ENTEROMEDICS INC

FORM 10-K
(Annual Report)

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	ST PAUL, MN 55113
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☑ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2016
Commission file number: 1-33818

ENTEROMEDICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**48-1293684**
(State or other jurisdiction of incorporation)	**(IRS Employer Identification No.)**

2800 Patton Road, St. Paul, Minnesota 55113
(Address of principal executive offices, including zip code)
(651) 634-3003
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Class	Name of Exchange on which Registered
Common stock, $0.01 par value per share	**The NASDAQ Capital Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

At June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant, based upon the closing price of a share of the registrant's common stock as reported by the NASDAQ Capital Market on that date was $3,672,097.

As of February 28, 2017, 6,873,878 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Specified portions of the registrant's Definitive Proxy Statement, which will be filed with the Commission pursuant to Regulation 14A in connection with the registrant's 2017 Annual Meeting of Stockholders, to be held May 3, 2017 (the Proxy Statement), are incorporated by reference into Part III of this report. Except with respect to information specifically incorporated by reference in this report, the Proxy Statement is not deemed to be filed as a part hereof.

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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 Annual Report on Form 10-K contains other trade names and trademarks and service marks of EnteroMedics and of other companies.

PART I.

ITEM 1. *BUSINESS*

This Annual Report on Form 10-K contains forward-looking statements. These forward-looking statements are based on our current expectations about our business and industry. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "could," "intends," "might," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue," or the negative of such terms and other comparable terminology. These statements involve known and unknown risks and uncertainties that may cause our results, levels of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among others, those discussed in this report in Item 1A "Risk Factors." Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Our Company

We are a medical device company with approvals to commercially launch our product, the vBloc Neuromodulation System (vBloc System). We are 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 a limited operating history and only recently received U.S. Food and Drug Administration (FDA) approval to sell our product in the United States. In addition, we have regulatory approval to sell our product in the European Economic Area and other countries that recognize the European CE Mark and do not have any other source of revenue. We were incorporated in Minnesota on December 19, 2002 and later reincorporated in Delaware on July 22, 2004. We have devoted substantially all of our resources to the development and commercialization of the vBloc System, which was formerly known as the Maestro or vBloc Rechargeable System.

The vBloc 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 System offers obese patients a minimally-invasive treatment that can result in significant, durable and sustained weight loss. We believe that our vBloc 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.

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc System, for the treatment of adult patients with obesity who have a Body Mass Index (BMI) of at least 40 to 45 kg/m2, or a BMI of at least 35 to 39.9 kg/m2 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. In 2015 we began a controlled commercial launch at select surgical centers in the United States and had our first commercial sales. During 2015, we initiated a controlled expansion of our commercial operations and started the process of building a sales force. In January 2016, we hired new executives to oversee this expansion. Our direct sales force is supported by field clinical engineers who provide training, technical and other support services to our customers. Throughout 2016, our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven surgical centers that met our certification criteria. Additionally, in 2016, through a distribution agreement with Academy Medical, LLC, U.S. Department of Veterans Affairs (VA) medical facilities now offer the vBloc System as a treatment option for veterans at little to no cost to veterans in accordance with their veteran healthcare benefits. We plan to build on these efforts in 2017 with self-pay and veteran focused direct-to-patient marketing, key opinion leader and center-specific partnering, and a multi-faceted reimbursement strategy. 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 System.

In 2016, we sold 62 units for $787,000 in revenue, and in 2015 we sold 24 units for $292,000 in revenue. We have incurred and expect to continue to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. Additionally, our selling, general and administrative expenses have increased since we commenced commercial operations, and we expect that they will continue to increase as we continue to build the infrastructure necessary to support our expanding commercial sales, operate as a public company and develop our

intellectual property portfolio. For these reasons, we expect to continue to incur operating losses for the next several years. We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on cash investments.

Data from our ReCharge trial was used to support the premarket approval (PMA) application for the vBloc System, submitted to the FDA in June 2013. The ReCharge trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial testing the effectiveness and safety of vBloc Therapy utilizing our vBloc System. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or sham control groups. The sham control group received a non-functional device during the trial period. All patients were expected to participate in a standard weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. As announced, the ReCharge trial met its primary safety endpoint with a 3.7% serious adverse event rate. The safety profile at 12 months was further supported by positive cardiovascular signals including a 5.5 mmHg drop in systolic blood pressure, a 2.8 mmHg drop in diastolic blood pressure and a 3.6 bpm drop in average heart rate.

Additionally, the trial demonstrated in the intent to treat (ITT) population (n=239) a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% (approximately 10% total body weight loss (TBL)) for vBloc Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL, although it did not meet its co-primary efficacy endpoints due to higher than expected weight loss levels in the sham control group. In the per protocol population, the trial demonstrated an EWL of 26.3% for vBloc Therapy-treated patients, with 56.8% of patients achieving at least 20% EWL. We subsequently announced that vBloc Therapy-treated patients were maintaining their weight loss at 18 months and 24 months with an EWL of 23.5% and 21.1%, respectively. The trial's positive safety profile also continued throughout this reported time period.

In the ReCharge trial, two-thirds of vBloc Therapy-treated patients achieved at least 5% TBL at 12 months. According to the Centers for Disease Control and Prevention (CDC), 5% TBL can have significant health benefits on obesity related risk factors, or comorbidities, including reduction in blood pressure, improvements in Type 2 diabetes and reductions in triglycerides and cholesterol. Further analysis of our data at 12 months showed a meaningful impact on these comorbidities as noted in the below table showing the improvements seen at 10% TBL, the average weight loss in vBloc Therapy-treated patients.

Risk Factor	10% TBL
Systolic BP (mmHg)	(9)
Diastolic BP (mmHg)	(6)
Heart Rate (bpm)	(6)
Total Cholesterol (mg/dL)	(15)
LDL (mg/dL)	(9)
Triglycerides (mg/dL)	(41)
HDL (mg/dL)	3
Waist Circumference (inches)	(7)
HbA1c (%)	(0.5)

We obtained European CE Mark approval for our vBloc System in 2011 for the treatment of obesity. The CE Mark approval for our vBloc System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. Additionally, the final vBloc System components were previously listed on the Australian Register of Therapeutic Goods by the Therapeutic Goods Administration. The costs and resources required to successfully commercialize the vBloc System internationally are currently beyond our capability. Accordingly, we will continue 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 System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates.

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 VBLOC-DM2 ENABLE trial 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.

Enrollment of the VBLOC-DM2 ENABLE trial began in 2008. The VBLOC-DM2 ENABLE trial is designed to evaluate the efficacy and safety of vBloc Therapy on obese subjects as well as its effect on glucose regulation in approximately 30 patients who are using the vBloc System. The trial is an international, open-label, prospective, multi-center study. At each designated trial endpoint the efficacy of vBloc Therapy is evaluated by measuring average percentage EWL, HbA1c (blood sugar), FPG (fasting plasma glucose), blood pressure, calorie intake, appetite and other endpoints at one week, one month, three, six, 12 and 18 months and longer. The following results were reported at 12 month intervals.

- Percent EWL (from implant, Company updated interim data):

Visit (post-device activation)	% EWL	N
12 Months	(24.5)	26
24 Months	(22.7)	22
36 Months	(24.3)	18

- HbA1c change in percentage points (Baseline HbA1c = 7.8 ± 0.2%) (Company updated interim data):

Visit (post-device activation)	% HbA1c change	N
12 Months	(1)	26
24 Months	(0.5)	24
36 Months	(0.6)	17

- Fasting Plasma Glucose change (Baseline 151.4 + 6.5 mg/dl average) (Company updated interim data):

Visit (post-device activation)	Glucose change (mg/dl)	N
12 Months	(27.6)	25
24 Months	(20.3)	24
36 Months	(24)	17

- Change in mean arterial pressure (MAP) in hypertensive patients (baseline 99.5 mmHg) (Company updated interim data):

Visit (post-device activation)	MAP change (mmHg)	N
12 Months	(7.8)	14
24 Months	(7.5)	12
36 Months	(7.3)	10

To date, no deaths related to our device or unanticipated adverse device effects have been reported during the VBLOC-DM2 ENABLE trial and the safety profile is similar to that seen in the other vBloc trials.

Caloric Intake Sub-study: A sub-study, conducted as part of the VBLOC-DM2 ENABLE trial, evaluated 12-month satiety and calorie intake in 10 patients with Type 2 diabetes mellitus enrolled in the trial. Follow-up measures among patients enrolled in the sub-study included EWL, 7-day diet records assessed by a nutritionist, calorie calculations and visual analogue scale (VAS) questions to assess satiety by 7-day or 24-hour recall at the following time periods: baseline, 4 and 12 weeks and 6 and 12 months post device initiation. A validated program, Food Works™, was used to determine calorie and nutrition content. Results include:

- Mean EWL for the sub-study was 33 ± 5% ($p<0.001$) at 12 months;

- Calorie intake decreased by 45% ($p<0.001$), 48% ($p<0.001$), 38% ($p<0.001$) and 30% ($p=0.02$), at 4 and 12 weeks, 6 months and 12 months, respectively, from a baseline of 2,062 kcal/day; and

- VAS recall data, using a repeated measures analysis, documented fullness at the beginning of meals ($p=0.005$), less food consumption ($p=0.02$) and less hunger at the beginning of meal ($p=0.03$) corroborating the reduction in caloric intake.

Our Product

The vBloc 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 System offers obese patients a minimally-invasive treatment that can result in significant, durable and sustained weight loss. We believe that our vBloc System allows laproscopically trained 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 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 System is powered by an internal rechargeable battery. The vBloc System is implanted by a laproscopically trained surgeon using a procedure that is typically performed within 60-90 minutes as an outpatient procedure. The physician activates the vBloc System after implantation. vBloc Therapy is then delivered intermittently through the neuroregulator each day as scheduled (recommended during the patient's waking hours when food is consumed). 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.

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 payers 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.

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.

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.

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. 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 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 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 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 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 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 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 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 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 . Since we received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc System, we have begun a controlled commercial launch at select bariatric centers of excellence in the United States. We had our first commercial sales in 2015 and sold 62 units in 2016. 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 and 2016 our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven bariatric centers of excellence that met our certification criteria. Additionally, in 2016, through a distribution agreement with Academy Medical, VA medical facilities now offer the vBloc System as a treatment option to veteran healthcare benefits. We intend to continue to build on these efforts in 2017 through self-pay patient and veteran focused direct-to-patient marketing and key opinion leader and center specific partnering.

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 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 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, almost all the patients that purchased the vBloc 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 and veterans in 2017. Additionally, through our distribution agreement with Academy Medical, VA medical facilities now offer the the vBloc System as a treatment option for veterans at little to no cost to veterans in accordance with their veteran healthcare benefits.

We are working to obtain coverage for our product from the U.S. Centers for Medicare and Medicaid Services (CMS), Medicare Administrative Contractors (MACs), 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, Winthrop University Hospital, in 2016 and are in active discussions with other IDNs throughout the country.

Identify Appropriate Coding, Obtain Coverage and Payment for the vBloc System. While payers 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 payer support for vBloc Therapy. We are seeking specific and appropriate coding, coverage and payment for our vBloc System from private insurers and CMS. We plan to establish a market price for the vBloc System in the United States that is competitive with other available weight loss surgical procedures and 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 payers, other governmental and private insurance coverage currently varies by carrier and geographic location. We are actively working with major insurance carriers, local coverage entities and self-insured plans, as well as CMS, on obtaining 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, in the first quarter of 2016, we announced that the Winthrop Hospital System in New York, a significant IDN in the northeast, would cover our therapy for their employees. 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 System.

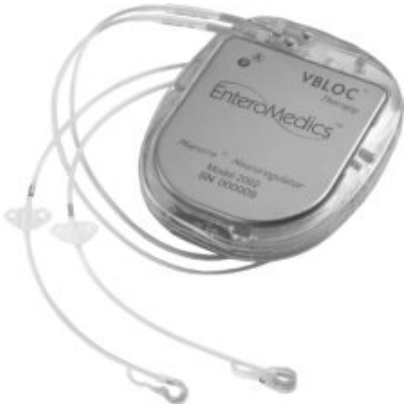
Expand and Protect Our Intellectual Property Position. We believe that our issued patents and our patent applications encompass a broad platform of neuromodulation therapies, including vagal blocking and combination therapy focused on obesity, diabetes, hypertension and other gastrointestinal disorders. 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 System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates. Specifically, we are currently evaluating Canada as a market due to its relatively low barrier to entry and an established cash-pay bariatric patient market.

The vBloc System, Implantation Procedure and Usage

The vBloc System . Our vBloc System delivers vBloc Therapy via two small electrodes that are laparoscopically implanted and placed in contact with the trunks of the vagus nerve just above the junction between the esophagus and the stomach, near the diaphragm. The vBloc System (shown below) is powered by an internal rechargeable battery.



The major components of the vBloc System include:

- ***Neuroregulator.*** The neuroregulator, a pacemaker-like device, is an implanted device that controls the delivery of vBloc Therapy to the vagus nerve. It is surgically implanted just below, and parallel to, the skin, typically on the side of the body over the ribs.

- ***Lead System.*** Proprietary leads are powered by the neuroregulator and deliver electrical pulses to the vagus nerve via the electrodes. The leads and electrodes are similar to those used in traditional cardiac rhythm management products.

- ***Mobile Charger.*** The mobile charger is an electronic device worn by the patient externally while recharging the device. It connects to the transmit coil and provides information on the battery status of the neuroregulator and the mobile charger.

- ***Transmit Coil.*** The transmit coil is positioned for short periods of time on top of the skin over the implanted neuroregulator to deliver radiofrequency battery charging and therapy programming information across the skin into the device.

- ***Clinician Programmer.*** The clinician programmer connects to the mobile charger to enable clinicians to customize therapy settings as necessary and retrieve reports stored in system components. The reports include patient use and system performance information used to manage therapy. The clinician programmer incorporates our proprietary software and is operated with a commercially available laptop computer.

Implantation Procedure . The vBloc System is implanted by a laproscopically trained surgeon using a procedure that is typically performed within 60-90 minutes. During the procedure, the surgeon laparoscopically implants the electrodes in contact with the vagal nerve trunks and then connects the lead wires to the neuroregulator, which is subcutaneously implanted. The implantation procedure and usage of the vBloc System carry some risks, such as the risks generally associated with laparoscopic procedures as well as the possibility of device malfunction. Adverse events related to the therapy, device or procedure may include, but are not limited to: transient pain at the implant site, heartburn, constipation, nausea, depression, diarrhea, infection, organ or nerve damage, surgical explant or revision, device movement, device malfunction and allergic reaction to the implant.

Usage of the vBloc System . The physician activates the vBloc System after implantation. vBloc Therapy is then delivered intermittently through the neuroregulator each day as scheduled (recommended during the patient's waking hours when food is consumed) 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. Although usage of our vBloc System generally proceeds without complications, as part of the therapy or intentional weight loss, patients in our clinical trials have observed side-effects such as transient pain at the implant site, heartburn, bloating, dysphagia, eructation, cramps, diarrhea, nausea, constipation, and excessive feelings of fullness, especially after meals. In addition, patient noncompliance with properly charging the vBloc System may render vBloc Therapy less effective in achieving long-term weight loss.

Our 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 EWL.

