the United States and we do not know when, or if, we will have the resources to commercialize our vBloc Rechargeable System internationally.

In order to market our vBloc Rechargeable System outside of the United States, we will need to establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries may differ from that required to obtain FDA approval. The regulatory approval process in other countries may also include all of the risks detailed below.

Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. While the vBloc Rechargeable System was previously listed on the ARTG and has received European CE Marking, we cannot assure you when, or if, we will be able to restart sales in Australia or the Middle East, commence sales in the European Economic Area or other countries that recognize the CE Mark or obtain approval to market our vBloc Rechargeable System in other countries outside the United States.

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 other regulatory bodies will review an application for approval of our vBloc Rechargeable System with greater scrutiny, which could cause that process to be lengthier and more involved than that for products without such characteristics. Such regulatory bodies can delay, limit or deny approval of our vBloc Rechargeable System for many reasons, including our inability to demonstrate safety or effectiveness to their satisfaction, insufficient or inadequate data from our clinical trials, the facilities of our third-party manufacturers or suppliers may not meet applicable requirements; and changes in the regulatory bodies’ 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.

We have limited data and experience regarding the safety and efficacy of the vBloc Rechargeable System. Any long-term data that is generated may not be positive or consistent with our limited short-term data, which would affect market acceptance of these products.

Because our technology is relatively new in the treatment of obesity, we have performed clinical trials only with limited patient populations. The long-term effects of using the vBloc Rechargeable System in a large number of

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patients have not been studied and the results of short-term clinical use of the vBloc Rechargeable System do not necessarily predict long-term clinical benefits or reveal long-term adverse effects.

Clinical trials conducted with the vBloc Rechargeable System have involved procedures performed by physicians who are very technically proficient. Consequently, both short and long-term results reported in these studies may be significantly more favorable than typical results achieved by physicians, which could negatively impact market acceptance of the vBloc Rechargeable System and materially harm our business.

We may be unable to complete our current clinical trials or any additional clinical trials, or we may experience significant delays in completing those clinical trials, which could impact market acceptance of our vBloc Rechargeable System and impair our financial position.

We continue to evaluate vBloc Therapy in human clinical trials, including the EMPOWER trial and ReCharge trial. Conducting a clinical trial, which involves screening, assessing, testing, treating and monitoring patients at several sites across the country and possibly internationally, and coordinating with patients and clinical institutions, is a complex and uncertain process.

The completion of our ongoing and future clinical trials, could be delayed, suspended or terminated for several reasons, including:

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

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

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

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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 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, 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 or maintaining 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, adversely affecting our ability to successfully commercialize our product.

Modifications to the vBloc Rechargeable System may require additional approval from regulatory authorities, which may not be obtained or may delay our commercialization efforts.

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

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

We believe we are the first and only company currently pursuing neuroblocking therapy for the treatment of obesity. Physicians tend to be slow to change their medical treatment practices because of the time and skill required to learn a new procedure, the perceived liability risks arising from the use of new products and procedures, and the uncertainty of third-party coverage and reimbursement. Physicians may not widely adopt our vBloc Rechargeable 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 vBloc Rechargeable System and vBloc Therapy. We believe that published peer-reviewed journal articles and recommendations and support by

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influential physicians regarding our vBloc Rechargeable 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 vBloc Rechargeable System or other products we may develop or our target markets may be much smaller than expected.

Healthcare providers generally rely on third-party payors, including governmental payors, such as Medicare and Medicaid in the United States, as well as private healthcare insurers, to adequately cover and reimburse the cost of medical devices. Importantly, third-party payors are increasingly challenging the price of medical products and services and instituting cost containment measures to control or significantly influence the purchase of medical products and services. We expect that third-party payors will continue to attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our vBloc Rechargeable 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 vBloc Rechargeable System will be impaired and our future revenue, if any, would be adversely affected. As such, even though we have obtained FDA approval for our vBloc Rechargeable System and began to market it in 2015, the availability and level of third-party coverage and reimbursement could substantially affect our ability to successfully commercialize our vBloc Rechargeable System and other products we may develop.

The efficacy, safety, ease of use and cost-effectiveness of our vBloc Rechargeable 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 vBloc Rechargeable System will be more difficult if healthcare providers and obese individuals do not consider the percentage of EWL from a pre-implementation baseline that our clinical trials have demonstrated to be 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 vBloc Rechargeable 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 vBloc Rechargeable System will be impaired and our future revenue, if any, would be adversely affected.

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

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated product problems, our vBloc Rechargeable System could be subject to restrictions or withdrawal from the market.

Completion of our clinical trials and commercialization of our vBloc Rechargeable 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 vBloc Rechargeable System, and do not currently plan to manufacture or assemble our vBloc Rechargeable 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

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inspections by our European Notified Body and the FDA and other regulatory bodies. In particular we and our manufacturers and suppliers are required to comply with ISO requirements, Good Manufacturing Practices, which for medical devices is called the Quality System Regulation (“QSR”), and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing approval. The FDA enforces the QSR through inspections, which may be unannounced, and the CE system enforces its certification through inspections and audits as well. Our quality system has received certification of compliance to the requirements of ISO 13485:2003 and will have to continue to successfully complete such inspections to maintain regulatory approvals for sales outside of the United States. Failure by us or one of our manufacturers or suppliers to comply with statutes and regulations administered by the FDA, CE authorities and other regulatory bodies, or failure to adequately respond to any observations, could result in enforcement actions against us or our manufacturers or suppliers, including, restrictions on our product or manufacturing processes, withdrawal of the product from the market, voluntary or mandatory recall, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

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

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

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

We may not be successful in our efforts to utilize our vBloc Therapy to treat comorbidities associated with obesity and other gastrointestinal diseases and disorders.

As part of our long-term business strategy, we plan to research the application of our vBloc Therapy to treat comorbidities associated with obesity and other gastrointestinal diseases and disorders. Research to identify new target applications requires substantial technical, financial and human resources, whether or not any new applications for our vBloc Therapy are ultimately identified. We may be unable to identify or pursue other applications of our technology. Even if we identify potential new applications for our vBloc Therapy, investigating the safety and efficacy of our therapy requires extensive clinical testing, which is expensive and time-consuming. If we terminate a clinical trial in which we have invested significant resources, our prospects

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will suffer, as we will have expended resources on a program that will not provide a return on our investment and missed the opportunity to allocate those resources to potentially more productive uses. We will also need to obtain regulatory approval for these new applications, as well as achieve market acceptance and an acceptable level of reimbursement.

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

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

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

In order to produce our vBloc Rechargeable 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 future demand, if any. 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 vBloc Rechargeable System. If we are unable to obtain a sufficient supply of our product, our revenue, business and financial prospects would be adversely affected.

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

We have limited experience as a company in sales, marketing and distribution of our product and began the process of developing a sales and marketing organization in 2015. We intend to market our products in the United States through a direct sales force supported by field technical managers who provide training, technical and other support services to our customers. We have begun to develop the necessary sales and marketing infrastructure in order to commercialize our product, but developing a sales force is expensive and time consuming. Additionally, we may be unable to develop an effective sales and marketing organization on a timely basis, if at all, which would delay or prevent us from generating enough revenue to become profitable. If we develop our own sales and marketing capabilities, our sales force will be competing with the experienced and well-funded marketing and sales organizations of our more established competitors. If we are unable to establish our own sales and marketing capabilities, we will need to contract with third parties to market and sell our product. In this event, our profit margins would likely be lower than if we performed these functions ourselves. In addition, we would necessarily be relying on the skills and efforts of others for the successful marketing of our product. If we are unable to establish and maintain effective sales and marketing capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

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When we have sufficient resources to commercialize our vBloc Rechargeable System internationally, we intend to use direct, dealer and distributor sales models as the targeted geography best dictates. We have entered into an agreement with Bader Sultan & Brothers, a third-party distributor in Kuwait, to sell our product in the Middle East. To generate sales and launch the commercialization of our product in other geographic regions we may need to identify and enter into other third-party distributor agreements. There is no assurance that we can do so on economically acceptable terms or that if we do so, that a third-party distributor will be successful in selling our product.

The commercialization of our product in countries outside the United States will expose our business to certain risks associated with international operations.

When we have sufficient resources to do so, we intend to commercialize our product in the European Economic Area, Australia and the Middle East and other international markets in which we obtain necessary regulatory approvals. Conducting international operations will subject us to unique risks, including:

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

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

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

Our success depends on the services of our senior management and other key employees. The loss of the services of one or more of our officers or key employees could delay or prevent the successful completion of our clinical trials and the commercialization of our vBloc Rechargeable System. Now that we have received regulatory approval for our product in the United States, we have begun a controlled expansion of our operations and have hired three new executives in January 2016 to oversee this expansion. Our continued growth will require hiring a number of qualified clinical, scientific, commercial and administrative personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

We may be unable to manage our growth effectively.