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

Findings from our clinical trials have resulted in publication in numerous peer-reviewed journals including The Journal of the American Medical Association, Journal of Obesity, Obesity Surgery, Surgery for Obesity and Related Diseases, Journal of Diabetes and Obesity, Surgery and Journal of Neural Engineering, and data have been presented at several scientific sessions including the American Society for Metabolic and Bariatric Surgery, International Federation for Surgery of Obesity and Metabolic Disorders, the Obesity Surgery Society of Australia & New Zealand and The Obesity Society.

Below is a more detailed description of our ongoing clinical studies:

ReCharge Trial

In October 2010, we received an unconditional Investigational Device Exemption (IDE) Supplement approval from the FDA to conduct a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial, called the ReCharge trial, testing the effectiveness and safety of vBloc Therapy utilizing our second generation vBloc System. Enrollment and implantation in the ReCharge trial was completed in December 2011 in 239 randomized patients (233

implanted) at 10 centers. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or control groups. The control group received a non-functional device during the trial period. All patients were expected to participate in a standard weight management counseling program. The primary endpoints of efficacy and safety were evaluated at 12 months. The ReCharge trial met its primary safety endpoint with a 3.7% serious adverse event rate, significantly lower than the threshold of 15% ($p<0.0001$). The safety profile at 12 months was further supported by positive cardiovascular signals including a 5.5 mmHg drop in systolic blood pressure, a 2.8 mmHg drop in diastolic blood pressure and a 3.6 bpm drop in average heart rate.

Although the trial did not meet its predefined co-primary efficacy endpoints, it did demonstrate in the ITT population (n=239) a clinically meaningful and statistically significant EWL of 24.4% (approximately 10% TBL) for vBloc Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. In the per protocol population, the trial demonstrated an EWL of 26.3% for vBloc Therapy-treated patients, with 56.8% of patients achieving at least 20% EWL. As a result of the positive safety and efficacy profile of vBloc Therapy, we used the data from the ReCharge trial to support a PMA application for the vBloc System, which was submitted to the FDA in June 2013 and was accepted for review and filing in July 2013. An Advisory Panel meeting was held on June 17, 2014 to review our PMA application for approval of the vBloc System. The Advisory Panel voted 8 to 1 “in favor” that the vBloc System is safe when used as designed and voted 4 to 5 “against” on the issue of a reasonable assurance of efficacy. The final vote, on whether the relative benefits outweighed the relative risk, was 6 to 2 “in favor,” with 1 abstention. We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc System, for the treatment of adult patients with obesity who have a BMI of at least 40 to 45 kg/m2, or a BMI of at least 35 to 39.9 kg/m2 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.

Further analysis of the 12 month data show that in the primary analysis (ITT) population (n=239), vBloc Therapy-treated patients achieved a 24.4% average EWL (approximately 10% TBL) compared to 15.9% for sham control patients. This 8.5% difference demonstrated statistical superiority over sham control ($p=0.002$), but not super-superiority at the pre-specified 10% margin ($p=0.705$). In total, 52.5% of vBloc Therapy-treated patients had 20% or more EWL compared to 32.5% in the control group ($p=0.004$), and 38.3% of vBloc Therapy-treated patients had 25% or more EWL compared to 23.4% in the sham control group ($p=0.02$). While the respective co-primary endpoint targets of 55% and 45% were not met, the endpoint targets were within the 95% confidence intervals for the observed rates and therefore the observed rates were not significantly lower than these pre-specified rates. These efficacy data demonstrate vBloc Therapy’s positive effect on weight loss.

In the per protocol group, which included only those patients who received therapy per the trial design (n=211), the vBloc Therapy-treated patients had a 26.3% average EWL (approximately 10% TBL) compared to 17.3% for the sham control group ($p=0.003$). In total, 56.8% of vBloc Therapy-treated patients achieved at least 20% EWL, which was above the predefined threshold of 55% compared to 35.4% in the sham control group ($p=0.004$). 41.8% of vBloc Therapy-treated patients also achieved at least 25% EWL in this population, which is slightly less than the predefined threshold of 45%, compared to 26.2% in the sham control group ($p=0.03$).

Additionally, two-thirds of vBloc Therapy-treated patients achieved at least 5% TBL at 12 months. According to the CDC, 5% TBL can have significant health benefits on obesity related risk factors, or comorbidities, including reduction in blood pressure, improvements in Type 2 diabetes and reductions in triglycerides and cholesterol. Further analysis of our data at 12 months showed a meaningful impact on these comorbidities as noted in the below table showing the improvements seen at 10% TBL, the average weight loss in vBloc Therapy-treated patients.

Risk Factor	10% TBL
Systolic BP (mmHg)	(9)
Diastolic BP (mmHg)	(6)
Heart Rate (bpm)	(6)
Total Cholesterol (mg/dL)	(15)
LDL (mg/dL)	(9)
Triglycerides (mg/dL)	(41)
HDL (mg/dL)	3
Waist Circumference (inches)	(7)
HbA1c (%)	(0.5)

Approximately 93% of patients reached the 12 month assessment in the trial, consistent with a rigorously executed trial. vBloc Therapy-treated patients maintained their weight loss at 18 months and 24 months with an EWL of 23.5% and 21.1%, respectively. The trial's positive safety profile also continued throughout this reported time period.

VBLOC-DM2 ENABLE Trial

Enrollment of the VBLOC-DM2 ENABLE trial began in 2008. The VBLOC-DM2 ENABLE trial is designed to evaluate the efficacy and safety of vBloc Therapy on obese subjects as well as its effect on glucose regulation in approximately 30 patients who are using the vBloc System. The trial is an international, open-label, prospective, multi-center study. At each designated trial endpoint the efficacy of vBloc Therapy is evaluated by measuring average percentage EWL, HbA1c (blood sugar), FPG (fasting plasma glucose), blood pressure, calorie intake, appetite and other endpoints at one week, one month, three, six, 12 and 18 months and longer. The following results were reported at 12 month intervals.

- Percent EWL (from implant, Company updated interim data):

Visit (post-device activation)	% EWL	N
12 Months	(24.5)	26
24 Months	(22.7)	22
36 Months	(24.3)	18

- HbA1c change in percentage points (Baseline HbA1c = 7.8 $\pm$ 0.2%) (Company updated interim data):

Visit (post-device activation)	% HbA1c change	N
12 Months	(1)	26
24 Months	(0.5)	24
36 Months	(0.6)	17

- Fasting Plasma Glucose change (Baseline 151.4 + 6.5 mg/dl average) (Company updated interim data):

Visit (post-device activation)	Glucose change (mg/dl)	N
12 Months	(27.6)	25
24 Months	(20.3)	24
36 Months	(24)	17

- Change in mean arterial pressure (MAP) in hypertensive patients (baseline 99.5 mmHg) (Company updated interim data):

Visit (post-device activation)	MAP change (mmHg)	N
12 Months	(7.8)	14
24 Months	(7.5)	12
36 Months	(7.3)	10

To date, no deaths related to our device or unanticipated adverse device effects have been reported during the VBLOC-DM2 ENABLE trial and the safety profile is similar to that seen in the other vBloc trials.

Caloric Intake Sub-study: A sub-study, conducted as part of the VBLOC-DM2 ENABLE trial, evaluated 12-month satiety and calorie intake in 10 patients with Type 2 diabetes mellitus enrolled in the trial. Follow-up measures among patients enrolled in the sub-study included EWL, 7-day diet records assessed by a nutritionist, calorie calculations and visual analogue scale (VAS) questions to assess satiety by 7-day or 24-hour recall at the following time

periods: baseline, 4 and 12 weeks and 6 and 12 months post device initiation. A validated program, Food Works™, was used to determine calorie and nutrition content. Results include:

- Mean EWL for the sub-study was 33 ± 5% ($p<0.001$) at 12 months;
- Calorie intake decreased by 45% ($p<0.001$), 48% ($p<0.001$), 38% ($p<0.001$) and 30% ($p=0.02$), at 4 and 12 weeks, 6 months and 12 months, respectively, from a baseline of 2,062 kcal/day; and
- VAS recall data, using a repeated measures analysis, documented fullness at the beginning of meals ($p=0.005$), less food consumption ($p=0.02$) and less hunger at the beginning of meal ($p=0.03$) corroborating the reduction in caloric intake.

EMPOWER Trial

The EMPOWER trial is a randomized, double-blind, controlled pivotal study that began in 2006 and was designed to evaluate the safety and efficacy of our first-generation vBloc RF System in the treatment of obesity in 294 patients. The purpose of the EMPOWER trial is to measure the safety and efficacy of our vBloc RF System in obese patients after 12 months of vBloc Therapy. After all patients completed 12 months of follow up, the trial was unblinded and all patients, including those in the control group, had the option to receive ongoing vBloc Therapy. Patients will continue to be followed out to 60 months as part of the trial and we will continue to monitor average percentage EWL and safety during this extended period. At 12 months from implant, patients in the treated group who used the system for greater than or equal to 12 hours a day saw an average EWL of nearly 30%. The trial produced the following safety results:

- No deaths, a one-year surgical revision rate of 4.8% and serious adverse event rate related to the device or implant/revision procedure of 3%;
- No therapy-related serious adverse events in the entire study population through 12 months; and
- No changes in intra-cardiac conduction, ventricular repolarization or ventricular arrhythmias were seen in either study group.

At the 36 month endpoint, EMPOWER EWL was approximately 20% in 45 subjects receiving at least 9 hours of therapy per day. In addition, a subgroup analysis of EMPOWER trial patients was conducted to determine if vBloc Therapy would improve blood pressure prior to significant weight loss in obese subjects with hypertension, as defined by elevated blood pressure at baseline by JNC-7 guidelines (n=37, Group A) or history of hypertension (n=58, Group B) at baseline. The analysis was performed in a subset of subjects receiving at least 9 hours of therapy per day to 12 months.

- Change in systolic blood pressure (SBP) and diastolic blood pressure (DBP) from baseline:

	Baseline	Week 2	Week 4	12 Months
Group A (subjects with elevated blood pressure) ($p<0.001$)				
SBP (mmHg)	145+/-2	-17+/-3	-17+/-3	(18+/(3)
DBP (mmHg)	89+/-2	-9+/-2	-8+/-2	(10+/(2)
% EWL	N/A	9+/-2	12+/-1	21+/-4
Group B (subjects with history of hypertension) ($p<0.001$)				
SBP (mmHg)	134+/-2	-10+/-2	-9+/-2	(13+/(2)
DBP (mmHg)	84+/-1	-6+/-1	-6+/-1	(7+/(1)
% EWL	NA	9+/-1	13+/-1	23+/-3

Our Research and Development

Current R&D Focus

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

- supporting the current vBloc System;
- developing the next-generation vBloc System;
- identifying the effect of vagal blocking on nerve and organ function; and
- investigating the vBloc platform for the treatment of gastrointestinal disorders and comorbidities in addition to obesity.

We have spent a significant portion of our capital resources on research and development. Our research and development expenses were $5.1 million in 2016, $8.1 million in 2015 and $11.0 million in 2014. Having obtained FDA approval in January 2015, our main focus has been on commercialization efforts, resulting in decreases in spending on research and development in each of 2015 and 2016 compared to 2014, when we were still working through the FDA approval process.

Other Diseases and Disorders

We believe that our vBloc Therapy may have the potential, if validated through appropriate clinical studies, to treat a number of additional gastrointestinal disorders or comorbidities frequently associated with obesity, including the following:

- ***Type 2 Diabetes.*** Type 2 diabetes is an escalating global health epidemic often related to obesity that affects nearly 200 million people worldwide, 50 million in the United States alone. Those with diabetes are susceptible to cardiovascular morbidity and mortality, and up to two out of three people with diabetes have high blood pressure. We believe that vBloc Therapy has significant potential in treating metabolic syndrome (diabetes with high blood pressure). We have launched an international feasibility trial, VBLOC-DM2 ENABLE, to further explore the efficacy of vBloc Therapy in this patient population and have reported preliminary findings in the "Our Clinical Experience" section above.

- ***Hypertension.*** Blood pressure normally rises and falls throughout the day. When it consistently stays too high for too long, it is called hypertension. Globally, nearly one billion people have high blood pressure (hypertension); of these, two-thirds are in developing countries. About one in three American adults has high blood pressure or hypertension. Hypertension is one of the most important causes of premature death worldwide and the problem is growing; in 2025, an estimated 1.56 billion adults will be living with hypertension. Hypertension kills nearly 8 million people every year worldwide. We believe that vBloc Therapy may improve mean systolic and diastolic blood pressure in hypertensive patients. We completed a subgroup analysis of EMPOWER trial patients and have included an evaluation of the blood pressure effects of vBloc Therapy in our international feasibility trial, VBLOC-DM2 ENABLE, to further explore the efficacy of vBloc Therapy in this patient population and have reported preliminary findings in the "Our Clinical Experience" section above.

- ***Pancreatitis.*** Primary and recurrent cases of acute pancreatitis are estimated to number from 150,000 to 200,000 annually, resulting in approximately 80,000 hospital admissions each year in the United States. In animal studies, we have shown that vBloc Therapy suppresses pancreatic exocrine secretion, suggesting its potential efficacy in treating pancreatitis.

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

None of the above conditions were included in our PMA application that was approved by the FDA on January 14, 2015, nor are they approved for sale internationally. Additional approvals will be required to market the vBloc System for these indications in the United States or internationally.

Medical Advisors

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

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

Our Competition

The market for obesity treatments is competitive, subject to technological change and significantly affected by new product development. Our primary competition in the obesity treatment market is currently from surgical obesity procedures and from various devices used to implement neurostimulation and gastric stimulation systems. We believe we are the first company having neuroblocking therapy for the treatment of obesity. There are currently no other FDA-approved neuromodulation or neuroblocking therapies for the treatment of obesity, but in the future we expect other new stimulation systems and neurotechnology devices to come on the market.

Balloon Band Sleeve Bypass

We expect our vBloc System will compete with surgical obesity procedures, including gastric bypass, gastric balloon, gastric banding and sleeve gastrectomy. These current surgical procedures are performed in less than 1% of all eligible obese patients today. Current manufacturers of approved gastric balloon and banding products include Apollo Endosurgery Inc. (Lap-Band and ORBERA Intragastric Balloon System), ReShape Medical, Inc. (ReShape Integrated Dual Balloon System), Obalon Therapeutics, Inc. (Obalon Balloon System) and Johnson & Johnson (Realize Adjustable Gastric Band).

In June of 2016, Aspire Bariatrics, Inc. received FDA approval on the Aspire Assist® System, an endoscopic alternative to weight loss surgery for people with moderate to severe obesity. We are also aware that GI Dynamics, Inc. has received approvals in various international countries to sell its EndoBarrier Gastrointestinal Liner.

We also compete against the manufacturers of pharmaceuticals that are directed at treating obesity and the 99% of obese patients eligible for surgery that are not willing to pursue a surgical option . We are aware of a number of drugs that are approved for long-term treatment of obesity in the United States: Orlistat, marketed by Roche as Xenical and GlaxoSmithKline as Alli, Belviq marketed by Arena Pharmaceuticals, Inc., Qsymia, marketed by VIVUS, Inc. and Contrave, marketed by Orexigen Therapeutics, Inc.

In addition to competition from surgical obesity procedures, we compete with several private early-stage companies developing neurostimulation devices for application to the gastric region and related nerves for the treatment of obesity. These companies may prove to be significant competitors, particularly through collaborative arrangements

with large and established companies. They also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

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

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

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

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

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payers;
- established distribution networks;
- greater experience in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals, obtaining reimbursement and marketing approved products; and
- greater financial and human resources.

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

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.

We also register the trademarks and trade names through which we conduct our business. To date, in the United States we have registered trademarks for vBLOC ®, ENTEROMEDICS ® and MAESTRO ®, each registered with the United States Patent and Trademark Office, and 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.

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

Our Manufacturers and Suppliers

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

Since we received FDA approval on January 14, 2015, and commenced commercialization of the vBloc System in the United States, we have increased our production volume slowly in connection with the controlled commercial launch of the vBloc System in the United States. Given that we rely primarily on third-party manufacturers and suppliers for the production of our products, our ability to increase production going forward will depend upon the experience, certification levels and large scale production capabilities of our suppliers and manufacturers. Qualified suppliers and contract manufacturers have been and will continue to be selected to supply products on a commercial scale according to our proprietary specifications. We have modestly increased our inventory levels to support commercial forecasts as we expand our implanting centers and intend to continue to increase our inventory levels as we determine necessary. Our FDA approval process required us to name and obtain approval for the suppliers of key components of our vBloc System.

Many of our parts are custom designed and as a result, we may not be able to quickly qualify and establish additional or replacement suppliers for the components of our vBloc System. Any new approvals of vendors required by the FDA or other regulatory agencies in other international markets for our vBloc System as a result of the need to qualify or obtain alternate vendors for any of our components would delay our ability to sell and market the vBloc System and could have a material adverse effect on our business.

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

Government Regulations

United States

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

Medical devices in the United States are classified into one of three classes, Class I, II or III, on the basis of the amount of risk and the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I, low risk, devices are subject to general controls (e.g., labeling and adherence to good manufacturing practices). Class II, intermediate risk, devices are subject to general controls and to special controls (e.g., performance standards, and premarket notification). Generally, Class III devices are those which must receive premarket approval by the FDA to ensure their safety and effectiveness (e.g., life-sustaining, life-supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices), and require clinical testing to ensure safety and effectiveness and FDA approval prior to marketing and distribution. The FDA also has the authority to require clinical testing of Class II devices. In both the United States and certain international markets, there have been a number of legislative and regulatory initiatives and changes, such as the Modernization Act, which could and have altered the healthcare system in ways that could impact our ability to sell our medical devices profitably.

The FFDCA provides two basic review procedures for medical devices. Certain products may qualify for a submission authorized by Section 510(k) of the FFDCA, where the manufacturer submits to the FDA a premarket notification of the manufacturer's intention to commence marketing the product. The manufacturer must, among other things, establish that the product to be marketed is substantially equivalent to another legally marketed product. Marketing may commence when the FDA issues a letter finding substantial equivalence. If a medical device does not qualify for the 510(k) procedure, the manufacturer must file a premarket approval (PMA) application with the FDA. This procedure requires more extensive pre-filing clinical and preclinical testing than the 510(k) procedure and involves a significantly longer FDA review process.

Premarket Approval

Our vBloc System is an implanted device that required PMA from the FDA to market in the United States. The FDA approved the vBloc System on January 14, 2015 with post-approval conditions intended to ensure the safety and effectiveness of the device. Failure to comply with the conditions of approval can result in material adverse enforcement action, including the loss or withdrawal of the approval. Even after approval of the PMA, new PMAs or supplemental PMAs will be required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the premarket approval process. Premarket approval supplements often require submission of the same type of information as a PMA except that the supplement is limited to information needed to support any

changes from the device covered by the original PMA. In addition, holders of an approved PMA are required to submit annual reports to the FDA that include relevant information on the continued use of the device.

Clinical Trials

A clinical trial is almost always required to support a PMA. Clinical trials for a "significant risk" device such as ours require submission to the FDA of an application for an IDE for clinical studies to be conducted within the United States. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device in the United States may begin once the IDE application is approved by the FDA and by the Institutional Review Boards (IRBs) overseeing the clinical trial at the various investigational sites.

Clinical trials require extensive recordkeeping and detailed reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for each participating clinical trial site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice requirements. We, the trial Data Safety Monitoring Board, the FDA or the IRB for each site at which a clinical trial is being performed may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Pervasive and Continuing U.S. Regulation

Numerous regulatory requirements apply. These include:

- Quality System Regulation, which requires manufacturers to follow design, testing, control, documentation, complaint handling and other quality assurance procedures during the design and manufacturing processes;
- regulations which govern product labels and labeling, prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling and promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- notices of correction or removal and recall regulations;
- periodic reporting of progress related to clinical trials, post approval studies required as conditions of PMA approval and relevant changes to information contained within the PMA approval; and
- reporting of transfers of value and payments to physicians and teaching hospitals.

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

Compliance with regulatory requirements is enforced through periodic facility inspections by the FDA, which may be unannounced. Because we rely on contract manufacturing sites and service providers, these additional sites are also subject to these FDA inspections. Failure to comply with applicable regulatory requirements can result in enforcement action, which may include any of the following sanctions:

- warning letters or untitled letters;
- fines, injunction and civil penalties;
- recall or seizure of our products;
- customer notification, or orders for repair, replacement or refund;

- operating restrictions, partial suspension or total shutdown of production or clinical trials;
- refusing our request for premarket approval of new products;
- withdrawing premarket approvals that are already granted; and
- criminal prosecution.

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ. The primary regulatory environment in Europe is that of the European Economic Community (EEC), which consists of 28 European Union (EU) member states encompassing nearly all the major countries in Europe. Additional countries that are not part of the EU, but are part of the European Economic Area (EEA), and other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the EEC with respect to medical devices. The EEC has adopted Directive 90/385/EEC as amended by 2007/47/EC for active implantable medical devices and numerous standards that govern and harmonize the national laws and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices that are marketed in member states. Medical devices that comply with the requirements of the national law of the member state in which their Notified Body is located will be entitled to bear CE marking, indicating that the device conforms to applicable regulatory requirements, and, accordingly, can be commercially marketed within the EEA and other countries that recognize this mark for regulatory purposes.

We obtained European CE Mark approval for our vBloc System in 2011 for the treatment of obesity. The CE Mark approval for our vBloc System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our vBloc System (which is considered an Active Implantable Medical Device (AIMD) in Australia and the EEA, and falls into Class III within the United States), the method involved a combination of self-assessment and issuance of declaration of conformity by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body of the design of the device and of our quality system. A Notified Body is a private commercial entity that is designated by the national government of a member state as being competent to make independent judgments about whether a product complies with applicable regulatory requirements. The assessment included, among other things, a clinical evaluation of the conformity of the device with applicable regulatory requirements. We use DEKRA Certification B.V. (formerly known as KEMA Quality) in the Netherlands as the Notified Body for our CE marking approval process.

Continued compliance with CE marking requirements is enforced through periodic facility inspections by the Notified Body, which may be unannounced. Because we rely on contract manufacturing sites and service providers, these additional sites may also be subject to these Notified Body inspections.

Patient Privacy Laws

United States and various international laws have been evolving to protect the confidentiality of certain patient health information, including patient medical records. These laws restrict the use and disclosure of certain patient health information. Enforcement actions, including financial penalties, related to patient privacy issues are globally increasing. The management of patient data may have an impact on certain clinical research activities and product design considerations.

Employees

As of December 31, 2016, we had a total of 32 employees. All of these employees are located in the United States.

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

Executive Officers

The following table sets forth information regarding our executive officers, including their ages, as of February 28, 2017:

Name	Age	Position
Dan W. Gladney	64	President and Chief Executive Officer
Scott P. Youngstrom	57	Chief Financial Officer and Chief Compliance Officer
Naqeeb (Nick) A. Ansari	55	Senior Vice President of Sales
Peter M. DeLange	48	Senior Vice President of Operations and Business Development
Paul F. Hickey	52	Senior Vice President of Marketing and Reimbursement

Dan W. Gladney has served as our President and Chief Executive Officer since November 16, 2015 and as Chairman of our board of directors since October 14, 2016. Mr. Gladney joined the Company on November 2, 2015 as President-Elect and a member of the board of directors. Prior to joining us, Mr. Gladney served as Chairman and Chief Executive Officer of Lanx, Inc., a medical device company focused on developing and commercializing innovative devices for spinal surgery. Prior to his time at Lanx, Inc., Mr. Gladney was a Healthcare Operating Partner at Norwest Equity Partners (NEP) from 2008 until 2010, where he was responsible for strategic planning, business growth and corporate governance for NEP portfolio companies and executing new investment opportunities for the firm. Prior to joining NEP, Mr. Gladney served as President and Chief Executive Officer of several medical device companies including Heart Leaflet Technologies and ACIST Medical Systems, both of which were acquired by The Bracco Group. He also served as Chairman, Chief Executive Officer and President of Complex Technologies, a publicly traded orthopedic and health and wellness electro therapy company, from 2002 until 2006. Mr. Gladney currently serves on the board of directors of ARIA CV, Inc. and has been a member of a number of other private and public company boards. After the sale of Lanx, he acted as a private investor and small business consultant.

Scott P. Youngstrom has served as our Chief Financial Officer and Chief Compliance Officer since October 3, 2016. Mr. Youngstrom has over 25 years of strategic financial and operational experience in a variety of medical device companies, most recently having served as Chief Financial Officer and Vice President, Finance at Galil Medical, a leading developer of cryotherapy technology. Prior to Galil Medical, from 2009-2014, Mr. Youngstrom served as Vice President, Chief Operating Officer, and Chief Financial Officer at DGIMED Ortho, Inc., a developer of orthopedic medical devices. Mr. Youngstrom has previously served as Chief Financial Officer and Vice President, Finance with Anulex Technologies, Enpath Medical, Compex Technologies, Acist Medical Systems, and Cardiotronics.

Naqeeb (Nick) A. Ansari has served as our Senior Vice President of Sales since January 6, 2016. Mr. Ansari has over 20 years of experience in the medical device industry, having held various senior sales positions at Stryker Corporation, DePuy, Medtronic, Inc., Lanx, Inc. and Globus Medical Inc. Prior to joining the Company he spent two years as the owner of an independent distributor solely selling Biomet products. Prior to this, he served as Senior Vice President of Sales at Lanx, Inc. from 2010 to 2013.

Peter M. DeLange has served as our Senior Vice President of Operations and Business Development since January 18, 2016. Mr. DeLange has spent the last 11 years as the owner and President of Devicix, LLC a medical device engineering development company that was sold in 2015. At Devicix, he contracted with large medical device companies and worked closely with individual surgeons to develop new technologies. Since 2011, Mr. DeLange has also served as a Co-Founder and Board Member of FocusStart LLC, an early stage technology development company utilizing a capital efficient business model to advance medical technology. Prior to Devicix, he held software engineer and product development positions at numerous companies including ACIST Medical Systems, Nellcor Puritan Bennett, Emerson EMC and Quester Technology.

Paul F. Hickey has served as our Senior Vice President of Marketing and Reimbursement since January 18, 2016. Mr. Hickey has over 15 years of experience as a medical device executive, most recently having served as Chief Executive Officer of Pantheon Spinal, a small spine implant start-up company based in Austin, Texas, since 2014. Prior to Pantheon, he spent three years as Senior Vice President, Global Commercialization at Lanx, Inc., which was acquired by Biomet Spine in 2013, where he oversaw marketing, clinical reimbursement and R&D. Mr. Hickey also spent 17

years at Zimmer-Spine where he held numerous marketing and developments positions, most recently as Vice President, Global R&D and Emerging Technology from 2004-2008.

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 October 2003, the two entities were combined and changed our name to EnteroMedics Inc. In 2004 we reincorporated in Delaware. We file reports and other information with the Securities and Exchange Commission (SEC) including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and proxy or information statements. Those reports and statements as well as all amendments to those documents filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (1) are available at the SEC's Public Reference Room at 100 F Street, N.E., Washington, DC 20549, (2) may be obtained by sending an electronic message to the SEC at *publicinfo@sec.gov* or by sending a fax to the SEC at 1-202-777-1027, (3) are available at the SEC's internet site (http://www.sec.gov), which contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC and (4) are available free of charge through our website as soon as reasonably practicable after electronic filing with, or furnishing to, the SEC. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

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 incorporated by reference into this Annual Report on Form 10-K and should not be considered a part of this Annual Report on Form 10-K.

ITEM 1A. *RISK FACTORS*

Risks Related to Our Business and Industry

We are a medical device company with a limited history of operations, no significant 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 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 Australia, 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 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 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 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, 2016, 2015 and 2014 was $23.4 million, $25.5 million and $26.1 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 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.

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 System and subsequent versions of our product. Cash used in operations was $20.6 million, $22.6 million and $19.4 million for the fiscal years ended December 31, 2016, 2015 and 2014, 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 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 System and any products that we may develop;
- the rate of market acceptance of our vBloc 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 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.

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

We 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 NASDAQ have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations result in increased legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act 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 .

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. The Patient Protection and Affordable Care Act, as amended, (the Affordable Care Act) as well as any future healthcare reform legislation, 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 January 2017, Congress voted in favor of a budget resolution that will produce legislation that would repeal certain aspects of the Affordable Care Act if enacted into law. Congress is also considering subsequent legislation to replace or repeal elements or all of the Affordable Care Act. In addition, there have been recent public announcements by members of Congress and the new presidential administration regarding their plans to repeal and replace the Affordable Care Act. Further, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. At this time, it is not clear whether the Affordable Care Act will be repealed in whole or in part, and, if it is repealed, whether it will be replaced in whole or in part by another plan. and what impact those changes will have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the Affordable Care Act. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and also indirectly affect the amounts that private payers are willing to pay. 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 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 System

Our efforts to commercialize our vBloc 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 System. Our efforts to commercialize this product may not succeed for a number of reasons, including:

- our vBloc System may not be accepted in the marketplace by physicians, patients and third-party payers;
- the price of our vBloc 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 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 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 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 System or to develop sales and marketing capabilities for our vBloc 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 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 payers, such as private healthcare insurers and governmental payers, 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 System in the United States, and had our first commercial sales within the United States in 2015. Previously, in 2012, we commenced commercial sales of our vBloc 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 System internationally. If we are not successful in the commercialization of our vBloc 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 System for the treatment of obesity.

We do not have the necessary regulatory approvals to market our vBloc System in any foreign market other than the European Economic Area for which we received CE Mark approval for our vBloc System in March 2011 for the treatment of obesity and other countries which accept these regulatory approvals. Additionally, the vBloc System was previously listed on the Australian Register of Therapeutic Goods (ARTG). The CE Mark approval for our vBloc System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. We commenced commercialization of our product in Australia and the Middle East in 2012, 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 System internationally.

In order to market our vBloc 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 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 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 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 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 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 System in a large number of patients have not been studied and the results of short-term clinical use of the vBloc System do not necessarily predict long-term clinical benefits or reveal long-term adverse effects.

Clinical trials conducted with the vBloc 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 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 System and impair our financial position.

We continue to evaluate the 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 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 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.

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 System may require additional approval from regulatory authorities, which may not be obtained or may delay our commercialization efforts.

The FDA 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 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 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 System and vBloc Therapy. We believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our vBloc 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 payers, there may be no commercially viable markets for our vBloc System or other products we may develop or our target markets may be much smaller than expected.