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

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

Our business exposes us to a risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices. The medical device industry has historically been subject to extensive litigation over product liability claims. We may be subject to product liability claims if our vBloc Rechargeable 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 product liability insurance, which covers the use of our vBloc Rechargeable System and vBloc Therapy in our clinical trials and any commercial sales, in an 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 vBloc Rechargeable 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 vBloc Rechargeable System and to perform the related vBloc Therapy. If these medical personnel are not properly trained or are negligent, the therapeutic effect of 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.

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 vBloc Rechargeable System and vBloc Therapy by establishing and maintaining intellectual property rights relating to or incorporated into our technology and products. We own numerous U.S. and foreign patents and have numerous patent applications pending, most of which pertain to treating gastrointestinal disorders. We have also received or applied for patents in Europe, Australia, China, India and Japan. In addition, we are the exclusive licensee of three U.S. patents owned by the 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

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

We cannot assure you that we will obtain any patent protection that we seek, that any protection we do obtain will be found valid and enforceable if challenged or that it will confer any significant commercial advantage. U.S. patents and patent applications may also be subject to interference proceedings and U.S. patents may be subject to re-examination proceedings in the U.S. Patent and Trademark Office ("USPTO"), or under more recently promulgated Inter Partes Review proceedings, depending on when the patent application was filed, 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 have recently changed with the adoption of the America Invents Act ("AIA"), 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. In most cases in the United States patent applications are published 18 months after filing 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.

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

As a result of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third-party and be required to pay license fees or royalties, or both. A license may not be available

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

Risks Relating to Ownership of Our Common Stock

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

The trading price of our common stock has been highly volatile. Further, our common stock has a limited trading history. Since our public offering in November 2007 through September 19, 2016 our stock price has fluctuated from a low of \$0.11 to a high of \$969.30, as adjusted for the 1-for-15 reverse split of our common stock that was effected on January 6, 2016. The market price for our common stock will be affected by a number of factors, including:

- the denial or delay of regulatory clearances or approvals of our product or receipt of regulatory approval of competing products;
- our ability to accomplish clinical, regulatory and other product development milestones and to do so in accordance with the timing estimates we have publicly announced;
- changes in policies affecting third-party coverage and reimbursement in the United States and other countries;
- changes in government regulations and standards affecting the medical device industry and our product;
- ability of our product 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;
- the issuance of common stock to the holders of Notes as principal amortization payments and conversions under the Notes or upon the exercise of options or warrants;
- 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;
- the trading volume of our common stock;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain or maintain analyst coverage of our common stock or our failure to achieve analyst earnings estimates;
- public statements by analysts or clinicians regarding their perceptions of our clinical results or the effectiveness of our products;
- decreases in market valuations of medical device companies; and

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- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors.

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

Our inability to comply with Nasdaq's listing requirements could result in our common stock being delisted, which could affect its market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests (including having stockholders' equity of at least \$2.5 million and a minimum closing bid price of \$1.00 per share for our common stock) to maintain the listing of our common stock on Nasdaq. If we do not maintain compliance with the continued listing requirements for Nasdaq within specified periods and subject to permitted extensions, our common stock may be recommended for delisting (subject to any appeal we would file). If our common stock were delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting would also impair our ability to raise capital.

In May 2016, we received written notices from Nasdaq stating that we were not in compliance with the following two Nasdaq listing requirements: (1) the requirement that we have a minimum of \$2.5 million stockholders' equity (the "Stockholders' Equity Requirement") and (2) the \$1.00 minimum bid price stock price requirement (the "Minimum Bid Requirement").

On July 19, 2016, we received a letter from Nasdaq granting us an extension until November 14, 2016 to regain compliance with the Stockholders' Equity Requirement. The extension was granted based on the plan we submitted to Nasdaq to regain compliance with the Stockholders' Equity Requirement through a combination of note conversions and accelerated principal amortizations and infusions of equity capital prior to the deadline.

We have 180 calendar days from the May 9, 2016 notice date to regain compliance with the Minimum Bid Requirement. In the event we do not regain compliance with this requirement, Nasdaq will provide us with written notification that our securities are subject to delisting. At that time, we may appeal the delisting determination to a Nasdaq Hearings Panel.

Alternatively, if we fail to regain compliance with the Minimum Bid Requirement prior to the expiration of the 180 calendar day period, we may be granted an additional 180 calendar days to regain compliance with the Minimum Bid Requirement if we (i) meet the continued listing requirement for market value of publicly held shares and all of the other applicable requirements for initial listing on Nasdaq other than the Minimum Bid Requirement, and (ii) provide written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary.

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

Our executive officers and directors and entities affiliated with them beneficially own, in the aggregate (including options and warrants exercisable currently or within 60 days of August 31, 2016), approximately 1.8% of our outstanding common stock. Our executive officers, directors and affiliated entities, if acting together, could be able to influence significantly all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other significant corporate transactions. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as

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

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

Sales of substantial amounts of our common stock by us or by our stockholders, announcements of the proposed sales of substantial amounts of our common stock or the perception that substantial sales may be made, could cause the market price of our common stock to decline. We may issue additional shares of our common stock in follow-on offerings to raise additional capital, as amortizing payments under our outstanding senior amortizing convertible notes (the "Notes"), upon the exercise of options or warrants, or in connection with acquisitions or corporate alliances. We also plan to issue additional shares to our employees, directors or consultants in connection with their services to us. All of the currently outstanding shares of our common stock are freely tradable under federal and state securities laws, except for shares held by our directors, officers and certain greater than five percent stockholders, which may be subject to volume limitations. Due to these factors, sales of a substantial number of shares of our common stock in the public market could occur at any time and could reduce the market price of our common stock.

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

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, to pay off our outstanding Notes, or for other corporate purposes, in the future we may offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may be lower than the current price per share of our common stock. In addition, investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in prior offerings.

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 Fifth Amended and Restated Certificate of Incorporation, as amended ("Certificate of Incorporation") and our Amended and Restated Bylaws ("Bylaws") and Section 203 of the Delaware General Corporation Law contain provisions that may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. These provisions include:

- the ability of our board of directors to create and issue preferred stock without stockholder approval, which could be used to implement anti-takeover devices;
- the authority for our board of directors to issue without stockholder approval up to the number of shares of common stock authorized in our Certificate of Incorporation, that, if issued, would dilute the ownership of our stockholders;
- the advance notice requirement for director nominations or for proposals that can be acted upon at stockholder meetings;

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- a classified and staggered board of directors, which may make it more difficult for a person who acquires control of a majority of our outstanding voting stock to replace all or a majority of our directors;
- the prohibition on actions by written consent of our stockholders;
- the limitation on who may call a special meeting of stockholders;
- the prohibition on stockholders accumulating their votes for the election of directors; and
- the ability of stockholders to amend our Bylaws only upon receiving a majority of the votes entitled to be cast by holders of all outstanding shares then entitled to vote generally in the election of directors, voting together as a single class.

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

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

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

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

Risks Relating to this Offering

If you purchase Class A Units in this offering, you will incur immediate and substantial dilution in the net tangible book value of your shares.

The public offering price of the Class A Unit is substantially higher than the net tangible book value per share of our common stock. Investors purchasing Class A Units in this offering will pay a price per share of common stock that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing Class A Units in this offering will incur immediate dilution of \$ _____ per share of common stock, based on a public offering price of \$ _____ per Class A Unit. See “Dilution.”

As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of a liquidation of our company.

Because our management will have broad discretion and flexibility in how the net proceeds from this offering are used, our management may use the net proceeds in ways with which you disagree or which may not prove effective.

We currently intend to use the net proceeds from this offering as discussed under “Use of Proceeds” in this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any of the

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foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

The Series A Preferred Stock are unlisted securities and there is no public market for them.

There is no established public trading market for the Series A Preferred Stock, and we do not expect a market to develop. In addition, the Series A Preferred Stock are not listed, and we do not intend to apply for listing of the Series A Preferred Stock on any securities exchange or trading system. Without an active market, the liquidity of the Series A Preferred Stock is limited, and investors may be unable to liquidate their investments in the Series A Preferred Stock.

The warrants may not have any value.

The warrants will be exercisable for five years from the closing date at an initial exercise price of \$ _____ per share. In the event that the price of a share of our common stock does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

The warrants are subject to an issuer call.

If, after the _____ year anniversary of the closing date, (i) the volume weighted average price for each of _____ consecutive trading days (the “Measurement Period,”) exceeds _____ % of the exercise price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and the like after the initial exercise date), (ii) the average daily volume for such Measurement Period exceeds \$ _____ per trading day and, (iii) the warrant holder is not in possession of any material non-public information which was provided by the Company, then the Company may, within 1 trading day of the end of such Measurement Period, call for cancellation of all or any portion of the warrants for which an exercise notice has not yet been delivered for consideration equal to \$0.01 per warrant share. The Company’s right to call the warrants shall be exercised ratably among the holders based on the then outstanding warrants. You may be unable to reinvest your proceeds from the call in an investment with a return that is as high as the return on the warrants would have been if they had not been called.

The warrants purchased in this offering do not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock.

Until you acquire shares of our common stock upon exercise of your warrants purchased in this offering, such warrants will not provide you any rights as a common stockholder, except as set forth in the warrants. Upon exercise of your warrants purchased in this offering, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

Because our management will have broad discretion and flexibility in how the net proceeds from this offering are used, our management may use the net proceeds in ways with which you disagree or which may not prove effective.

We currently intend to use the net proceeds from this offering as discussed under “Use of Proceeds” in this prospectus. We have not allocated specific amounts of the net proceeds from this offering for any of the foregoing purposes. Accordingly, our management will have significant discretion and flexibility in applying the net proceeds of this offering. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether

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the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the information incorporated by reference in it contain “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as “anticipate,” “intend,” “plan,” “goal,” “seek,” “believe,” “project,” “estimate,” “expect,” “strategy,” “future,” “likely,” “may,” “should,” “will” and similar references to future periods. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our businesses, financial condition and results of operations, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, you should not place undue reliance on any of these forward-looking statements. Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, but are not limited to, those listed below.

Without limiting the foregoing, all statements relating to our future outlook, anticipated capital expenditures, future cash flows and borrowings, and sources of funding are forward-looking statements. These forward-looking statements are based on numerous assumptions that we believe are reasonable, but they are open to a wide range of uncertainties and business risks and actual results may differ materially from those discussed in these statements.

Among the factors that could cause actual results to differ materially are:

- our limited history of operations;
- limited cash resources, uncertainty regarding future financing plans and need for substantial capital;
- our ability to accomplish clinical, regulatory and other product development milestones and to do so in accordance with the timing estimates we have publicly announced;
- an inability to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to market and sell our vBloc Rechargeable System;
- physicians may not widely adopt our vBloc Rechargeable System and vBloc Therapy;
- uncertainty regarding coverage or payment levels for our product by governmental healthcare programs and other third-party payors;
- issues with manufacturers and suppliers of various critical components of our vBloc Rechargeable System;
- unanticipated product problems;
- departures of key scientific or management personnel;
- uncertainty regarding approval from the regulatory body in any country other than the United States or the European Community;
- significant delays in completing our clinical trials;
- complications regarding third parties who manage our trials and perform related data collection and analysis;
- an inability to be successful in our efforts to utilize our vBloc Therapy to treat comorbidities associated with obesity and other gastrointestinal diseases and disorders;
- risks associated with international operations;

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- potential for product liability claims;
- uncertainty in the industry due to government healthcare reform;
- our ability to obtain a waiver from the holders of the Notes to the prohibition on the issuance of further securities for a period of one year after the First Closing;
- United States federal and state healthcare fraud and abuse and false claims laws and regulations; and
- our competitors ability to develop and market products that are safer or more effective than our products.

In some cases, you can identify forward-looking statements by terms such as “may,” “could,” “will,” “should,” “would,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “project” or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the heading “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements.

Any forward-looking statement in this prospectus reflects our current views with respect to future events and is subject to these and other risks, uncertainties and assumptions relating to our operations, results of operations, industry and future growth. Except as required by law, we assume no obligation to publicly update or revise any forward-looking statements contained in this prospectus, whether as a result of new information, future events or otherwise.

USE OF PROCEEDS

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

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

Absent this offering, 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.

CAPITALIZATION

The following table sets forth our unaudited actual cash and cash equivalents and our capitalization as of June 30, 2016 adjusted to give effect to the sale of the securities offered hereby and the use of proceeds, as described in the section entitled “Use of Proceeds.”

You should read this information in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes appearing in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2016, which is incorporated by reference into this prospectus.

	As of June 30, 2016 (in thousands, except share and per share data)	
	Actual	As Adjusted
Cash and cash equivalents	\$ 11,517,041	\$
Current portion of convertible notes payable (at fair value)	6,504,543	
Convertible notes payable, less current portion (net of discounts of \$102,450 at June 30, 2016)	7,830,458	
Common stock warrant liability	463,422	
Stockholders’ equity:		
Common stock, \$0.01 par value; 150,000,000 shares authorized at June 30, 2016; 13,223,069 shares issued and outstanding at June 30, 2016	132,231	
Additional paid-in capital	286,242,634	
Accumulated deficit	(289,984,465)	
Total stockholders’ (deficit) equity	(3,609,600)	

In the discussion and table above, we assume no exercise of outstanding options or warrants. The above discussion and table are based on 13,223,069 shares outstanding as of June 30, 2016 and excludes:

- 4,062,571 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2016 at a weighted average exercise price of \$4.12 per share;
- 664,242 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2016 at a weighted average exercise price of \$28.17 per share;
- 651,089 shares of our common stock reserved for future issuance under our Amended and Restated 2003 Stock Incentive Plan as of June 30, 2016; and
- shares of our common stock initially issuable upon the exercise of the warrants to be sold in this offering.

Market For Our Common Stock

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

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As of June 30, 2016, there were approximately 30 holders of record of our common stock and 13,223,069 shares of common stock outstanding. No dividends have been paid on our common stock to date, and we do not anticipate paying any dividends in the foreseeable future.

The following table sets forth the high and low sales prices of our common stock as quoted on the Nasdaq Capital Market for the periods indicated. These prices have been adjusted to reflect the 1-for-15 reverse split of our common stock that was effected after trading on January 6, 2016.

Price Range of Common Stock

	Price Range	
	High	Low
Fiscal 2014		
First Quarter	\$39.90	\$25.20
Second Quarter	\$32.55	\$21.15
Third Quarter	\$24.75	\$16.50
Fourth Quarter	\$22.05	\$14.85
Fiscal 2015		
First Quarter	\$30.75	\$13.65
Second Quarter	\$21.00	\$ 8.85
Third Quarter	\$ 9.90	\$ 3.00
Fourth Quarter	\$ 4.95	\$ 1.50
Fiscal 2016		
First Quarter	\$ 2.25	\$ 0.82
Second Quarter	\$ 1.24	\$ 0.27

The closing price for our common stock as reported by the Nasdaq Capital Market on September 19, 2016 was \$0.14 per share.

Dividend Policy

We have never paid cash dividends on our common stock. The board of directors presently intends to retain all earnings for use in our business and does not anticipate paying cash dividends in the foreseeable future. We do not have a dividend reinvestment plan or a direct stock purchase plan.

DILUTION

A purchaser of our securities in this offering will be diluted to the extent of the difference between the price per share of our common stock in this offering and the net tangible book value per share of our common stock after this offering. As of June 30, 2016, our historical net tangible book value was \$(3.6) million, or \$(0.27) per share of common stock, based on 13,223,069 shares of our common stock outstanding at June 30, 2016. Our historical net tangible book value per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of our common stock outstanding as of June 30, 2016.

After giving effect to our sale in this offering of _____ shares of common stock at a public offering price of \$ _____ per Unit and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our net tangible book value as of June 30, 2016 would have been \$ _____ million, or \$ _____ per share of our common stock. This amount represents an immediate increase of net tangible book value to our existing stockholders of \$ _____ per share and an immediate dilution of \$ _____ per share to the new investors purchasing securities in this offering. The following table illustrates this per share dilution:

Public offering price per Unit	\$
Historical net tangible book value per share at June 30, 2016	\$(0.27)
Increase per share attributable to investors purchasing securities in this offering	\$
Net tangible book value per share, as adjusted to give effect to this offering	\$
Dilution per share to investors in this offering	\$

The above discussion and table are based on 13,223,069 shares outstanding as of June 30, 2016 and excludes:

- 4,062,571 shares of common stock issuable upon the exercise of warrants outstanding as of June 30, 2016 at a weighted average exercise price of \$4.12 per share;
- 664,242 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2016 at a weighted average exercise price of \$28.17 per share;
- 651,089 shares of our common stock reserved for future issuance under our Amended and Restated 2003 Stock Incentive Plan as of June 30, 2016; and
- _____ shares of our common stock initially issuable upon the exercise of the warrants to be sold in this offering.

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

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table shows the beneficial ownership of our common stock by each person or group who beneficially owned 5% or more of our common stock, each of our directors, each of our executive officers, and our directors and executive officers as a group, as of August 31, 2016. Percentage ownership calculations for beneficial ownership are based on 57,129,000 shares outstanding as of August 31, 2016. The information regarding the beneficial owners of more than 5% of our common stock is based upon information supplied to us by our directors, officers and principal stockholders or on Schedules 13G filed with the SEC. Unless otherwise noted, the stockholders listed in the table have sole voting and investment power with respect to the shares of common stock owned by them and their address is c/o EnteroMedics Inc., 2800 Patton Road, St. Paul, Minnesota 55113.