Healthcare providers generally rely on third-party payers, including governmental payers, 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 payers 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 payers 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 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 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 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 System and other products we may develop.

The efficacy, safety, ease of use and cost-effectiveness of our vBloc 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 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 payers 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 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 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 System could be subject to restrictions or withdrawal from the market.

Completion of our clinical trials and commercialization of our vBloc 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 System, and do not currently plan to manufacture or assemble our vBloc System ourselves in the future.

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by our European Notified Body and the FDA and other regulatory bodies. In particular we and our manufacturers and suppliers are required to comply with ISO requirements, Good Manufacturing Practices, 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, 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 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 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 System. The loss of any of these manufacturer or supplier relationships could prevent or delay commercialization of our vBloc System.

We rely entirely on third parties to manufacture our vBloc System and to supply us with all of the critical components of our vBloc 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 System could be interrupted for an extended period of time, which could delay completion of our clinical trials or commercialization of our vBloc 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 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 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 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 and have continued its development in 2016 and 2017. We 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 and we may be unable to develop an effective sales and marketing organization on a timely basis, if at all, or maintain our current sales and marketing capabilities, either of which would delay or prevent us from generating enough revenue to become profitable. 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 and maintain 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.

When we have sufficient resources to commercialize our vBloc 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 Device Technologies, a third-party distributor in Australia, to sell our product in Australia and 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 System. We have begun a controlled expansion of our operations and 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.

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 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 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 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 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 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 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.

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 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 February 28, 2017 our stock price has fluctuated from a low of $1.75 to a high of $67,851.00, as adjusted for the 1-for-70 reverse split of our common stock that was effected

after trading on December 27, 2016 and 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;
- 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
- 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 the listing requirements of the NASDAQ Stock Market could result in our common stock being delisted, which could affect its market price and liquidity and reduce our ability to raise capital.

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

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, 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.

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

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

- the ability of our board of directors to create and issue preferred stock without stockholder approval, which could be used to implement anti-takeover devices;
- the authority for our board of directors to issue without stockholder approval up to 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;
- 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. 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.

ITEM 1B. *UNRESOLVED STAFF COMMENTS*

Not applicable.

ITEM 2. *PROPERTIES*

We lease approximately 28,388 square feet of lab and office space in St. Paul, Minnesota. The original lease agreement began October 1, 2008 and was set to expire September 30, 2015. On August 25, 2015 we entered into an amendment extending the term of the lease for three years until September 30, 2018.

ITEM 3. *LEGAL PROCEEDINGS*

On February 28, 2017, we received a class action and derivative complaint filed on February 24, 2017 in U. S. District Court for the District of Delaware by Vinh Du, one of our shareholders. The complaint names as defendants EnteroMedics, our board of directors and four members of our senior management, namely, Scott Youngstrom, Nick Ansari, Peter DeLange and Paul Hickey, and contains a purported class action claim for breach of fiduciary duty against our board of directors and derivative claims for breach of fiduciary duty against our board of directors and unjust enrichment against our senior management. The allegations in the complaint relate to the increase in the number of shares authorized for grant under our Second Amended and Restated 2003 Stock Incentive Plan (the "Plan"), which was approved by our shareholders at the Special Meeting of Shareholders held on December 12, 2016 (the "Special Meeting"), and to our subsequent grant of stock options on February 8, 2017, to our Directors and senior management to purchase an aggregate of 1,093,450 shares of our common stock (the "Option Grants"). In the complaint, the plaintiff contends that (i) the number of shares authorized for grant under the Plan, as adjusted by our board of directors after the Special Meeting for the subsequent recapitalization of the Company, resulted from an alleged breach of fiduciary duties by the Board, and (ii) our senior management was allegedly unjustly enriched by the subsequent Option Grants. The plaintiff seeks relief in the form of an order rescinding the Plan as approved by the shareholders at the Special Meeting, an order cancelling the Option Grants, and an award to plaintiff for his costs, including fees and disbursements of

attorneys, experts and accountants. We believe the allegations in the complaint are without merit, and intend to defend the action vigorously.

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

ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

PART II.

ITEM 5. *MARKET FOR REGISTRANT'S COMMON EQUIT Y, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*

Market For Our Common Stock

Our common stock has been traded on the NASDAQ Stock Market under the symbol "ETRM" since our initial public offering (IPO) on November 15, 2007. Prior to that date, there was no public market for our common stock. Our 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.

As of February 28, 2017, there were approximately 37 holders of record of our common stock and 6,873,878 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 Stock Market for the periods indicated. These prices have been adjusted to reflect the 1-for-70 reverse split of our common stock that was effected after trading on December 27, 2016 and 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 2015		
First Quarter	$ 2,152.50	$ 955.50
Second Quarter	$ 1,470.00	$ 619.50
Third Quarter	$ 693.00	$ 210.00
Fourth Quarter	$ 346.50	$ 105.00
Fiscal 2016		
First Quarter	$ 157.50	$ 57.40
Second Quarter	$ 86.80	$ 18.90
Third Quarter	$ 31.50	$ 7.70
Fourth Quarter	$ 9.80	$ 1.95

The closing price for our common stock as reported by the NASDAQ Stock Market on February 28, 2017 was $6.36 per share.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item regarding equity compensation plans is incorporated by reference to the information set forth in Part III, Item 12 of this Annual Report on Form 10-K.

Unregistered Sales of Equity Securities

None.

Uses of Proceeds from Sale of Registered Securities

None.

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.

Issuer Purchases of Equity Securities

None.

ITEM 6. *SELECTED FINANCIAL DATA*

Not applicable.

ITEM 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS*

Except for the historical information contained herein, the matters discussed in this "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere in this Form 10-K are forward-looking statements that involve risks and uncertainties. The factors listed in Item 1A "Risk Factors," as well as any cautionary language in this Form 10-K, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from those projected. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.

Overview

We are a medical device company with approvals to commercially launch our product, the vBloc Neuromodulation System (vBloc System), in the United States, the European Economic Area and other countries that recognize the European CE Mark. We are 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 a limited operating history and only recently received U.S. Food and Drug Administration (FDA) approval to sell our product in the United States. In addition, we have regulatory approval to sell our product in the European Economic Area and other countries that recognize the European CE Mark and currently do not have any other source of revenue. We were incorporated in Minnesota on December 19, 2002 and later reincorporated in Delaware on July 22, 2004. We have devoted substantially all of our resources to the development and commercialization of the vBloc System, which was formerly known as the Maestro Rechargeable System.

The vBloc System 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 System offers obese patients a minimally-invasive treatment that can result in significant, durable and sustained weight loss. We believe that our vBloc 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.

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc System, for the treatment of adult patients with obesity who have a Body Mass Index (BMI) of at least 40 to 45 kg/m2, or a BMI of at least 35 to 39.9 kg/m2 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. In 2015 we began a controlled commercial launch at select surgical centers in the United States and had our first commercial sales. During 2015, we initiated a controlled expansion of our commercial operations and started the process of building a sales force. In January 2016, we hired new executives to oversee this expansion. Our direct sales force is supported by field clinical engineers who provide training, technical and other support services to our customers. Throughout 2016, our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven surgical centers that met our certification criteria. Additionally, in 2016, through a distribution agreement with Academy Medical, LLC, U.S. Department of Veterans Affairs (VA) medical facilities now offer the vBloc System as a treatment option to veterans using their veteran healthcare benefits. We plan to build on these efforts in 2017 with self-pay and veteran patient focused direct-to-patient marketing, key opinion leader and center specific partnering, and a multi-faceted reimbursement strategy. 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 System.

Recharge Trial

Data from our ReCharge trial was used to support the premarket approval (PMA) application for the vBloc System, submitted to the FDA in June 2013. The ReCharge trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial testing the effectiveness and safety of vBloc Therapy utilizing our vBloc System. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or sham control groups. The sham control group received a non-functional device during the trial period. All patients were expected to participate in a standard weight management counseling program. The primary endpoints of efficacy and safety were

evaluated at 12 months. As announced, the ReCharge trial met its primary safety endpoint with a 3.7% serious adverse event rate. The safety profile at 12 months was further supported by positive cardiovascular signals including a 5.5 mmHg drop in systolic blood pressure, a 2.8 mmHg drop in diastolic blood pressure and a 3.6 bpm drop in average heart rate.

Additionally, the trial demonstrated in the intent to treat (ITT) population (n=239) a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% (approximately 10% total body weight loss (TBL)) for vBloc Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL, although it did not meet its co-primary efficacy endpoints. In the per protocol population, the trial demonstrated an EWL of 26.3% for vBloc Therapy-treated patients, with 56.8% of patients achieving at least 20% EWL. We subsequently announced that vBloc Therapy-treated patients were maintaining their weight loss at 18 months and 24 months with an EWL of 23.5% and 21.1%, respectively. The trial's positive safety profile also continued throughout this reported time period. For more information on our Recharge Trial and our other ongoing clinical trials, please see Item 1, Business, " *Our Clinical Experience,"* in this Annual Report on Form 10-K for the Year Ended December 31, 2016.

We obtained European CE Mark approval for our vBloc System in 2011 for the treatment of obesity. The CE Mark approval for our vBloc System was expanded in 2014 to also include use for the management of Type 2 diabetes in obese patients. In January 2012, the final vBloc System components were listed on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA). The costs and resources required to successfully commercialize the vBloc System internationally are currently beyond our capability. Accordingly, we will continue 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 System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates.

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 VBLOC-DM2 ENABLE trial 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.

In 2016, we continued our commercialization efforts in the United States, deriving revenues from our primary business activity. We expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our selling, general and administrative expenses to increase as we continue to add the infrastructure necessary to support our commercial sales, operate as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur operating losses for the next several years. We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments.

During 2016, our board of directors and stockholders approved two reverse stock splits (collectively, the Reverse Stock Splits). Neither reverse stock split changed the par value of our common stock or the number of preferred shares authorized by our certificate of incorporation. The first reverse stock split was a 1-for-15 reverse split (the First Reverse Stock Split) of our outstanding common stock that became effective after trading on January 6, 2016. The First Reverse Stock Split also decreased the number of shares of common stock authorized by our certificate of incorporation proportionately, and proportional adjustments were also made to our outstanding stock options and warrants and the number of shares authorized under our Amended and Restated 2003 Stock Incentive Plan . In connection with the First Reverse Stock Split, an amendment to our certificate of incorporation was also approved to increase the number of shares of our common stock authorized for issuance to 150 million shares, effective immediately after the First Reverse Stock Split on January 6, 2016.

The second reverse stock split was a 1-for-70 reverse split (the Second Reverse Stock Split) of our outstanding common stock that became effective after trading on December 27, 2016 pursuant to our Sixth Amended and Restated Certificate of Incorporation, which was filed in connection with the Second Reverse Stock Split. In connection with the Second Reverse Stock Split, proportional adjustments were also made to our outstanding stock options and warrants. Additionally, in connection with the Second Reverse Stock Split, a second amendment was approved to increase the

number of shares of our common stock authorized for issuance to 300 million shares, effective after the Second Reverse Stock Split on December 27, 2016.

Critical Accounting Policies and Significant Judgments and Estimates

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

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, title or risk of loss has passed, the selling price is fixed or determinable and collection is reasonably assured. Products are sold through direct sales or medical device distributors and revenue is recognized upon sale to a bariatric center of excellence or a medical device distributor when no right of return or price protection exists. Terms of sales to international distributors are generally EXW, reflecting that goods are shipped "ex works," in which risk of loss is assumed by the distributor at the shipping point. A provision for returns is recorded only if product sales provide for a right of return. No provision for returns was recorded for the year ended December 31, 2016, as the product sales recorded did not provide for rights of return.

Inventory

From inception, inventory related purchases had been used for research and development related activities and had accordingly been expensed as incurred. In December 2011, we began receiving ARTG listings for components of the vBloc System from the Australian TGA, with the final components being listed on the ARTG in January 2012. As a result, we determined certain assets were recoverable as inventory beginning in December 2011 and have recorded a current inventory balance of $1,790,000 and $1,686,000 as of December 31, 2016 and 2015, respectively. We account for inventory at the lower of cost or market and record any long-term inventory as other assets in the consolidated balance sheets. There was $676,000 and $519,000 of long-term inventory as of December 31, 2016 and 2015, respectively.

Senior Amortizing Convertible Notes

The senior amortizing convertible notes issued on November 9, 2015, January 11, 2016 and May 2, 2016 (the Notes) included a conversion feature which requires bifurcation and liability classification and measurement, at fair value, and requires evaluation at each reporting period. Under Accounting Standards Codification (ASC) 825, Financial Instruments, the Financial Accounting Standards Board (FASB) provides an alternative to bifurcation and companies may instead elect fair value measurement for the entire instrument, including the debt and conversion feature. We have elected the fair value alternative in order to simplify our accounting and reporting of the senior amortizing convertible notes upon issuance. The fair value of these senior amortizing convertible notes is re-measured at each financial reporting period, with any changes in fair value being recognized as a component of other income (expense) in the consolidated statements of operations.

We concluded that the fair value of the Notes at issuance is equal to the gross proceeds received less the fair value of the warrants issued in conjunction with the Notes. Both at the date of issuance and during the years ended December 31, 2016 and 2015, a Binomial Lattice model was used to value the Notes. The fair value of the warrants was recorded as a discount to the Notes and amortized to interest expense following the effective interest rate method over the term of the Notes. During the year ended December 31, 2016, all remaining principal and interest amounts outstanding under the Notes were paid off, primarily via conversions to common shares.

Common Stock Warrant Liability

Common stock warrants that were issued in connection with the July 8, 2015 public offering (the Series A Warrants) and the Notes (the Note Warrants) are classified as a liability in the consolidated balance sheets, as the common stock warrants issued provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair value of these common stock warrants is re-measured at each financial reporting period and immediately before exercise, with any changes in fair value being recognized as a component of other income (expense) in the consolidated statements of operations.

The fair value of the Company's common stock warrant liability is calculated using a Black-Scholes valuation model and is classified as Level 2 in the fair value hierarchy. The fair values are presented below along with valuation assumptions

	Series A Warrants		November 2015 Note Warrants	
	December 31, 2016	July 8, 2015	December 31, 2016	November 9, 2015
Risk-free interest rates	1.20 %	0.91 %	1.47 %	1.75 %
Expected life	24 months	42 months	46 months	60 months
Expected dividends	— %	— %	—	— %
Expected volatility	122.03 %	89.89 %	102.29 %	84.85 %
Fair value	$ 36,000	$ 6,004,000	$ 449	$ 169,000

	January 2016 Note Warrants		May 2016 Note Warrants	
	December 31, 2016	January 11, 2016	December 31, 2016	May 2, 2016
Risk-free interest rates	1.93 %	1.58 %	1.93 %	1.32 %
Expected life	48 months	60 months	52 months	60 months
Expected dividends	— %	— %	— %	— %
Expected volatility	108.57 %	85.90 %	106.37 %	89.28 %
Fair value	$ 1,633	$ 515,157	$ 1,037	$ 150,195

Stock-Based Compensation

We account for share-based payments using the fair value method, which requires compensation expense to be recognized using a fair-value-based method for costs related to all share-based payments including stock options. Companies are required to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. Calculating stock-based compensation expense requires the input of highly subjective assumptions, which represent our best estimates and involve inherent uncertainties and the application of management's judgment. Estimates of stock-based compensation expenses are significant to our consolidated financial statements, but these expenses are based on the Black-Scholes pricing model and will never result in the payment of cash by us. All option grants are expensed on a straight-line basis over the vesting period.