Name of Beneficial Owner	Amount and Nature of Beneficial Ownership ⁽¹⁾	Percent of Class
Hudson Bay Capital Management L.P. ⁽³⁾⁽⁴⁾ 777 Third Avenue, 30th Floor New York, NY 10017	5,707,187	9.99%
CVI Investments, Inc. ⁽⁵⁾ P.O. Box 309GT Ugland House South Church Street George Town, Grand Cayman KY1-1104 Cayman Islands	5,707,187	9.99%
Dan W. Gladney	134,745	*
Greg S. Lea ⁽²⁾⁽³⁾	63,135	*
Scott A. Shikora, M.D. ⁽²⁾	4,895	*
Paul F. Hickey	—	*
Naqeeb (Nick) A. Ansari	—	*
Peter M. DeLange ⁽⁶⁾	27,544	*
Gary D. Blackford ⁽²⁾	487	*
Carl Goldfischer, M.D. ⁽²⁾⁽³⁾⁽⁷⁾	459,160	*
Bobby I. Griffin ⁽²⁾	13,150	*
Mark B. Knudson, Ph.D. ⁽²⁾⁽³⁾	307,221	*
Lori C. McDougal ⁽²⁾	2,015	*
Nicholas L. Teti, Jr. ⁽²⁾	11,016	*
Jon T. Tremmel ⁽²⁾	24,482	*
All directors and executive officers as a group (13 persons) ⁽⁸⁾	1,047,850	1.8%

* The percentage of shares of common stock beneficially owned does not exceed one percent of the outstanding shares of common stock.

- (1) For purposes of this table, a person or group of persons is deemed to have “beneficial ownership” of any shares of common stock which that person has the right to acquire within 60 days following August 31, 2016. For purposes of computing the percentage of outstanding shares of common stock held by each person or group of persons named above, any shares which that person or persons has or have the right to acquire within 60 days following August 31, 2016, is deemed to be outstanding, but is not deemed to be outstanding for the purpose of computing the percentage ownership of any other person.
- (2) Includes the following shares subject to options exercisable currently or within 60 days of August 31, 2016: Mr. Lea, 62,285 shares; Dr. Shikora, 4,895 shares; Mr. Blackford, 487 shares; Dr. Goldfischer, 7,665 shares; Mr. Griffin, 9,486 shares; Dr. Knudson, 260,542 shares; Ms. McDougal, 2,015 shares; Mr. Teti, 10,293 shares; and Mr. Tremmel 24,321 shares. Dr. Goldfischer has assigned the shares underlying his options to Bay City Capital Fund IV, L.P. and Bay City Capital Fund IV Co-Investment Fund, L.P. upon the exercise of these options.

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- (3) Includes the following shares subject to warrants exercisable currently or within 60 days of August 31, 2016: Mr. Lea, 666 shares; Dr. Goldfischer (see footnote (7)), 124,532 shares; and Dr. Knudson, 1,666 shares.
- (4) Based on information known to us or contained in a Schedule 13G filed with the SEC on February 8, 2016 by Hudson Bay Capital Management, L.P. (“Hudson Bay”). As of August 31, 2016, Hudson Bay has voting power and dispositive power of (i) 312,973 shares and (ii) shares issuable upon conversion of 7.0% senior convertible notes originally issued on January 11, 2016 and May 2, 2016, in the original principal amounts of \$3,520,000 and \$2,000,000, respectively (the “Hudson Bay Notes”). When issued, the Hudson Bay Notes were not convertible to the extent that the total number of shares then beneficially owned by a reporting person and its affiliates and any other persons whose beneficial ownership of shares would be aggregated with such reporting person for purposes of Section 13(d) of the Exchange Act of 1934, as amended (the “Exchange Act”), would exceed 4.99% (the “Maximum Percentage”). However, pursuant to a pre-existing right contained in the Hudson Bay Notes, on June 28, 2016, Hudson Bay instructed EnteroMedics to increase the Maximum Percentage from 4.99% to 9.99% effective 61 days following the date of the instruction (i.e., August 28, 2016). As of August 31, 2016, the Hudson Bay Notes were convertible within 60 days into 5,394,214 shares.
- (5) Based on information known to us or contained in a Schedule 13G jointly filed with the SEC on August 26, 2016 by CVI Investments, Inc. (“CVI”) and Heights Capital Management (“Heights”). As of August 31, 2016, CVI and Heights have shared voting power and shared dispositive power of (i) 804,850 shares and (ii) shares issuable upon conversion of 7.0% senior convertible notes originally issued on January 11, 2016 and May 2, 2016, in the original principal amounts of \$3,080,000 and \$1,750,000, respectively (the “CVI Notes”). When issued, the CVI Notes were not convertible to the extent that the total number of shares then beneficially owned by a reporting person and its affiliates and any other persons whose beneficial ownership of shares would be aggregated with such reporting person for purposes of Section 13(d) of the Exchange Act would exceed 4.99% (the “Maximum Percentage”). However, pursuant to a pre-existing right contained in the CVI Notes, on August 17, 2016, CVI instructed EnteroMedics to increase the Maximum Percentage from 4.99% to 9.99% effective 61 days following the date of the instruction (i.e., October 17, 2016). As of August 31, 2016, the CVI Notes were convertible within 60 days into 4,902,337 shares.
- (6) Consists of 27,373 shares owned by Mr. DeLange and 171 shares owned by Mr. DeLange’s son.
- (7) Based on information supplied to us or filed with the SEC by Bay City Capital LLC (“BCC”) on behalf of Bay City Capital Fund IV, L.P. (“Fund IV”), Bay City Capital Fund IV Co-Investment Fund, L.P. (“Co-Investment IV”) and Bay City Capital Management IV LLC (“Management IV”), each of which has shared voting power and shared dispositive power of 326,963 shares and 124,532 warrants. BCC is the manager of Management IV, which is the general partner of Fund IV and Co-Investment IV. BCC is also an advisor to Fund IV and Co-Investment IV. Carl Goldfischer, a Managing Director of BCC and a member of Management IV, is a member of our Board of Directors and has sole voting and dispositive power of 6,023 shares.
- (8) Includes 508,843 shares of common stock issuable upon exercise of options and warrants currently exercisable or exercisable within 60 days of August 31, 2016, inclusive of the options and warrants exercisable as described in footnotes (2) and (3), respectively.

DESCRIPTION OF SECURITIES

Description of Units

We are offering up to _____ Class A Units, with each Class A Unit consisting of two shares of common stock and a warrant to purchase one share of our common stock (together with the shares of common stock underlying such warrants) at a public offering price of \$ _____ per Class A Unit. Each warrant included in the Class A Units entitles its holder to purchase one share of Common Stock at an exercise price of \$ _____.

We are also offering to those purchasers, whose purchase of Class A Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering, the opportunity to purchase, in lieu of Class A Units that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, Class B Units, with each Class B Unit consisting of one share of Series A Preferred Stock, par value \$0.01 per share, convertible into a number of shares of common stock equal to \$ _____ divided by the Conversion Price and warrants to purchase a number of shares of common stock equal to \$ _____ divided by the Conversion Price (together with the shares of common stock underlying such warrants) at a public offering price of \$ _____ per Class B Unit. Each warrant included in the Class B Units entitles its holder to purchase one share of Common Stock at an exercise price of \$ _____ per share.

The securities of which the units are composed (the “underlying securities”) are being sold in this offering only as part of the units. However, the Class A Units and Class B Units will not be certificated and the underlying securities comprising such units are immediately separable. Each underlying security purchased in this offering will be issued independent of each other underlying security and not as part of a unit. Upon issuance, each underlying security may be transferred independent of any other underlying security, subject to applicable law and transfer restrictions.

Description of Warrants Included in the Units

The material terms and provisions of the warrants being offered pursuant to this prospectus are summarized below. This summary of some provisions of the warrants is not complete. For the complete terms of the warrants, you should refer to the form of warrant filed as an exhibit to the registration statement of which this prospectus is a part.

Pursuant to a warrant agency agreement between us and Wells Fargo Bank, National Association, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Each Class A Unit includes a warrant to purchase one share of our common stock at an exercise price of \$ _____ per share at any time for up to five years after the date of the closing of this offering. Each Class B Unit issued in this offering includes a warrant to purchase a number of shares of common stock equal to the \$ _____ divided by the Conversion Price at any time for up to five years after the date of the closing of this offering. The warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a warrant will not be deemed a holder of our underlying Common Stock until the warrant is exercised, except as set forth in the warrants.

Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder’s affiliates, and any persons acting as a group together with such holder or any of such holder’s affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the holder, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the “Beneficial Ownership Limitation”); provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the

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Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The warrant holders must pay the exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part, effective when the warrants are exercised.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the warrants will be entitled to receive upon exercise of the warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity shall assume the obligations under the warrants.