The application of share-based payment principles may be subject to further interpretation and refinement over time. There are significant differences among option valuation models, and this may result in a lack of comparability with other companies that use different models, methods and assumptions. If factors change and we employ different assumptions in the application of share-based payment accounting in future periods, or if we decide to use a different valuation model, the compensation expense that we record in the future may differ significantly from what we have recorded in the current period and could materially affect our operating loss, net loss and net loss per share.

The fair value method is applied to all share-based payment awards issued to employees and where appropriate, nonemployees, unless another source of literature applies. When determining the measurement date of a nonemployee's share-based payment award, the Company measures the stock options at fair value and remeasures such stock options to the current fair value until the performance date has been reached. For stock options granted to nonemployees, the fair value of the stock options is estimated using the Black-Scholes valuation model. This model utilizes the estimated fair value of common stock and requires that, at the date of grant and each subsequent reporting period until the services are completed or a significant disincentive for nonperformance occurs, we make assumptions with respect to the expected term of the option, the volatility of the fair value of our common stock, risk free interest rates and expected dividend yields of our common stock. Different estimates of volatility and expected life of the option could materially change the value of an option and the resulting expense.

Net Operating Losses and Tax Credit Carryforwards

At December 31, 2016, we had federal net operating loss carryforwards of approximately $161.4 million. These net operating loss carryforwards will expire in varying amounts from 2022 through 2035, if not utilized. The Internal Revenue Code (IRC) imposes restrictions on the utilization of various carryforward tax attributes in the event of a change in ownership of the Company, as defined by IRC Section 382. In addition, IRC Section 382 may limit our built-in items of deduction, including capitalized start-up costs and research and development costs. During 2011, we completed an IRC Section 382 review and the results of this review indicate ownership changes have occurred which would cause a limitation on the utilization of carryforward attributes. Our gross net operating loss carryforwards, start-up costs and research and development credits are all subject to limitation. Under these tax provisions, the limitation is applied first to any built-in losses, then to any net operating losses and then to any general business credits. It is likely that ownership changes have occurred since we completed our IRC Section 382 review in 2011 and could result in further limitations on the utilization of carryforward attributes. A valuation allowance has been established to reserve for the potential benefits of the remaining carryforwards and tax credits in our consolidated financial statements to reflect the uncertainty of future taxable income required to utilize available tax loss carryforwards and other deferred tax assets.

Financial Overview

Revenue

We received FDA approval on January 14, 2015 for vBloc Therapy. In 2015 we began a controlled commercial launch at select surgical centers in the United States and had our first commercial sales. During 2015, we initiated a controlled expansion of our commercial operations and started the process of building a sales force. In January 2016, we hired new executives to oversee this expansion. Our direct sales force is supported by field clinical engineers who provide training, technical and other support services to our customers. Throughout 2016, our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven surgical centers that met our certification criteria. Additionally, in 2016, through a distribution agreement with Academy Medical, VA medical facilities now offer the vBloc System as a treatment option to veterans using their veteran healthcare benefits. We plan to build on these efforts in 2017 with self-pay and veteran patient focused direct-to-patient marketing, key opinion leader and center specific partnering, and a multi-faceted reimbursement strategy.

We had our first commercial sales within the United States in 2015 and for the year ended December 31, 2015 and we recognized $292,000 in revenue. During the year ended December 31, 2016, we continued our commercialization efforts and recognized $787,000 in revenue.

We obtained European CE Mark approval for our vBloc System in 2011 for the treatment of obesity, which enables commercialization in the European Economic Area and other countries that recognize the European CE Mark. The CE Mark approval for our vBloc 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. We intend to explore select international markets to commercialize the vBloc System as our resources permit, using direct, dealer and distributor sales models as the targeted market best dictates. Specifically, Canada is a market with a relatively low barrier to entry and an established cash-pay bariatric patient market.

The vBloc System remains a relatively new product in the United States and internationally and it is difficult to predict the amount of revenue it will generate going forward. In any event, such revenue will only modestly reduce our continued losses resulting from our research and development and other activities.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of compensation for executive, finance, market development and administrative personnel, including stock-based compensation. Other significant expenses include costs associated with attending medical conferences, professional fees for legal services, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, reimbursement development and accounting services, cash management fees, consulting fees and travel expenses.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development, quality assurance and clinical and regulatory expenses, incurred in the development of our VBloc System. Research and development expenses also include employee compensation, including stock-based compensation, consulting services, outside services, materials, clinical trial expenses, including supplies, devices, explants and revisions, depreciation and travel. We expense research and development costs as they are incurred.

Results of Operations

Comparison of the Years Ended December 31, 2016 and 2015

Sales . Sales were $787,000 for the year ended December 31, 2016 compared with $292,000 for the year ended December 31, 2016. The increase of $495,000 is the result of the continued controlled commercial launch of the vBloc System at select surgical centers in the United States which resulted in sales of 62 units during 2016 versus 24 units during 2015. We received FDA approval to sell the vBloc System on January 14, 2015.

Cost of Goods Sold . Cost of goods sold were $431,000 for the year ended December 31, 2016 compared to $125,000 for the year ended December 31, 2015. The increase was driven primarily by the 158% increase in the number of units sold in 2016 over 2015. Gross margin percentage for 2016 was 45.2% versus 57.2% for the prior year. The decline in gross margin percentage was primarily due to higher supply chain costs in 2016 than in 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $18.0 million for the year ended December 31, 2016, compared to $19.9 million for the year ended December 31, 2015. The decrease of $1.9 million, or 9.6%, was primarily due to a $3.4 million decrease in payroll-related expenses, partially offset by a $1.1 million increase in professional services expenses and a $366,000 increase in severance expenses. The increase in professional services expenses are the result of increasing commercialization efforts as we continue the controlled commercial launch of the vBloc System at select surgical centers in the United States.

Research and Development Expenses. Research and development expenses were $5.2 million for the year ended December 31, 2016, compared to $8.1 million for the year ended December 31, 2015. The decrease of $3.0 million or 36.5%, was primarily due to decreases of $2.0 million, $436,000 and $119,000 in payroll-related expenses, supply expenses and professional services expenses, respectively. The decreases are the result of a continued shift away from a research and development focus toward commercialization. The Company plans to increase it research and development expenses in 2017 to support a next generation product and to support our post-clinical trial requirements.

Interest Expense . Interest expense was $4.1 million for the year ended December 31, 2016, compared to $939,000 for the year ended December 31, 2015. The increase of $3.2 million was driven by interest costs from the three Note closings that occurred on November 9, 2015, January 11, 2016 and May 2, 2016, and increased interest costs due to conversions of remaining amounts due under the Notes into common shares by holders of the Notes during the year ended December 31, 2016, and, as a result, accelerations of “make whole” interest amounts due under the Notes. Additionally, $277,000 in debt issuance costs were expensed during the quarter ended June 30, 2016.

Change in Value of Warrant Liability . The value of the common stock warrant liability increased $217,000 for the year ended December 31, 2016, compared to the year ended December 31, 2015. Common stock warrant liabilities were recorded during the year ended December 31, 2015 for the Series A Warrants on July 8, 2015 and for the Note Warrants issued on November 9, 2015. In addition, Note Warrants were issued on January 11, 2016 and May 2, 2016. The decline in the value of the warrants was driven by the decrease in the Company’s stock price, which declined throughout 2016, from $136.50 per share on December 31, 2015 to $2.00 on December 31, 2016.

Comparison of the Years Ended December 31, 2015 and 2014

Sales . Sales were $292,000 for the year ended December 31, 2015, compared to no sales for the year ended December 31, 2014. The increase of $292,000 is the result of receiving FDA approval on January 14, 2015 and commencing a controlled commercial launch of the vBloc System at select bariatric centers of excellence in the United States.

Cost of Goods Sold . Cost of goods sold were $125,000 for the year ended December 31, 2015, compared to no cost of goods sold for the year ended December 31, 2014. Gross margin was 57.2% for the year ended December 31, 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $19.9 million for the year ended December 31, 2015, compared to $14.6 million for the year ended December 31, 2014. The increase of $5.3 million, or 36.6%, was primarily due to increases of $2.1 million, $1.7 million, $1.0 million and $505,000 in payroll-related expenses, professional services, employee stock-based compensation and travel, respectively. The increases in payroll-related expenses, professional services and travel are primarily the result of receiving FDA approval on January 14, 2015 and beginning a controlled commercial launch at select bariatric centers of excellence in the United States. The increase in payroll-related expenses is also the result of a special one-time bonus and an increase in the 2014 management incentive plan accrual in recognition of achieving FDA approval on January 14, 2015. The increase in employee stock-based compensation is also a result of stock option grants made in recognition of the receipt of FDA approval and in connection with new hires in 2015.

Research and Development Expenses. Research and development expenses were $8.1 million for the year ended December 31, 2015, compared to $11.0 million for the year ended December 31, 2014. The decrease of $2.9 million, or 26.2%, was primarily due to decreases of $2.3 million, $254,000, $171,000 and $160,000 in professional services, payroll-related expenses, devices and travel. Professional services in 2014 were primarily related to preparation for the advisory panel meeting with the FDA, which was held June 17, 2014. Decreases in payroll-related expenses, devices and travel were primarily the result of decreased emphasis in research and development as efforts were focused on the commercial launch as a result of receiving FDA approval on January 14, 2015.

Interest Expense . Interest expense was $939,000 for the year ended December 31, 2015, compared to $530,000 for the year ended December 31, 2014. The increase of $409,000, or 77.1%, is primarily due to $532,000 and $33,000 of financing costs that were assigned to the common stock warrants issued with the July 8, 2015 financing and the Notes, respectively, both being recognized immediately as interest expense as the warrants are exercisable upon issuance, together with a $187,000 success fee paid to Silicon Valley Bank as a result of achieving FDA approval on January 14, 2015. These increases were offset by a reduction of interest expense due to the declining principal balance through monthly principal and interest loan payments that began on April 1, 2013.

Change in Value of Warrant Liability . The value of the common stock warrant liability decreased $3.3 million for the year ended December 31, 2015, compared to no change for the year ended December 31, 2014. Common stock warrant liabilities were recorded on July 8, 2015 and November 9, 2015 as the common stock warrants issued with the July 8, 2015 public offering and with the Notes provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair market value was calculated using the Black-Scholes valuation model, which resulted in $3.2 million and $51,000 decreases for the year ended December 31, 2015 for the common stock warrants issued with the July 8, 2015 public offering and the Notes, respectively as our stock price decreased from $388.50 on July 8, 2015 and $178.50 on November 9, 2015 to $136.50 on December 31, 2015.

Liquidity and Capital Resources

As of December 31, 2016, we had $3.3 million in cash bank deposits. While we had no short-term money market funds or other investments at December 31, 2016, we periodically invest in short-term money market funds that are not considered to be bank deposits and are not insured or guaranteed by the Federal Deposit Insurance Company or other government agency. These money market funds seek to preserve the value of the investment at $1.00 per share; however, it is possible to lose money investing in these funds. Periodically, we invest cash in excess of immediate requirements in accordance with our investment policy, primarily with a view to liquidity and capital preservation. At times, such deposits may be in excess of insured limits. We have not experienced any losses on our deposits of cash and cash equivalents.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of December 31, 2016, we had $3.3 million of cash and cash equivalents to fund its operations into early 2017. On January 23, 2017, we received $19.0 million in gross proceeds, prior to deducting offering expenses of approximately $2.5 million, at the closing of an underwritten public offering of units in order to

fund our future operations (see Note 18, "Subsequent Events," to the Consolidated Financial Statements on Form 10-K for the Year Ended December 31, 2016).

The following financing transactions occurred in 2015, 2016 and early 2017 to fund the Company's operations:

Early 2017 (***see Note 18, "Subsequent Events," to the Consolidated Financial Statements on Form 10-K for the Year Ended December 31, 2016)***

- On January 23, 2017, the Company closed an underwritten public offering consisting of units of common stock, convertible preferred stock and warrants to purchase common stock. Gross proceeds of the offering were $19.0 million, prior to deducting underwriting discounts and commissions and offering expenses of approximately $2.5 million.
- Between January 1, 2017 and March 6, 2017, common stock warrants for 559,256 shares of common stock were exercised by warrant holders with proceeds to the Company of $3.1 million

2015 and 2016

- On July 8, 2015, we closed a public offering of units consisting of common stock and the Series A Warrants. Gross proceeds of the offering were $16.0 million, prior to deducting offering expenses of approximately $2.5 million.
- On November 4, 2015, we entered into a securities purchase agreement (the Purchase Agreement) with institutional investors to issue up to $25.0 million of senior amortizing convertible notes (the Notes) and Note Warrants, in three separate closings, $18.75 million of which were issued. $1.5 million of the Notes was funded at the first closing on November 9, 2015 (the First Closing). $11.0 million of the Notes was funded at the second closing on January 11, 2016 (the Second Closing) and after entering into an amendment to the Purchase Agreement on May 2, 2016 (the First Amendment) that divided the scheduled third closing into two separate closings, $6.25 million was funded at the third closing on May 2, 2016 (the Third Closing). Pursuant to a second amendment to the Purchase Agreement entered into on July 14, 2016 (the Second Amendment), a deadline of December 30, 2016 was set for the final closing. As the final closing did not occur prior to December 30, 2016, the remaining $6.25 million of Notes was not funded.

The Company's anticipated operations include plans to expand the controlled commercial launch of vBloc Therapy, delivered via the vBloc System. The Company believes that it has the flexibility to manage the growth of its expenditures and operations depending on the amount of available cash flows. However, the Company will ultimately need to achieve sufficient revenues from product sales and/or obtain additional debt or equity financing to support its operations.

Sales Agreement—June 2014

On June 13, 2014, we entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of our common stock having aggregate gross sales proceeds of up to $25.0 million, from time to time, through an at-the market facility (ATM) under which Cowen will act as our sales agent (the Cowen ATM). We will determine, at our sole discretion, the timing and number of shares to be sold under the Cowen ATM. We will pay Cowen a commission for its services in acting as agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of December 31, 2015, we have sold 5,256 shares under the Cowen ATM at a weighted-average selling price of $1,442.00 per share for gross proceeds of $7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM subsequent to December 31, 2015 through March 6, 2017. We can direct Cowen to sell up to $17.4 million in common stock, provided we remain in compliance with all of the conditions under the Cowen ATM.

Sales Agreement—July 2015

On July 8, 2015, we closed a public offering, where we sold 30,476 units at an aggregate price of $525.00 per unit, for gross proceeds of $16.0 million, before deducting estimated offering expenses of approximately $1.4 million, of which $532,000 was assigned to the warrants issued with each unit sold. Each unit consisted of: (A)(i) one share of common stock or (ii) one pre-funded Series C warrant to purchase one share of common stock at an exercise price equal

to $525.00 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price equal initially to $630.00 per share (Series A Warrant). Each purchaser of a unit could elect to receive a Series C Warrant in lieu of a share of common stock. No Series C Warrants were issued.

The Series A Warrants are exercisable for a period of 42 months from the closing date of the public offering. The exercise price and number of shares of common stock issuable on the exercise of the Series A Warrants are subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of the Series A Warrant does not have the right to exercise any portion of the Series A Warrant if the holder, together with its affiliates, would, subject to certain limited exceptions, beneficially own in excess of 9.99% of our common stock outstanding immediately after the exercise or 4.99% as may be elected by the purchaser.

The exercise price of the Series A Warrants was reduced to $168.00 per share on November 9, 2015 as a result of the issuance of the Notes and was further reduced to $67.90 per share on January 29, 2016, the 16th trading day following the First Reverse Stock Split, per the terms of the Series A Warrants and was further reduced at various times during the year ended December 31, 2016 as a result of installment and acceleration payments made on the Notes. As of December 31, 2016, the exercise price of the Series A Warrants was $2.80 per share and on January 20, 2017, the 16th trading day following the Second Reverse Stock Split, the exercise price of the Series A Warrants was adjusted to $2.18 per share, per the terms of the Series A Warrants.

Senior Amortizing Convertible Notes

On November 4, 2015, we entered into the Purchase Agreement to issue and sell to four institutional investors 7% senior amortizing convertible notes due 2017 in three separate closings. The Notes were initially convertible into shares of our common stock at a price equal to $304.50 per share with an aggregate principal amount of $25.0 million. Each Note was sold with a Note Warrant with an exercise price of $325.50 per share. We issued and sold Notes and Note Warrants for aggregate total proceeds of $12.5 million in the First Closing and Second Closing. Subsequent to the Second Closing, we entered into the First Amendment, which provided that the scheduled third closing would be divided into two separate closings, issued and sold Notes and Note Warrants for aggregate total proceeds of $6.25 million in the Third Closing. After the Third Closing, we entered into the Second Amendment, which set a deadline of December 30, 2016 for the final closing and provided the consent of the holders of the Notes to we reduce the conversion price of the Notes from time to time in order to incentivize the holders of the Notes to convert their Notes into shares of our common stock. As the final closing did not occur prior to the December 30, 2016 deadline, the remaining $6.25 million of Notes was not funded. Additionally, after entering into the Second Amendment, we reduced the conversion price of the Notes frequently in order to incentivize the holders of the Notes to convert all of the outstanding amounts outstanding under the Notes. As of December 31, 2016, all of the Notes were fully repaid.

During the year ended December 31, 2016, $18.7 million of aggregate principal amount of Notes were converted by holders of the Notes into approximately 2,632,000 shares of the Company's common stock.

Description of the Notes

The Notes were payable in monthly installments, accrued interest at a rate of 7.0% per annum from the date of issuance and had a maturity date 24 months after the First Closing. The Notes were repayable, at the Company's election, in either cash or shares of our common stock at a discount to the then-current market price. The Notes were also convertible from time to time, at the election of the holders, into shares of our common stock at an initial conversion price of $304.50 per share. The conversion price was adjusted to $76.30 per share on January 29, 2016, the 16th trading day following the First Reverse Stock Split, per the terms of the Notes. The Notes also allowed us to reduce the conversion price from time-to-time, upon the holders' consent, which was provided in the Second Amendment.

The holder of each Note has the right to convert any portion of such Note unless the holder, together with its affiliates, beneficially owned in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the conversion, as such percentage ownership was determined in accordance with the terms of the Notes. The holders were also able to increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage would not be effective until 61 days after providing us notice.

The First Closing occurred on November 9, 2015. At the First Closing, we issued and sold Notes with an aggregate principal amount of $1.5 million, along with Note Warrants exercisable for 1,679 shares. During the quarter ended September 30, 2016, all remaining principal and interest amounts outstanding under the Notes issued at the First Closing were paid off via conversions to common shares.

The Second Closing occurred on January 11, 2016 after we received approval of the offering by the Company's stockholders and the satisfaction of certain customary closing conditions. At the Second Closing, we issued and sold Notes with an aggregate principal amount of $11.0 million, along with Note Warrants exercisable for 12,312 shares. The fair value of Note Warrants issued on January 11, 2016 was determined to be $515,000 using a Black-Scholes valuation model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 85.90%; (3) weighted average risk –free interest rate of 1.58%; and (4) expected life of 5.0 years. During the year and quarter ended December 31, 2016, all remaining principal and interest amounts outstanding under Notes issued at the Second Closing were paid off via conversions to common shares.

The Third Closing occurred on May 2, 2016 after we entered into the First Amendment and satisfied certain closing conditions. At the Third Closing, we issued and sold Notes with an aggregate principal amount of $6.25 million, along with Note Warrants exercisable for 6,995 shares. The fair value of the Note Warrants issued on May 2, 2016 was determined to be $150,195 using a Black-Scholes valuation model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 89.28%; (3) weighted average risk –free interest rate of 1.32%; and (4) expected life of 5.0 years. During the quarter and year ended December 31, 2016, all remaining principal and interest amounts outstanding under Notes issued at the Third Closing were paid off via conversions to common shares.

The following table summarizes the installment amounts and additional conversions by the holders of the Notes through December 31, 2016:

First Closing:

	Principal	Interest	Total	Common Shares
Installment amount at December 31, 2015	$ 65,217	$ 23,651	$ 88,868	814
Holder conversions during the quarter ended December 31, 2015	18,261	2,375	20,636	189
Total installments and conversions, December 31, 2015	83,478	26,026	109,504	1,003
Installment amount at February 29, 2016	65,217	23,681	88,898	1,314
Installment amount at March 31, 2016	65,217	14,827	80,044	1,271
Holder conversions during the quarter ended March 31, 2016	104,784	12,762	117,546	1,524
Total installments and conversions, March 31, 2016	318,696	77,296	395,992	5,112
Installment amount at April 30, 2016	65,217	13,853	79,070	1,454
Installment amount at May 31, 2016	65,217	13,082	78,299	2,121
Installment amount at June 30, 2016	54,217	11,275	65,492	3,590
Holder conversions during the quarter ended June 30, 2016	1,627	174	1,801	29
Total installments and conversions, June 30, 2016	504,974	115,680	620,654	12,306
Installment amount at July 31, 2016	65,217	10,148	75,365	5,521
Installment amount at August 31, 2016	46,957	5,830	52,787	4,593
Holder conversions during the quarter ended September 30, 2016	882,852	78,634	961,486	72,528
Total installments and conversions, September 30, 2016 and December 31, 2016	$ 1,500,000	$ 210,292	$ 1,710,292	94,948

Second Closing :

	Principal	Interest	Total	Common Shares
Installment amount at March 2, 2016	$ 404,762	$ 149,300	$ 554,062	*
Holder conversions during the quarter ended March 31, 2016	987,000	124,050	1,111,050	14,974
Total installments and conversions, March 31, 2016	1,391,762	273,350	1,665,112	14,974
Installment amount at April 29, 2016	404,762	149,497	554,259	10,190
Installment amount at May 31, 2016	291,428	86,518	377,946	10,238
Installment amount at June 30, 2016	404,762	82,913	487,675	22,842
Holder conversions during the quarter ended June 30, 2016	25,373	2,995	28,368	414
Total installments and conversions, June 30, 2016	2,518,087	595,273	3,113,360	58,658
Installment amount at July 31, 2016	213,429	47,457	260,886	19,113
Installment amount at August 31, 2016	631,429	116,511	747,940	64,810
Installment amount at September 30, 2016	404,762	45,846	450,608	51,698
Holder conversions during the quarter ended September 30, 2016	4,868,679	418,847	5,287,526	418,253
Total installments and conversions, September 30, 2016	8,636,386	1,223,934	9,860,320	612,532
Installment amount at Oct 31, 2016	340,000	24,738	364,738	70,665
Installment amount at Nov 30, 2016	291,429	27,528	318,957	81,952
Installment amount at December 31, 2016	156,867	11,425	168,292	57,453
Holder conversions during the quarter ended December 31, 2016	1,575,318	122,624	1,697,942	450,385
Total installments and conversions, December 31, 2016	$ 11,000,000	$ 1,410,249	$ 12,410,249	1,272,987

Third Closing:

	Principal	Interest	Total	Common Shares
Installment amount at June 30, 2016	$ 212,158	$ 90,659	$ 302,817	16,600
Holder conversions during the quarter ended June 30, 2016	—	—	—	—
Total installments and conversions, June 30, 2016	212,158	90,659	302,817	16,600
Installment amount at July 31, 2016	147,368	32,374	179,742	13,168
Cash Payment – July 31, 2016 installment	42,105	6,107	48,212	*
Installment amount at August 31, 2016	336,842	62,059	398,901	34,684
Installment amount at September, 2016	263,158	41,822	304,980	34,523
Holder conversions during the quarter ended September 30, 2016	1,915,698	175,092	2,090,790	155,272
Total installments and conversions, September 30, 2016	2,917,329	408,113	3,325,442	254,247
Installment amount at Oct 31, 2016	221,053	35,004	256,057	48,192
Installment amount at Nov 30, 2016	221,053	31,259	252,312	64,828
Installment amount at December 31, 2016	221,053	14,526	235,579	81,872
Holder conversions during the quarter ended December 31, 2016	2,669,512	170,359	2,839,871	816,707
Total installments and conversions, December 31, 2016	$ 6,250,000	$ 659,261	$ 6,909,261	1,265,846

* Cash payments

Description of the Note Warrants

Each Note Warrant is exercisable immediately and for a period of 60 months from the date of the issuance of the Warrant. The Note Warrants entitle the holders of the Note Warrants to purchase, in aggregate, 27,982 shares of our common stock upon the completion of the Third Closing, subject to certain adjustments. The Note Warrants are initially exercisable at an exercise price equal to $325.50, subject to adjustment on the eighteen month anniversary of issuance, and certain other adjustments. The exercise price and number of shares of common stock issuable on the exercise of the Note Warrants is subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock

split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of each Note Warrant does not have the right to exercise any portion of such Note Warrant if the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Note Warrants. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing us notice.

The exercise price of the Note Warrants issued November 9, 2015 was reduced to $76.30 per share on January 29, 2016, the 16th trading day following the First Reverse Stock Split, per the terms of the Note Warrants. Per the terms of the Note Warrants, the exercise price of each of the Note Warrants issued January 11, 2016 and May 2, 2016 remained $325.50 until January 20, 2017, the 16th trading day following the Second Reverse Stock Split, at which point the exercise price of all of the Note Warrants was adjusted to $2.18 per share. All of the Note Warrants remain subject to adjustment on the eighteen month anniversary of issuance.

Net Cash Used in Operating Activities

Net cash used in operating activities was $20.6 million, $22.6 million and $19.4 million for the years ended December 31, 2016, 2015 and 2014, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, less noncash expenses for stock-based compensation, depreciation and amortization, provision for doubtful accounts, change in value of warrant liability, and partially offset by changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities was $14,000, $39,000 and $89,000 for the years ended December 31, 2016, 2015 and 2014, respectively. Net cash used in investing activities is primarily related to the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $16.0 million, $19.0 million and $7.8 million for the years ended December 31, 2016, 2015 and 2014, respectively. For the year ended December 31, 2016, net cash provided by financing activities was primarily the result of gross proceeds from the Second Closing and Third Closing of the Notes, which totaled $17.3 million, less cash principal payments on Notes of $447,000 and debt issuance costs of $750,000.

For the year ended December 31, 2015, net cash provided by financing activities was primarily the result of gross proceeds of $16.0 million from the July 8, 2015 public offering, ATM draws of $6.7 million and $1.5 million in gross proceeds from the issuance of the Notes on November 9, 2015. These increases were offset by $1.7 million in financing costs, $477,000 of debt issuance costs and principal repayments of $3.0 million on our long-term debt.

For the year ended December 31, 2014, net cash provided by financing activities was primarily the result of gross proceeds from ATM draws of $9.8 million and proceeds of $2.2 million from the exercise of common stock warrants. These increases were offset by $285,000 in financing costs and $4.0 million in principal repayments on our long-term debt.

Operating Capital and Capital Expenditure Requirements

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc System, and began a controlled commercial launch at select bariatric centers of excellence in the United States. We had our first commercial sales within the United States in 2015 and for the years ended December 31, 2015 and 2016, we recognized $292,000 and $787,000 in revenue, respectively. We anticipate that we will continue to incur net losses for the next several years as we develop our products, commercialize our vBloc System, develop the corporate infrastructure required to sell our products, operate as a publicly-traded company and pursue additional applications for our technology platform.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of December 31, 2016, we had $3.3 million of cash and cash equivalents to fund our anticipated operations into early 2017. On January 23, 2017, we received $19.0 million in gross proceeds, prior to deducting offering expenses of approximately $2.5 million, at the closing of an underwritten public offering of units

consisting of common stock, convertible preferred stock and common stock warrants in order to fund our operations. Additionally, between January 1, 2017 and March 6, 2017, common stock warrants for 559,256 shares of common stock were exercised by warrant holders with proceeds to the Company of $3.1 million (see also Note 18, "Subsequent Events," to the Consolidated Financial Statements on Form 10-K for the Year Ended December 31, 2016).

Our anticipated operations include plans that consider the controlled commercial launch of vBloc Therapy, delivered via the vBloc System. We believe that we have the flexibility to manage the growth of our expenditures and operations depending on the amount of our cash flows However, we will ultimately need to achieve sufficient revenues from product sales and/or obtain additional debt or equity financing in order to support our operations. Obtaining funds through the warrant holders' exercise of outstanding common stock warrants or the sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. The sale of additional equity may require us to obtain approval from our stockholders to increase the number of shares of common stock we have authorized under our certificate of incorporation. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to products or proprietary technologies, or grant licenses on terms that are not favorable.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of products and the cost to commercialize our products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part I, Item 1A, *Risk Factors* , of our Annual Report on Form 10-K. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our vBloc System and any products that we may develop;
- the rate of market acceptance of our vBloc 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 System or our future products;
- the scope, rate of progress, results and cost of our 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 any of these types of transactions.

Contractual Obligations

On August 25, 2015, we entered into an amendment extending the term of our operating lease for three years until September 30, 2018, with monthly base rent ranging from $18,925 to $20,345. The following table summarizes our contractual obligations as of December 31, 2016 and the effect those obligations are expected to have on our financial condition and liquidity position in future periods:

	Payments Due By Period				
Contractual Obligations	**Total**	**Less Than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
Operating lease	$ 420,852	$ 237,749	$ 183,103	$ —	$ —
Total contractual cash obligations	$ 420,852	$ 237,749	$ 183,103	$ —	$ —

The table above reflects only payment obligations that are fixed and determinable based on our current agreements. Our operating lease commitment relates to our corporate headquarters in St. Paul, Minnesota. The above table does not include the Notes due to the variability in timing and the option to settle the Notes through the issuance of shares.

Off-balance-sheet Arrangements

Since our inception, we have not engaged in any off-balance-sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities as defined by rules enacted by the SEC and FASB, and accordingly, no such arrangements are likely to have a current or future effect on our financial position, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

In April 2015, FASB issued *Simplifying the Presentation of Debt Issuance Costs* , *(Accounting Standards Update No. 2015-03 (ASU 2015-03))* , which changes the presentation of debt issuance costs in the financial statements. Under ASU 2015-03, an entity presents such costs in the balance sheet as a direct deduction from the recognized debt liability rather than as an asset. Amortization of the costs is reported as interest expense. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2015. We have evaluated the impact of adopting ASU 2015-03 and do not believe the new guidance will have a material effect on our financial position, results of operations or cash flows.