In the event of a fundamental transaction other than one in which a successor entity that is a publicly traded corporation whose stock is quoted or listed on a trading market assumes the warrant such that the warrant shall be exercisable for the publicly traded common stock of such successor entity, then the Company or any successor entity will pay at the holder's option, exercisable at any time concurrently with or within 30 days after the consummation of the fundamental transaction, an amount of cash equal to the value of the remaining unexercised portion of the warrants on the date of consummation of the fundamental transaction as determined in accordance with the Black Scholes option pricing model.

Upon the holder's exercise of a warrant, we will issue the shares of common stock issuable upon exercise of the warrant within three trading days following our receipt of a notice of exercise, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision).

Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Warrant holders may exercise warrants only if the issuance of the shares of common stock upon exercise of the warrants is covered by an effective registration statement, or an exemption from registration is available under the Securities Act and the securities laws of the state in which the holder resides. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part effective when the warrants are exercised. The warrant holders must pay the exercise price in cash upon exercise of the warrants unless there is not an effective registration statement or, if required, there is not an effective state law registration or exemption covering the issuance of the shares underlying the warrants (in which case, the warrants may only be exercised via a "cashless" exercise provision).

If a warrant is exercised via the "cashless" exercise provision, the holder will receive the number of shares equal to the quotient obtained by dividing (i) the difference between the VWAP (as determined pursuant to the terms of the warrants) and the exercise price of the warrant multiplied by the number of shares issuable under the warrant by (ii) the VWAP.

The warrants are callable by us in certain circumstances. Subject to certain exceptions, in the event that the warrants are outstanding and following the _____ year anniversary of the closing date, (i) the volume weighted

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average price of our common stock for each of _____ consecutive trading days (the “Measurement Period”) exceeds _____ % of the initial Exercise Price (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds \$ _____ per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company, then we may, within one trading day of the end of such Measurement Period, upon notice (a “Call Notice”), call for cancellation of all or any portion of the warrants for which a notice of exercise has not yet been delivered (a “Call”) for consideration equal to \$0.01 per share. Any portion of a warrant subject to such Call Notice for which a notice of exercise shall not have been received by the Call Date (as hereinafter defined) will be canceled at 6:30 p.m. (New York City time) on the tenth trading day after the date the Call Notice is sent by the Company (such date and time, the “Call Date”). Our right to call the warrants shall be exercised ratably among the holders based on the outstanding warrants.

We intend to apply to list the warrants on the Nasdaq Capital Market under the symbol “ETRMW”.

Description of Capital Stock

We are authorized to issue 150,000,000 shares of common stock, \$0.01 par value per share, and 5,000,000 shares of preferred stock, \$0.01 par value per share. As of August 31, 2016, there were 57,129,000 shares of common stock outstanding, which were held of record by approximately 30 stockholders, no shares of preferred stock outstanding, 896,667 common stock options outstanding and 4,062,571 common stock warrants outstanding. The following description summarizes the most important terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description you should refer to our Certificate of Incorporation and Bylaws, copies of which have been incorporated by reference herein, and to the applicable provisions of the Delaware General Corporation Law.

Common Stock

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote can elect all of the directors standing for election. Subject to preferences that may be applicable to any outstanding shares of preferred stock, holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available for dividend payments. All outstanding shares of our common stock are fully paid and nonassessable, and the shares of our common stock to be sold pursuant to this prospectus will be fully paid and nonassessable. The holders of common stock have no preferences or rights of conversion, exchange, pre-emption or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. In the event of any liquidation, dissolution or winding-up of our affairs, holders of our common stock will be entitled to share ratably in our assets that are remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock, if any.

Preferred Stock

The preferred stock, if issued, would have priority over our common stock with respect to dividends and other distributions, including the distribution of assets upon liquidation. Our board of directors has the authority, without further stockholder authorization, to issue from time to time shares of preferred stock in one or more series and to fix the terms, limitations, relative rights and preferences and variations of each series. Although we have no present plans to issue any shares of preferred stock, the issuance of shares of preferred stock, or the issuance of rights to purchase such shares, could decrease the amount of earnings and assets available for distribution to the holders of common stock, could adversely affect the rights and powers, including voting rights, of the common stock, and could have the effect of delaying, deterring or preventing a change in control of us or an unsolicited acquisition proposal.

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Series A Preferred Stock. Our board of directors has designated _____ shares of our preferred stock as Series A Convertible Preferred Stock (“Series A Preferred Stock”), none of which are currently issued and outstanding. The preferences and rights of the Series A Preferred Stock will be as set forth in a Certificate of Designation (the “Series A Certificate of Designation”) filed as an exhibit to the registration statement of which this prospectus is a part.

Pursuant to a transfer agency agreement between us and American Stock Transfer & Trust Company, LLC, as transfer agent, the Series A Preferred Stock will be issued in book-entry form and shall initially be represented only by one or more global certificates deposited with The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

In the event of a liquidation, the holders of Series A Preferred Shares are entitled to participate on an as-converted-to-Common Stock basis with holders of the Common Stock in any distribution of assets of the Company to the holders of the Common Stock. The Series A Certificate of Designation provides, among other things, that we shall not pay any dividends on shares of Common Stock (other than dividends in the form of Common Stock) unless and until such time as we pay dividends on each Series A Preferred Share on an as-converted basis. Other than as set forth in the previous sentence, the Series A Certificate of Designation provides that no other dividends shall be paid on Series A Preferred Shares and that we shall pay no dividends (other than dividends in the form of common stock) on shares of common stock unless we simultaneously comply with the previous sentence. The Series A Certificate of Designation does not provide for any restriction on the repurchase of Series A Preferred Shares by us while there is any arrearage in the payment of dividends on the Series A Preferred Shares. There are no sinking fund provisions applicable to the Series A Preferred Shares.

With certain exceptions, as described in the Series A Certificate of Designation, the Series A Preferred Shares have no voting rights. However, as long as any shares of Series A Preferred Shares remain outstanding, the Series A Certificate of Designation provides that we shall not, without the affirmative vote of holders of a majority of the then-outstanding Series A Preferred Shares, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Shares or alter or amend the Series A Certificate of Designation, (b) increase the number of authorized shares of Series A Preferred Shares or (c) effect a stock split or reverse stock split of the Series A Preferred Shares or any like event.

Each Series A Preferred Share is convertible at any time at the holder’s option into a number of shares of common stock equal to \$ _____ divided by the Series A Conversion Price. The “Series A Conversion Price” is initially \$ _____ and is subject to adjustment for stock splits, stock dividends, distributions, subdivisions and combinations. Notwithstanding the foregoing, the Series A Certificate of Designation further provides that we shall not effect any conversion of Series A Preferred Shares, with certain exceptions, to the extent that, after giving effect to an attempted conversion, the holder of Series A Preferred Shares (together with such holder’s affiliates, and any persons acting as a group together with such holder or any of such holder’s affiliates) would beneficially own a number of shares of Common Stock in excess of 4.99% (or, at the election of the holder, 9.99%) of the shares of our Common Stock then outstanding after giving effect to such exercise (the “Preferred Stock Beneficial Ownership Limitation”); provided, however, that upon notice to the Company, the holder may increase or decrease the Preferred Stock Beneficial Ownership Limitation, provided that in no event shall the Preferred Stock Beneficial Ownership Limitation exceed 9.99% and any increase in the Preferred Stock Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

Beginning on the third anniversary of the closing date of this offering, we will have the right to cause each holder of Series A Preferred Stock to convert all or part of such holder’s Series A Preferred Stock upon 20 calendar days prior written notice to such holder (which notice may be given by the transfer agent), subject to the Preferred Stock Beneficial Ownership Limitation. Such notice may not be given prior to the third anniversary of the closing date of this offering and shall be given in accordance with any applicable procedures of the depository for the Series A Preferred Stock.

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Additionally, subject to certain exceptions, at any time prior to the _____ year anniversary of the issuance of the Series A Preferred Stock, subject to the Preferred Stock Beneficial Ownership Limitation, we will have the right to cause each holder of the Series A Preferred Stock to convert all or part of such holder's Series A Preferred Stock in the event that (i) the volume weighted average price of our common stock for _____ consecutive trading days (the "Measurement Period") exceeds _____ % of the exercise price of the warrants (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds \$ _____ per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company and subject to the Preferred Beneficial Ownership Limitation. Our right to cause each holder of the Series A Preferred Stock to convert all or part of such holder's Series A Preferred Stock shall be exercised ratably among the holders of the then outstanding preferred stock.

We do not intend to apply for listing of the Series A Preferred Shares on any securities exchange or other trading system.

Warrants

As of August 31, 2016, there were warrants outstanding to purchase a total of 4,062,571 shares of our common stock, which expire between September 28, 2016 and April 16, 2022. Each of these warrants entitles the holder to purchase one share of common stock at prices ranging from \$0.16 to \$58.50 per common share, with a weighted average exercise price of \$4.07 per share. Certain of these warrants have a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants contain a provision requiring a reduction to the exercise price in the event we issue common stock, or securities convertible into or exercisable for common stock, at a price per share lower than the warrant exercise price.

The holders of certain of these warrants have registration rights that are outlined below under the heading "Registration Rights."

Effects of Anti-Takeover Provisions of Our Certificate of Incorporation, Our Bylaws and Delaware Law

The provisions of (1) Delaware law, (2) our Certificate of Incorporation and (3) our Bylaws discussed below could discourage or make it more difficult to prevail in a proxy contest or effect other change in our management or the acquisition of control by a holder of a substantial amount of our voting stock. It is possible that these provisions could make it more difficult to accomplish, or could deter, transactions that stockholders may otherwise consider to be in their best interests or our best interests. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change in control of our company. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. These provisions also are intended to discourage certain tactics that may be used in proxy fights. These provisions also may have the effect of preventing changes in our management.

Delaware Statutory Business Combinations Provision. We are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a "business

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combination” is defined broadly to include a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and, subject to certain exceptions, an “interested stockholder” is a person who, together with his or her affiliates and associates, owns (or within three years prior, did own) 15% or more of the corporation’s voting stock.

Classified Board of Directors; Appointment of Directors to Fill Vacancies; Removal of Directors for Cause. Our Certificate of Incorporation provides that our board of directors will be divided into three classes as nearly equal in number as possible. Each year the stockholders will elect the members of one of the three classes to a three-year term of office. All directors elected to our classified board of directors will serve until the election and qualification of their respective successors or their earlier resignation or removal. The board of directors is authorized to create new directorships and to fill any positions so created and is permitted to specify the class to which any new position is assigned. The person filling any of these positions would serve for the term applicable to that class. The board of directors (or its remaining members, even if less than a quorum) is also empowered to fill vacancies on the board of directors occurring for any reason for the remainder of the term of the class of directors in which the vacancy occurred. Members of the board of directors may only be removed for cause and only by the affirmative vote of holders of a majority of our outstanding voting stock. These provisions are likely to increase the time required for stockholders to change the composition of the board of directors. For example, in general, at least two annual meetings will be necessary for stockholders to effect a change in a majority of the members of the board of directors.

Advance Notice Provisions for Stockholder Proposals and Stockholder Nominations of Directors. Our Bylaws provide that, for nominations to the board of directors or for other business to be properly brought by a stockholder before a meeting of stockholders, the stockholder must first have given timely notice of the proposal in writing to our Secretary. For an annual meeting, a stockholder’s notice generally must be delivered not less than 90 days nor more than 120 days prior to the anniversary of the mailing date of the proxy statement for the previous year’s annual meeting. For a special meeting, the notice must generally be delivered no less than ten days following the day on which public announcement of the meeting is first made. Detailed requirements as to the form of the notice and information required in the notice are specified in our Bylaws. If it is determined that business was not properly brought before a meeting in accordance with our bylaw provisions, this business will not be conducted at the meeting.

Special Meetings of Stockholders. Special meetings of the stockholders may be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors.

No Stockholder Action by Written Consent. Our Certificate of Incorporation does not permit our stockholders to act by written consent. As a result, any action to be effected by our stockholders must be effected at a duly called annual or special meeting of the stockholders.

Transfer Agent and Registrar

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

Listing

Our common stock trades on the Nasdaq Capital Market under the symbol “ETRM.”

UNDERWRITING

We have entered into an underwriting agreement dated _____, 2016 with Ladenburg Thalmann & Co. Inc., as the representative of the underwriters (the “representative”) named below and the sole book-running manager of this offering. Subject to the terms and conditions of the underwriting agreement, the underwriters have agreed to purchase the number of our securities set forth opposite its name below.

<u>Underwriter</u>	<u>Class A Units</u>	<u>Class B Units</u>
Ladenburg Thalmann & Co. Inc.		
Total		

A copy of the underwriting agreement will be filed as an exhibit to the registration statement of which this prospectus is part.

We have been advised by the underwriters that they propose to offer the units directly to the public at the public offering price set forth on the cover page of this prospectus. Any securities sold by the underwriters to securities dealers will be sold at the public offering price less a selling concession not in excess of \$ _____ per share. The underwriters may allow and these selected dealers may re-allow a concession of not more than \$ _____ per share to other brokers and dealers.

The underwriting agreement provides that the underwriters’ obligation to purchase the securities we are offering is subject to conditions contained in the underwriting agreement.

No action has been taken by us or the underwriters that would permit a public offering of the units, or the shares, of common stock, shares of preferred stock and warrants included in the units, in any jurisdiction outside the United States where action for that purpose is required. None of our securities included in this offering may be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sales of any of the securities offering hereby be distributed or published in any jurisdiction except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons who receive this prospectus are advised to inform themselves about and to observe any restrictions relating to this offering of securities and the distribution of this prospectus. This prospectus is neither an offer to sell nor a solicitation of any offer to buy the securities in any jurisdiction where that would not be permitted or legal.

The underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Underwriting Discount and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

	<u>Per Class A Unit(1)</u>	<u>Per Class B Unit(1)</u>	<u>Total</u>
Public offering price			
Underwriting discount to be paid to the underwriters by us (_____ %)(2)			
Proceeds to us (before expenses)			

- (1) The public offering price and underwriting discount corresponds to (x) in respect of the Class A Units (i) a public offering price per share of common stock of \$ _____ and (ii) a public offering price per warrant of \$ _____ and (y) in respect of the Class B Units (i) a public offering price per share of Series A Preferred Stock of \$ _____ and (ii) a public offering price per warrant of \$ _____.
- (2) We have granted a 45 day option to the underwriter to purchase up to an additional shares of common stock (up to 15% of the shares of common stock plus the number of shares of common stock issuable upon _____).

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conversion of shares of Series A Preferred Stock) and/or up to an additional _____ warrants exercisable for up to an additional _____ shares of common stock (up to 15% of the warrants sold in this offering) at the public offering price per share of common stock and the public offering price per warrant set forth above less the underwriting discounts and commissions solely to cover over-allotments, if any.

We estimate the total expenses payable by us for this offering to be approximately \$ _____ which amount includes (i) the underwriting discount of \$ _____ (if the underwriters' over-allotment option is exercised in full) and (ii) reimbursement of the accountable expenses of the representative equal to \$130,000 including the legal fees of the representative being paid by us and (iii) other estimated company expenses of approximately \$ _____ which includes legal accounting printing costs and various fees associated with the registration and listing of our shares.

The securities we are offering are being offered by the underwriters subject to certain conditions specified in the underwriting agreement.

Over-allotment Option

We have granted to the underwriters an option exercisable not later than 45 days after the date of this prospectus to purchase up to a number of additional shares of common stock and/or warrants equal to 15% of the number of shares of common stock sold in the primary offering (including the number of shares of common stock issuable upon conversion of shares of Series A Preferred Stock but excluding any shares of common stock underlying the warrants issued in this offering and any shares of common stock issued upon any exercise of the underwriter's over-allotment option) and/or 15% of the warrants sold in the primary offering at the public offering price per share of common stock and the public offering price per warrant set forth on the cover page hereto less the underwriting discounts and commissions. The underwriters may exercise the option solely to cover over-allotments, if any, made in connection with this offering. If any additional shares of common stock, the underwriters will offer these shares of common stock on the same terms as those on which the other securities are being offered.

Determination of Offering Price

Our Common stock is currently traded on the Nasdaq Capital Market under the symbol "ETRM." On _____, 2016 the closing price of our common stock was \$ _____ per share. We intend to apply to list the warrants on the Nasdaq Capital Market under the symbol "ETRMW". We do not intend to apply for listing of the Series A Preferred Stock on any securities exchange or other trading system.

The public offering price of the securities offered by this prospectus will be determined by negotiation between us and the underwriters among the factors considered in determining the public offering price of the shares were;

- our history and our prospects;
- the industry in which we operate;
- our past and present operating results;
- the previous experience of our executive officers; and
- the general condition of the securities markets at the time of this offering.

The offering price stated on the cover page of this prospectus should not be considered an indication of the actual value of the shares of common stock sold in this offering. That price is subject to change as a result of market conditions and other factors and we cannot assure you that the shares of common stock sold in this offering can be resold at or above the public offering price.