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))* , which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2017. We do not believe that the adoption of the new standard will have a material effect on our consolidated financial statements in that the accounting related to our current revenue-based business practices will not change under the new standard.

In August 2014, FASB issued *Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern* , (Accounting Standards Update No. 2014-15 (ASU 2014-15)), which provides a framework for entities to evaluate going concern issues as well as potential related disclosures. This guidance became effective and the Company adopted it for the year ended December 31, 2016. See Note 3, Liquidity and Management's Plans.

In March 2016, FASB issued *Improvements to Employee Share-Based Payment Accounting,* (Accounting Standards Update No. 2016-09 (ASU 2016-09)), which is intended to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, the estimation of forfeitures, shares withheld for taxes and classification of shares withheld for taxes on the statement of cash flows. As part of the adoption of this guidance we have elected to account for forfeitures of share-

based awards as they occur. The Company will adopt ASU 2016-09 as required on January 1, 2017 and the adoption will not have a material effect on its consolidated financial statements.

Various other accounting standards and interpretations have been issued with 2016 effective dates and effective dates subsequent to December 31, 2016. We have evaluated the recently issued accounting pronouncements that are currently effective or will be effective in 2016 and believe that none of them have had or will have a material effect on our financial position, results of operations or cash flows.

ITEM 7A. ***QUANTITATIVE AND QUALITATIVE DISCLOSUR E ABOUT MARKET RISK***

Our exposure to market risk is confined to our cash and cash equivalents. As of December 31, 2016 we had $3.3 million in cash and cash equivalents. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio, if any, are not leveraged, are classified as either available for sale or held-to-maturity and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any material negative impact on interest income recognized in our statement of operations. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk.

ITEM 8. *FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA*

Index to Financial Statements

Report of Independent Registere d Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of EnteroMedics Inc. and subsidiary (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota
March 8, 2017

ENTEROMEDICS INC.

Consolidated Balance Sheets

	December 31, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,310,787	$ 7,927,240
Accounts receivable (net of allowance for bad debts of $20,000 at December 31, 2016)	143,692	57,928
Inventory	1,789,578	1,686,324
Prepaid expenses and other current assets	476,624	831,495
Total current assets	5,720,681	10,502,987
Property and equipment, net	200,720	326,296
Other assets	1,119,405	757,802
Total assets	$ 7,040,806	$ 11,587,085
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of convertible notes payable	$ —	$ 717,391
Accounts payable	1,311,706	172,050
Accrued expenses	2,751,415	3,595,415
Accrued interest payable	—	1,172
Total current liabilities	4,063,121	4,486,028
Convertible notes payable, less current portion (net of discounts of $149,340 at December 31, 2015)	—	549,791
Common stock warrant liability	39,119	2,877,817
Total liabilities	4,102,240	7,913,636
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Common stock, $0.01 par value; 300,000,000 and 13,333,333 shares authorized; 2,736,621 and 102,415 shares issued and outstanding at December 31, 2016 and 2015 respectively	27,366	1,024
Additional paid-in capital	303,852,582	281,252,963
Accumulated deficit	(300,941,382)	(277,580,538)
Total stockholders' equity	2,938,566	3,673,449
Total liabilities and stockholders' equity	$ 7,040,806	$ 11,587,085

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

Consolidated Statements of Operations

	Year Ended December 31,		
	2016	2015	2014
Sales	$ 786,660	$ 292,000	$ —
Cost of goods sold	431,476	125,047	—
Gross profit	355,184	166,953	—
Operating expenses:			
Selling, general and administrative	17,981,525	19,892,424	14,561,656
Research and development	5,169,286	8,141,323	11,031,619
Total operating expenses	23,150,811	28,033,747	25,593,275
Operating loss	(22,795,627)	(27,866,794)	(25,593,275)
Other income (expense):			
Interest income	5,837	1,819	3,331
Interest expense	(4,104,003)	(939,182)	(530,222)
Change in value of warrant liability	3,512,816	3,295,536	—
Other, net	20,133	9,874	(8,554)
Net loss	$ (23,360,844)	$ (25,498,747)	$ (26,128,720)
Net loss per share—basic and diluted	$ (37.53)	$ (298.97)	$ (404.25)
Shares used to compute basic and diluted net loss per share	622,431	85,290	64,635

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

Consolidated Statements of Stockholders' Equity

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance December 31, 2013	60,599	$ 606	$ 240,631,842	$ (225,953,071)	$ 14,679,377
Net loss	—	—	—	(26,128,720)	(26,128,720)
Employee stock-based compensation expense	—	—	6,138,384	—	6,138,384
Nonemployee stock-based compensation expense	—	—	181,323	—	181,323
Issuance of common stock through "at-the-market" equity offerings in 2014 for cash from $1,157.80 to $2,664.20 per share, net of financing costs of $284,698	4,468	44	9,551,722	—	9,551,766
Exercise of 1,265 warrants in 2014 for cash from $1,197.00 to $2,299.50 per share	1,265	13	2,242,252	—	2,242,265
Balance December 31, 2014	66,332	$ 663	$ 258,745,523	$ (252,081,791)	$ 6,664,395
Net loss	—	—	—	(25,498,747)	(25,498,747)
Employee stock-based compensation expense	—	—	6,974,489	—	6,974,489
Nonemployee stock-based compensation expense	—	—	(34,712)	—	(34,712)
Issuance of common stock through "at-the-market" equity offerings in 2015 for cash from $1,162.00 to $1,589.00 per share, net of financing costs of $259,560	4,604	46	6,392,326	—	6,392,372
Issuance of common stock, net of warrants to purchase approximately 301,905 shares of common stock valued at $6,003,932, in registered public offering in July 2015 for cash at an aggregate price of $525.00 per unit, net of financing costs of $929,920	30,476	305	9,065,843	—	9,066,148
Issuance of common stock for payments made in shares on convertible notes payable	1,003	10	109,494	—	109,504
Balance December 31, 2015	102,415	1,024	281,252,963	(277,580,538)	3,673,449
Net loss	—	—	—	(23,360,844)	(23,360,844)
Employee stock-based compensation expense	—	—	2,327,402	—	2,327,402
Nonemployee stock-based compensation expense	—	—	3,535	—	3,535
Common stock financing costs	—	—	(28,000)	—	(28,000)
Exercise of 1,428 warrants in 2016 for cash at $3.50 per share	1,428	14	4,986	—	5,000
Issuance of common stock for payments made in shares on convertible notes payable	2,632,778	26,328	20,291,696	—	20,318,024
Balance December 31, 2016	2,736,621	$ 27,366	$ 303,852,582	$ (300,941,382)	$ 2,938,566

See accompanying notes to consolidated financial statements.

ENTEROMEDICS INC.

Consolidated Statements of Cash Flows

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$ (23,360,844)	$ (25,498,747)	$ (26,128,720)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	139,576	188,606	188,904
Provision for doubtful accounts	20,000		
Loss on sale of equipment	—	885	—
Stock-based compensation	2,330,937	6,939,777	6,319,707
Amortization of commitment fees, debt issuance costs and original issue discount	1,836,340	825,735	123,068
Change in value of warrant liability	(3,512,816)	(3,295,536)	—
Change in operating assets and liabilities:			
Accounts receivable	(105,625)	(55,116)	14,930
Inventory	(103,254)	(705,805)	147,422
Prepaid expenses and other current assets	354,732	(409,822)	125,071
Other assets	(600,634)	349,709	(74,372)
Accounts payable	1,139,656	(222,636)	267,356
Accrued expenses	(891,060)	(235,351)	(355,294)
Accrued interest payable	2,097,199	(487,739)	(11,735)
Net cash used in operating activities	(20,655,793)	(22,606,040)	(19,383,663)
Cash flows from investing activities:			
Purchases of property and equipment	(14,000)	(38,915)	(88,680)
Net cash used in investing activities	(14,000)	(38,915)	(88,680)
Cash flows from financing activities:			
Proceeds from warrants exercised	5,000	—	2,242,265
Proceeds from sale of common stock and warrants for purchase of common stock	—	22,651,932	9,836,464
Common stock financing costs	(28,000)	(1,721,794)	(284,698)
Proceeds from convertible notes payable	17,250,000	1,500,000	—
Repayments on convertible notes payable	(446,867)	—	—
Repayments on notes payable	—	(3,000,000)	(4,000,000)
Debt issuance costs	(726,793)	(477,110)	—
Net cash provided by financing activities	16,053,340	18,953,028	7,794,031
Net (decrease) increase in cash and cash equivalents	(4,616,453)	(3,691,927)	(11,678,312)
Cash and cash equivalents:			
Beginning of period	7,927,240	11,619,167	23,297,479
End of period	$ 3,310,787	$ 7,927,240	$ 11,619,167
Supplemental disclosure:			
Cash paid for interest	$ 155,407	$ 601,185	$ 418,889
Noncash investing and financing activities:			
Conversion of convertible notes and interest payable	$ 20,318,024	$ 109,504	—

See accompanying notes to consolidated financial statements.

EnteroMedics Inc.

Notes to Consolidated Financial Statements

(1) Description of the Business; Risks and Uncertainties of the Business

Description of Business

EnteroMedics Inc. (the Company) develops and sells implantable systems to treat obesity, metabolic diseases and other gastrointestinal disorders. The Company was incorporated in the state of Minnesota on December 19, 2002, originally as two separate legal entities, Alpha Medical, Inc. and Beta Medical, Inc., both of which were owned 100% by a common stockholder. Effective October 1, 2003, the two entities were combined and the combined entity changed its name to EnteroMedics Inc. The Company reincorporated in Delaware on July 22, 2004. The Company has devoted substantially all of its resources to recruiting personnel, developing its product technology, obtaining patents to protect its intellectual property, commercialization activities and raising capital and has recently commenced commercial operations in the United States deriving revenues from its primary business activity in 2015. The Company is headquartered in St. Paul, Minnesota.

EnteroMedics Europe Sárl (EnteroMedics Europe), a wholly owned subsidiary of the Company, was formed in January 2006. EnteroMedics Europe is a Swiss entity established as a means to conduct clinical trials in Switzerland. Upon establishment there were 20 shares of EnteroMedics Europe issued and outstanding with a par value of 1,000 Swiss Francs. EnteroMedics purchased 100% of the shares and then issued one share to a fiduciary agent. The one share is the property of EnteroMedics and is held by the fiduciary in a fiduciary capacity under terms of the Fiduciary Agreement. The functional currency of EnteroMedics Europe has been determined to be the U.S. Dollar.

During 2016, the Company's board of directors and stockholders approved two reverse stock splits (collectively, the Reverse Stock Splits). Neither reverse stock split changed the par value of the Company's common stock or the number of preferred shares authorized by the Company's certificate of incorporation. The first reverse stock split was a 1-for-15 reverse split (the First Reverse Stock Split) of the Company's outstanding common stock that became effective after trading on January 6, 2016. The First Reverse Stock Split also decreased the number of shares of common stock authorized by the Company's certificate of incorporation proportionately, and proportional adjustments were also made to the Company's outstanding stock options and warrants and the number of shares authorized under the Company's Amended and Restated 2003 Stock Incentive Plan . In connection with the First Reverse Stock Split, an amendment to the Company's certificate of incorporation was also approved to increase the number of shares of the Company's common stock authorized for issuance to 150 million shares, effective immediately after the First Reverse Stock Split on January 6, 2016.

The second reverse stock split was a 1-for-70 reverse split (the Second Reverse Stock Split) of the Company's outstanding common stock that became effective after trading on December 27, 2016 pursuant to the Company's Sixth Amended and Restated Certificate of Incorporation. In connection with the Second Reverse Stock Split, proportional adjustments were also made to the Company's outstanding stock options and warrants. Additionally, in connection with the Second Reverse Stock Split, a second amendment was approved to increase the number of shares of the Company's common stock authorized for issuance to 300 million shares, effective after the Second Reverse Stock Split on December 27, 2016.

All share and per-share amounts have been retroactively adjusted to reflect the Reverse Stock Splits for all periods presented.

Risks and Uncertainties

The Company is focused on the design and development of medical devices that use neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders and currently has approvals to commercially launch the vBloc System in the United States, the European Economic Area and other countries that recognize the European CE Mark. The Company has devoted substantially all of its resources to recruiting personnel, developing its product technology, obtaining patents to protect its intellectual property and raising capital, and has recently commenced commercial operations in the United States deriving revenues from its primary business activity in 2015 and 2016.

The Company's products require approval from the U.S. Food and Drug Administration (FDA) or corresponding foreign regulatory agencies prior to commercial sales. The Company received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the vBloc System, and has begun a controlled commercial launch at select surgical centers in the United States. The vBloc System has also received CE Mark and was previously listed on the Australian Register of Therapeutic Goods (ARTG).

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

The Company's activities are subject to significant risks and uncertainties, including the ability to obtain additional financing, and there can be no assurance that the Company will be successful in obtaining additional financing on favorable terms, or at all. If adequate funds are not available, the Company may have to further reduce its cost structure until financing is obtained and/or delay development or commercialization of products or license to third parties the rights to commercialize products or technologies that the Company would otherwise seek to commercialize.

(2) Summary of Significant Accounting Policies

Basis of Presentation

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

Use of Estimates

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

Principles of Consolidation

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash and cash equivalents. Cash and cash equivalents are primarily deposited in demand and money market accounts. At times, such deposits may be in excess of insured limits. Investments in money market funds are not considered to be bank deposits and are not insured or guaranteed by the federal deposit insurance company or other government agency. These money market funds seek to preserve the value of the investment at $1.00 per share; however, it is possible to lose money investing in these funds. The Company has not experienced any losses on its deposits of cash and cash equivalents.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. The Company's common stock warrants are required to be reported at fair value and the Company elected to report its senior amortizing convertible notes at fair value. The fair values of common stock warrants and investments in debt and equity securities, if any, are disclosed in Note 4. The fair value of the Company's senior amortizing convertible notes is disclosed in Notes 4 and 8.

Common Stock Warrant Liability

The common stock warrants that were issued in connection with the July 8, 2015 public offering (the Series A Warrants) and the common stock warrants issued in connection with the November 9, 2015, January 11, 2016 and May 2, 2016 senior amortizing convertible notes (the Note Warrants) are classified as a liability in the consolidated balance sheets, as the common stock warrants issued provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair value of these common stock warrants is re-measured at each financial reporting period and immediately before exercise, with any changes in fair value being recognized as a component of other income (expense) in the consolidated statements of operations.

Cash and Cash Equivalents

The Company considers highly liquid investments generally with maturities of 90 days or less when purchased to be cash equivalents. Cash equivalents are stated at cost, which approximates market value. The Company's cash equivalents are primarily in money market funds and certificates of deposit. The Company deposits its cash and cash equivalents in high-quality credit institutions.

Short-Term Investments

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

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

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

Inventory

The Company accounts for inventory at the lower of cost or market and records any long-term inventory as other assets in the consolidated balance sheets.

Property and Equipment, Net

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

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets for impairment by comparison of the carrying amounts to future net undiscounted cash flows expected to be generated by such assets when events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Should an impairment exist, the impairment loss would be

measured based on the excess carrying value of the asset over the asset's fair value or estimates of future discounted cash flows. The Company has not identified any such impairment losses to date.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance for deferred income tax assets is recorded when it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The Company has provided a full valuation allowance against the gross deferred tax assets as of December 31, 2016 and 2015 (see Note 12). The Company's policy is to classify interest and penalties related to income taxes as income tax expense in the consolidated statements of operations.