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Lock-up Agreements

Our officers, directors and each of their respective affiliates and associated partners have agreed with the representative to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. We have also agreed, in the underwriting agreement, to similar lock-up restrictions on the issuance and sale of our securities for 90 days following the closing of this offering, although we will be permitted to issue stock options or stock awards to directors, officers and employees under our existing plans. The lock-up period is subject to an additional extension to accommodate for our reports of financial results or material news releases. The representative may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Other Relationships

Upon completion of this offering, we have granted the representative a right of first refusal to act as sole bookrunner or exclusive placement agent in connection with any subsequent public or private offering of equity securities or other capital markets financing by us. This right of first refusal extends for 12 months from the closing date of this offering. The terms of any such engagement of the representative will be determined by separate agreement.

Transfer Agent and Registrar

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

Stabilization, Short Positions and Penalty Bids

The underwriters may engage in syndicate covering transactions stabilizing transactions and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of our common stock;

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. Such a naked short position would be closed out by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the securities in the open market after pricing that could adversely affect investors who purchase in the offering.
- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specific maximum.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the securities originally sold by the syndicate member are purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These syndicate covering transactions, stabilizing transactions, and penalty bids may have the effect of raising or maintaining the market prices of our securities or preventing or retarding a decline in the market prices of our securities. As a result the price of our common stock may be higher than the price that might otherwise exist in the open market. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on the Nasdaq Capital Market, in the over-the-counter market or on any other trading market and, if commenced, may be discontinued at any time.

In connection with this offering, the underwriters also may engage in passive market making transactions in our common stock in accordance with Regulation M during a period before the commencement of offers or sales of

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shares of our common stock in this offering and extending through the completion of the distribution. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specific purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

Neither we, nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the prices of our securities. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transactions, once commenced will not be discontinued without notice.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including certain liabilities arising under the Securities Act or to contribute to payments that the underwriters may be required to make for these liabilities.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of material U.S. federal income considerations relating to the purchase, ownership and disposition of our common stock, Series A Preferred Stock or warrants. This discussion is based on current provisions of the Internal Revenue Code of 1986 (the “Internal Revenue Code”), existing and proposed U.S. Treasury Regulations promulgated or proposed thereunder and current administrative and judicial interpretations thereof, all as in effect as of the date of this prospectus and all of which are subject to change or to differing interpretation, possibly with retroactive effect. We have not sought and will not seek any rulings from the Internal Revenue Service (the “IRS”) regarding the matters discussed below. There can be no assurance that the IRS or a court will not take a contrary position.

This discussion is limited to U.S. holders and non-U.S. holders who hold our common stock, Series A Preferred Stock or warrants as capital assets within the meaning of Section 1221 of the Internal Revenue Code (generally, as property held for investment). This discussion does not address all aspects of U.S. federal income taxation, such as the U.S. alternative minimum income tax and the additional tax on net investment income, nor does it address any aspect of state, local or non-U.S. taxes, or U.S. federal taxes other than income taxes, such as federal estate taxes. This discussion does not consider any specific facts or circumstances that may apply to a holder and does not address the special tax considerations that may be applicable to particular holders, such as:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- controlled foreign corporations;
- passive foreign investment companies;
- corporations that accumulate earnings to avoid U.S. federal income tax;
- certain U.S. expatriates;
- persons that have a “functional currency” other than the U.S. dollar;
- persons that acquire our common stock as compensation for services;
- owners that hold our common stock, Series A Preferred Stock or warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- partnerships or other entities treated as partnerships for U.S. federal income tax purposes.

If any entity taxable as a partnership for U.S. federal income tax purposes holds our common stock, Series A Preferred Stock or warrants, the U.S. federal income tax treatment of a partner in the partnership generally will depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. A partner in a partnership or other transparent entity that holds our common stock, Series A Preferred Stock or warrants should consult his, her or its own tax advisor regarding the applicable tax consequences.

For purposes of this discussion, the term “U.S. holder” means a beneficial owner of our common stock, Series A Preferred Stock or warrants that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized in or under the laws of the United States or of any political subdivision of the United States;

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- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

A “non-U.S. holder” is a beneficial owner of our common stock, Series A Preferred Stock or warrants that is not a U.S. holder.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of purchasing, holding and disposing of our common stock, Series A Preferred Stock or warrants.

U.S. Holders

Purchase of Units

For U.S. federal income tax purposes, the purchase of a Class A Unit will be treated as the purchase of two components: a component consisting of two shares of our common stock and a component consisting of one warrant to purchase one share of our common stock. The purchase of a Class B Unit will be treated as the purchase of two components: a component consisting of one share of our Series A Preferred Stock and a component consisting of warrants to purchase a number of shares of our common stock equal to \$ _____ divided by the Conversion Price. The purchase price for each Unit will be allocated between its components in proportion to the relative fair market value of each at the time the Unit is purchased by the holder. This allocation of the purchase price for each Unit will establish a holder’s initial tax basis for U.S. federal income tax purposes in the shares and warrants that compose each Unit.

Exercise of Warrants

A U.S. holder generally will not recognize gain or loss on the exercise of a warrant and related receipt of shares of our common stock (unless cash is received in lieu of the issuance of a fractional share of our common stock). A U.S. holder’s initial tax basis in the shares of our common stock received upon the exercise of a warrant will be equal to the sum of (a) such U.S. holder’s tax basis in such warrant plus (b) the exercise price paid by such U.S. holder on the exercise of such warrant. A U.S. holder’s holding period for the shares of our common stock received upon the exercise of a warrant will begin on the day after the date that the warrant is exercised.

In certain limited circumstances, a U.S. holder may be permitted to undertake a cashless exercise of warrants into shares of our common stock. The U.S. federal income tax treatment of a cashless exercise of warrants into shares of common stock is unclear, and the tax consequences of a cashless exercise could differ from the consequences upon the exercise of a warrant described in the preceding paragraph. U.S. holders should consult their own tax advisors regarding the U.S. federal income tax consequences of a cashless exercise of warrants.

Certain Adjustments to the Warrants or Series A Preferred Stock

An adjustment to the number of shares of our common stock that will be issued upon the exercise of a warrant or conversion of a share of Series A Preferred Stock, or an adjustment to the exercise price of a warrant, may be treated as a constructive distribution to a U.S. holder of the warrant or share depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to our shareholders). Adjustments to the exercise price of warrants or conversion price of Series A Preferred Stock made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holders thereof generally should not be considered to result in a constructive distribution. Any such constructive distribution would be taxable whether or not there is an actual distribution of cash or other property. See the more detailed discussion of the rules applicable to distributions made by us under the heading “Distributions on Common Stock or Series A Preferred Stock” below.

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Expiration of the Warrants without Exercise

Upon the lapse or expiration of a warrant, a U.S. holder will recognize a loss in an amount equal to such U.S. holder's tax basis in the warrant. Any such loss generally will be a capital loss and will be long-term capital loss if the warrant is held for more than one year. Deductions for capital losses are subject to significant limitations.

Conversion of Series A Preferred Stock

A U.S. holder generally will not recognize gain or loss upon the conversion of a share of Series A Preferred Stock into common stock. A U.S. holder's initial tax basis in the shares of our common stock received upon the conversion of a share of Series A Preferred Stock will be equal to such U.S. holder's tax basis in the share of Series A Preferred Stock. A U.S. holder's holding period for the shares of our common stock received upon the conversion of a share of Series A Preferred Stock will include the U.S. holder's holding period in such share of Series A Preferred Stock.

Distributions on Common Stock or Series A Preferred Stock

If we pay distributions of cash or property with respect to our common stock or Series A Preferred Stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants or Series A Preferred Stock"), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. 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 U.S. holder's investment, up to such holder's tax basis in its shares of our common stock or Series A Preferred Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition."

Gain on Sale, Exchange or Other Taxable Disposition

Upon the sale or other taxable disposition of common shares, Series A Preferred Stock or warrants, a U.S. holder generally will recognize capital gain or loss in an amount equal to the difference between (a) the amount of cash plus the fair market value of any property received and (b) such U.S. holder's tax basis in such common shares, Series A Preferred Stock or warrants sold or otherwise disposed of. Such gain or loss generally will be long-term capital gain or loss if, at the time of the sale or other disposition, the common shares, Series A Preferred Stock or warrants have been held by the U.S. holder for more than one year. Preferential tax rates may apply to long-term capital gain of a U.S. holder that is an individual, estate, or trust. Deductions for capital losses are subject to significant limitations.

Non-U.S. Holders

Distributions on Common Stock or Series A Preferred Stock

If we pay distributions of cash or property with respect to our common stock or Series A Preferred Stock (including constructive distributions as described above under the heading "Certain Adjustments to the Warrants or Series A Preferred Stock"), those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. 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-U.S. holder's investment, up to such holder's tax basis in its shares of our common stock or Series A Preferred Stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Sale, Exchange or Other Taxable Disposition." Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. In the case of any constructive distribution, it is possible that this

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tax would be withheld from any amount owed to the non-U.S. holder, including, but not limited to, distributions of cash, common stock or sales proceeds subsequently paid or credited to that holder. If we are unable to determine, at the time of payment of a distribution, whether the distribution will constitute a dividend, we may nonetheless choose to withhold any U.S. federal income tax on the distribution as permitted by U.S. Treasury Regulations.

Distributions that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States are generally not subject to the 30% withholding tax if the non-U.S. holder provides a properly executed IRS Form W-8ECI stating that the distributions are not subject to withholding because they are effectively connected with the non-U.S. holder's conduct of a trade or business in the United States. If a non-U.S. holder is engaged in a trade or business in the United States and the distribution is effectively connected with the conduct of that trade or business, the distribution will generally have the consequences described above for a U.S. holder (subject to any modification provided under an applicable income tax treaty). Any U.S. effectively connected income received by a non-U.S. holder that is treated as a corporation for U.S. federal income tax purposes may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate (or such lower rate as may be specified by an applicable income tax treaty).

A non-U.S. holder who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E, as applicable, and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty generally may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders should consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Gain on Sale, Exchange or Other Taxable Disposition

Subject to the discussion below in "—Information Reporting and Backup Withholding" and "—Foreign Account Tax Compliance Act," a non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a sale, exchange or other taxable disposition of our common stock, Series A Preferred Stock or warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the regular graduated rates and in the manner applicable to a U.S. holder, and, if the non-U.S. holder is a corporation, an additional branch profits tax at a rate of 30%, or a lower rate as may be specified by an applicable income tax treaty, may also apply;
- the non-U.S. holder is an individual 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-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the amount by which such non-U.S. holder's capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition; or
- we are or were a "U.S. real property holding corporation" during the shorter of the five-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" (within the meaning of the Internal Revenue Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. We believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes.

Information Reporting and Backup Withholding

Distributions on, and the payment of the proceeds of a disposition of, our common stock, Series A Preferred Stock or warrants generally will be subject to information reporting if made within the United States or through certain U.S.-related financial intermediaries. Information returns are required to be filed with the IRS and copies of information returns may be made available to the tax authorities of the country in which a holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding may also apply if the holder fails to provide certification of exempt status or a correct U.S. taxpayer identification number and otherwise comply with the applicable backup withholding requirements. Generally, a holder will not be subject to backup withholding if it provides a properly completed and executed IRS Form W-9 or appropriate IRS Form W-8, as applicable. Backup withholding is not an additional tax. Amounts withheld under the backup withholding rules may be refunded or credited against the holder's U.S. federal income tax liability, if any, provided certain information is timely filed with the IRS.

Foreign Account Tax Compliance Act

Legislation commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on payments to certain non-U.S. entities (including certain intermediaries) unless such persons comply with FATCA's information reporting and withholding regime. This regime and its requirements are different from, and in addition to, the certification requirements described elsewhere in this discussion. The FATCA withholding rules apply to dividend payments and, in the case of certain sales or other dispositions occurring after December 31, 2018 (including a distribution to the extent it is treated as a return of capital or capital gain), the gross proceeds of such disposition.

The United States has entered into, and continues to negotiate, intergovernmental agreements (each, an "IGA") with a number of other jurisdictions to facilitate the implementation of FATCA. An IGA may significantly alter the application of FATCA and its information reporting and withholding requirements with respect to any particular investor. FATCA is particularly complex and its application remains uncertain. Prospective investors should consult their own tax advisors regarding how these rules may apply in their particular circumstances.

LEGAL MATTERS

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

EXPERTS

The consolidated financial statements incorporated in this prospectus by reference from our Annual Report on Form 10-K for the year ended December 31, 2015, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report which is incorporated herein by reference. Such financial statements have been so incorporated in reliance upon that report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

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

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. When used in this prospectus, the term "registration statement" includes amendments to the registration statement as well as the exhibits, schedules, financial statements and notes filed as part of the registration statement. This prospectus, which constitutes a part of the registration statement, does not contain all of the information in the registration statement. This prospectus omits information contained in the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and the common stock offered by this prospectus, reference is made to the registration statement. Statements herein concerning the contents of any contract or other document are not necessarily complete and in each instance reference is made to the copy of such contract or other document filed with the SEC as an exhibit to the registration statement, each such statement being qualified by and subject to such reference in all respects.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference the information we file with them. This allows us to disclose important information to you by referencing those filed documents. We have previously filed the following documents with the SEC and are incorporating them by reference into this prospectus:

- The Company's Annual Report on Form 10-K for the year ended December 31, 2015;
- The Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2016 and June 30, 2016;
- The Company's Current Reports on Form 8-K filed with the SEC on January 8, 2016; January 13, 2016; January 22, 2016; February 3, 2016; May 6, 2016 (excluding Item 2.02); May 10, 2016; May 13, 2016; June 28, 2016; July 6, 2016; July 15, 2016; July 20, 2016; August 17, 2016; and September 12, 2016; and
- the description of our common stock contained in any registration statement on Form 8-A that we have filed, and any amendment or report filed for the purpose of updating this description.

We also are incorporating by reference any future information filed (rather than furnished) by us with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, after the date of the initial filing of the registration statement of which this prospectus is a part and before the effective date of the registration statement and after the date of this prospectus until the termination of the offering. The most recent information that we file with the SEC automatically updates and supersedes more dated information.

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You can obtain a copy of any documents which are incorporated by reference in this prospectus or prospectus supplement, except for exhibits which are specifically incorporated by reference into those documents, at no cost, by writing or telephoning us at:

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

PART II.**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 13. Other Expenses of Issuance and Distribution**

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

SEC registration fee	\$
Legal fees and expenses	
Printing expenses	
Accountants’ fees and expenses	
Transfer agent and registrar fees	
Blue sky fees and expenses	
Miscellaneous expenses	
Total	\$

Item 14. Indemnification of Directors and Officers

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

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

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

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

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

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

Item 16. Exhibits and Financial Statement Schedules

Exhibit Number	Description of Document
1.1*	Form of Underwriting Agreement.
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-3 filed on May 9, 2014 (File No. 333-195855)).
3.2	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 8, 2016 (File No. 1-33818)).
3.3	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation. (Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on January 8, 2016 (File No. 1-33818)).
3.4	Amended and Restated Bylaws of the Company, as currently in effect. (Incorporated herein by reference to Exhibit 3.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).
4.1*	Form of Certificate of Designation of Series A Preferred Stock.
4.2*	Form of Series A Preferred Stock Certificate.
4.3*	Form of Warrant to purchase shares of Common Stock.

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<u>Exhibit Number</u>	<u>Description of Document</u>
5.1*	Opinion of Dorsey & Whitney LLP.
23.1**	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Dorsey & Whitney LLP (included in Exhibit 5.1).
24.1**	Power of Attorney (included on signature page to this registration statement).

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

** Filed herewith.

Item 17. Undertakings

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

The undersigned registrant hereby undertakes that:

(i) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

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

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of St. Paul, State of Minnesota, on September 20, 2016.

ENTEROMEDICS INC.

By: /s/ Dan W. Gladney
Dan W. Gladney, Ph.D.
President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Dan W. Gladney and Greg S. Lea, and each of them, his true and lawful attorneys-in-fact and agents, each acting alone, with the powers of substitution and revocation, for him and in his name, place and stead, in any and all capacities, to sign a Registration Statement on Form S-1, and any and all amendments (including post-effective amendments or any registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933) thereto, relating to the offer and sale by EnteroMedics Inc. of equity securities of the Company, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto such attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming that all such attorneys-in-fact and agents or any of them, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Dan W. Gladney</u> Dan W. Gladney	President and Chief Executive Officer and Director (principal executive officer)	September 20, 2016
<u>/s/ Greg S. Lea</u> Greg S. Lea	Chief Financial Officer and Chief Compliance Officer (principal financial and accounting officer)	September 20, 2016
<u>/s/ Mark B. Knudson, Ph.D.</u> Mark B. Knudson, Ph.D.	Chairman of the Board	September 20, 2016
<u>/s/ Gary D. Blackford</u> Gary D. Blackford	Director	September 20, 2016
<u>/s/ Carl Goldfischer, M.D.</u> Carl Goldfischer, M.D.	Director	September 20, 2016
<u>/s/ Bobby I. Griffin</u> Bobby I. Griffin	Director	September 20, 2016

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<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Lori C. McDougal</u> Lori C. McDougal	Director	September 20, 2016
<u>/s/ Nicholas L. Teti, Jr.</u> Nicholas L. Teti, Jr.	Director	September 20, 2016
<u>/s/ Jon T. Tremmel</u> Jon T. Tremmel	Director	September 20, 2016

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in this Registration Statement on Form S-1 of our report dated March 28, 2016, relating to the consolidated financial statements of EnteroMedics Inc. and subsidiary (the "Company"), appearing in the Annual Report on Form 10-K of the Company for the year ended December 31, 2015, and to the reference to us under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Deloitte & Touche LLP

Minneapolis, Minnesota

September 20, 2016