Medical Device Excise Tax

On January 14, 2015, the Company received FDA approval for vBloc Therapy, delivered via the vBloc Rechargeable System, and starting in the second quarter of 2015 revenues were generated from sales in the United States. As a result, the Company is now required to pay a quarterly medical device tax under the Affordable Care Act, which imposes a 2.3% excise tax on the sale of certain medical devices by device manufactures, producers or importers (the Medical Device Tax). The Medical Device Tax was effective on sales of devices made after December 31, 2012. The Company records the Medical Device Tax as an operating expense in the consolidated statements of operations, which totaled $1,363 for 2015. A moratorium was placed on the Medical Device Tax for 2016 and 2017 and, consequently, the Company was not required to pay the Medical Device Tax in 2016.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a company during a period from transactions and other events and circumstances excluding transactions resulting from distributions to owners. There was no difference from reported net loss for the years ended December 31, 2016, 2015 and 2014.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, title or risk of loss has passed, the selling price is fixed or determinable and collection is reasonably assured. Products are sold through direct sales or medical device distributors and revenue is recognized upon sale to a bariatric center of excellence or a medical device distributor when no right of return or price protection exists. Terms of sales to international distributors are generally EXW, reflecting that goods are shipped "ex works," in which risk of loss is assumed by the distributor at the shipping point. A provision for returns is recorded only if product sales provide for a right of return. No provision for returns was recorded for the years ended December 31, 2015 and December 31, 2016, as the product sales recorded did not provide for rights of return.

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses include, but are not limited to, product development, clinical trial expenses, including supplies, devices, explants and revisions, quality assurance, regulatory expenses, payroll and other personnel expenses, materials and consulting costs.

Patent Costs

Costs associated with the submission of a patent application are expensed as incurred given the uncertainty of the patents resulting in probable future economic benefits to the Company. Patent-related legal expenses included in general and administrative costs were $269,000, $200,000, and $338,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

Stock-Based Compensation

The fair value method is applied to all share-based payment awards issued to employees and where appropriate, nonemployees, unless another source of literature applies. When determining the measurement date of a nonemployee's share-based payment award, the Company measures the stock options at fair value and remeasures such stock options to the current fair value until the performance date has been reached. All option grants are expensed on a straight-line basis over the vesting period.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is based on the weighted-average common shares outstanding during the period plus dilutive potential common shares calculated using the treasury stock method. Such potentially dilutive shares are excluded when the effect would be to reduce a net loss per share. The Company's potential dilutive shares, which include outstanding common stock options and warrants, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

The following table sets forth the computation of basic and diluted net loss per share for the years ended December 31, 2016, 2015 and 2014:

	Year Ended December 31,		
	2016	2015	2014
Numerator:			
Net loss	$ (23,360,844)	$ (25,498,747)	$ (26,128,720)
Denominator for basic and diluted net loss per share:			
Weighted-average common shares outstanding	622,431	85,290	64,635
Net loss per share—basic and diluted	$ (37.53)	$ (298.97)	$ (404.25)

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

	December 31,	
	2016	2015
Stock options outstanding	19,840	21,935
Warrants to purchase common stock	55,044	54,875

Recently Issued Accounting Standards

In April 2015, the Financial Accounting Standards Board (FASB) issued *Simplifying the Presentation of Debt Issuance Costs* , *(Accounting Standards Update No. 2015-03 (ASU 2015-03))* , which changes the presentation of debt issuance costs in the financial statements. Under ASU 2015-03, an entity presents such costs in the balance sheet as a direct deduction from the recognized debt liability rather than as an asset. Amortization of the costs is reported as interest expense. This guidance was effective for interim and annual reporting periods beginning after December 15, 2015. The new guidance did not have a material effect on the Company's financial position, results of operations or cash flows.

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))* , which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2017. The Company does not believe that the adoption of the new standard will have a material effect on its consolidated financial statements in that the accounting related to its current revenue-based business practices will not change under the new standard.

In August 2014, FASB issued *Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern, (Accounting Standards Update No. 2014-15 (ASU 2014-15))* , which provides a framework for entities to evaluate going concern issues as well as potential related disclosures. This guidance became effective and the Company adopted it for the year ended December 31, 2016. See Note 3, Liquidity and Management's Plans.

In March 2016, FASB issued *Improvements to Employee Share-Based Payment Accounting, (Accounting Standards Update No. 2016-09 (ASU 2016-09))* , which is intended to simplify several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, the estimation of forfeitures, shares withheld for taxes and classification of shares withheld for taxes on the statement of cash flows. As part of the adoption of this guidance the Company has elected to account for forfeitures of share-based awards as they occur. The Company will adopt ASU 2016-09 as required on January 1, 2017 and the adoption will not have a material effect on its consolidated financial statements.

Various other accounting standards and interpretations have been issued with 2016 effective dates and effective dates subsequent to December 31, 2016. The Company has evaluated the recently issued accounting pronouncements that are currently effective or will be effective in 2016 and believe that none of them have had or will have a material effect on the Company's financial position, results of operations or cash flows.

(3) Liquidity and Management's Plans

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has financed its operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of December 31, 2016, the Company had $3.3 million of cash and cash equivalents to fund its operations into early 2017. On January 23, 2017, the Company received $19.0 million in gross proceeds, prior to deducting offering expenses of approximately $2.5 million, at the closing of an underwritten public offering of units in order to fund its operations (see Note 18, Subsequent Events).:

The following financing transactions occurred in 2015, 2016 and early 2017 to fund the Company's operations:

- On July 8, 2015, the Company closed a public offering of units consisting of common stock and the Series A Warrants. Gross proceeds of the offering were $16.0 million, prior to deducting offering expenses of approximately $1.4 million
- On November 4, 2015 the Company entered into a securities purchase agreement (the Purchase Agreement) with institutional investors to issue up to $25.0 million of senior amortizing convertible notes (the Notes) and Note Warrants, in three separate closings. $1.5 million of the Notes was funded at the first closing on November 9, 2015 (the First Closing).
- An additional $11.0 million of the Notes was funded at the second closing on January 11, 2016 (the Second Closing).
- An additional $6.25 million of the Notes was funded at the third closing on May 2, 2016 (the Third Closing).
- On January 23, 2017, the Company closed an underwritten public offering consisting of units of common stock, convertible preferred stock and warrants to purchase common stock. Gross proceeds of the offering were $19.0 million, prior to deducting underwriting discounts and commissions and offering expenses of approximately $2.5 million (see Note18, Subsequent Events).
- Between January 1, 2017 and March 6, 2017, common stock warrants for 559,256 shares of common stock were exercised by warrant holders with proceeds to the Company of $3.1 million (see Note 18, Subsequent Events).

The Company's anticipated operations include plans to expand the controlled commercial launch of vBloc Therapy, delivered via the vBloc System. The Company believes that it has the flexibility to manage the growth of its expenditures and operations depending on the amount of available cash flows. Additionally, the Company has evaluated

its projected cash flows through March 2018 using the guidance of ASU 2014-15, *Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern* (ASC 205-40), and believes that its current available cash should enable it to sustain operations into March 2018. However, the Company will ultimately need to achieve sufficient revenues from product sales and/or obtain additional debt or equity financing to support its operations.

(4) Fair Value Measurements

Fair value of financial assets and liabilities is defined as the price that would be received to sell an asset or transfer a liability in an orderly transaction between market participants at the measurement date. A fair value hierarchy has been established that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

- Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2—Quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active or model-derived valuations for which all significant inputs are observable, either directly or indirectly.
- Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable.

The Company did not hold any short-term investments classified as available for sale or held to maturity as of December 31, 2016 and 2015.

The fair value of the Company's common stock warrant liability is calculated using a Black-Scholes valuation model and is classified as Level 2 in the fair value hierarchy. The fair values are presented below along with valuation assumptions:

	Series A Warrants		November 2015 Note Warrants	
	December 31, 2016	December 31, 2015	December 31, 2016	December 31, 2015
Risk-free interest rates	1.20 %	0.91 %	1.47 %	1.75 %
Expected life	24 months	42 months	46 months	60 months
Expected dividends	— %	— %	— %	— %
Expected volatility	122.03 %	89.89 %	102.29 %	84.85 %
Fair value	$ 36,000	$ 2,759,583	$ 449	$ 118,234

	January 2016 Note Warrants		May 2016 Note Warrants	
	December 31, 2016	January 11, 2016	December 31, 2016	May 2, 2016
Risk-free interest rates	1.93 %	1.58 %	1.93 %	1.32 %
Expected life	48 months	60 months	52 months	60 months
Expected dividends	— %	— %	— %	— %
Expected volatility	108.57 %	85.90 %	106.37 %	89.28 %
Fair value	$ 1,633	$ 515,157	$ 1,037	$ 150,195

The following table summarizes fair value measurements of the Note Warrants issued in 2016 by level at December 31, 2016:

	Level 1	Level 2	Level 3	Total
December 31, 2015				
Senior amortizing convertible notes (net of discounts of $149,340)	$ —	$ —	$ 1,267,182	$ 1,267,182
Common stock warrants	—	2,877,817	—	2,877,817
Total December 31, 2015	$ —	$ 2,877,817	$ 1,267,182	$ 4,144,999
December 31, 2016				
Common stock warrants	$ —	$ 39,119	$ —	$ 39,119

During the year ended December 31, 2016 all the amounts outstanding under the Notes were paid off via conversions into shares of common stock.

As of December 31, 2015, the fair value of the outstanding Notes from the First Closing was determined to be $1.3 million. The fair value of the Notes issued with the Second Closing was determined to be $2.4 million on the January 11, 2016 issue date. The fair value of the Notes issued with the Third Closing was determined to be $6.0 million on the May 2, 2016 issue date. The fair values were calculated using a Binomial Lattice model and the following assumptions:

	November 2015 Notes		January 2016 Notes	
	December 31, 2016	December 31, 2015	December 31, 2016	January 11, 2016
Risk-free interest rates	N/A	1.11 %	N/A	1.01 %
Expected life	N/A	1.86 years	N/A	1.83 years
Expected dividends	N/A	— %	N/A	— %
Expected volatility	N/A	57.5 %	N/A	60.0 %
Fair value per share of common stock	N/A	$ 1.95	N/A	$ 1.33

	May 2016 Notes	
	December 31, 2016	May 2, 2016
Risk-free interest rates	N/A	0.69 %
Expected life	N/A	1.52 years
Expected dividends	N/A	— %
Expected volatility	N/A	65.0 %
Fair value per share of common stock	N/A	$ 0.80

For the years ended December 31, 2016 and December 31, 2015, respectively, the Company converted $20.3 million and $0.1 million of principal and interest of the Notes into shares of common stock. There were no gains or losses resulting from the Notes recognized in the consolidated statements of operations for the years ended December 31, 2016 or December 31, 2015.

(5) Inventory

From inception, inventory related purchases had been used for research and development related activities and had accordingly been expensed as incurred. In December 2011, the Company began receiving Australian Register of Therapeutic Goods (ARTG) listings for components of the vBloc System from the Australian Therapeutic Goods Administration, with the final components being listed on the ARTG in January 2012. As a result, the Company determined certain assets were recoverable as inventory beginning in December 2011. The Company accounts for inventory at the lower of cost or market and records any long-term inventory as other assets in the consolidated balance sheets. There was approximately $676,000 and $519,000 of long-term inventory, primarily consisting of raw materials, as of December 31, 2016 and 2015, respectively.

Current inventory consists of the following as of:

	December 31, 2016	December 31, 2015
Raw materials	$ 335,606	$ 576,898
Work-in-process	1,437,957	1,066,345
Finished goods	16,015	43,081
Inventory	$ 1,789,578	$ 1,686,324

(6) Property and Equipment

Property and equipment consists of the following as of:

	December 31,	
	2016	2015
Furniture and equipment	$ 2,302,878	$ 2,299,290
Computer hardware and software	596,292	585,880
Leasehold improvements	62,651	62,651
	2,961,821	2,947,821
Less accumulated depreciation and amortization	(2,761,101)	(2,621,525)
Property and equipment, net	$ 200,720	$ 326,296

(7) Accrued Expenses

Accrued expenses consist of the following as of:

	December 31,	
	2016	2015
Professional service related expenses	$ 1,858,912	$ 1,912,775
Payroll related expenses	507,327	1,270,208
Other expenses	385,176	412,432
Accrued expenses	$ 2,751,415	$ 3,595,415

(8) Senior Amortizing Convertible Notes

On November 4, 2015, the Company entered into the Purchase Agreement to issue and sell to four institutional investors 7% senior amortizing convertible notes due 2017 in three separate closings. The Notes were initially convertible into shares of the Company's common stock at a price equal to $304.50 per share with an aggregate principal amount of $25.0 million. Each Note was sold with Note Warrant with an exercise price of $325.50 per share. The Company issued and sold Notes and Note Warrants for aggregate total proceeds of $12.5 million in the First Closing and Second Closing and after entering into the First Amendment, which provided that the scheduled third closing would be split into two separate closings, issued and sold Notes and Note Warrants for aggregate total proceeds of $6.25 million in the Third Closing. After the Third Closing, the Company entered into the Second Amendment, which set a deadline of December 30, 2016 for the final closing and provided the consent of the holders of the Notes to the Company reducing the conversion price of the Notes from time to time in order to incentivize the holders of the Notes to convert their Notes into shares of the Company's common stock. As the final closing did not occur prior to the December 30, 2016 deadline, the remaining $6.25 million of Notes was not funded. Additionally, after entering into the Second Amendment, the Company reduced the conversion price of the Notes frequently in order to incentivize the holders of the Notes to convert all of the outstanding amounts outstanding under the Notes. As of December 31, 2016, all of the Notes were fully repaid.

During the year ended December 31, 2016, $18.7 million of aggregate principal amount of Notes were converted by holders of the Notes into approximately 2,632,000 shares of the Company's common stock.

Description of the Notes

The Notes were payable in monthly installments, accrued interest at a rate of 7.0% per annum from the date of issuance and had a maturity date 24 months after the First Closing. The Notes were repayable, at the Company's election, in either cash or shares of the Company's common stock at a discount to the then-current market price. The Notes were also convertible from time to time, at the election of the holders, into shares of the Company's common stock at an initial conversion price of $304.50 per share. The conversion price was adjusted to $76.30 per share on January 29, 2016, the 16th trading day following the First Reverse Stock Split, per the terms of the Notes. The Notes also allowed the Company to reduce the conversion price from time-to-time, upon the holders' consent, which was provided for in the Second Amendment.

The holder of each Note had the right to convert any portion of such Note unless the holder, together with its affiliates, beneficially owned in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the conversion, as such percentage ownership was determined in accordance with the terms of the Notes. The holders were also able to increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage would not be effective until 61 days after providing notice to the Company.

The Company determined that the conversion feature in the Notes requires bifurcation and liability classification and measurement, at fair value, and requires evaluation at each reporting period. Under Accounting Standards Codification (ASC) 825, Financial Instruments, the FASB provides an alternative to bifurcation and companies may instead elect fair value measurement for the entire instrument, including the debt and conversion feature. The Company elected the fair value alternative in order to simplify its accounting and reporting of the Notes upon issuance. The fair value of the Note Warrants was recorded as a discount to the Notes and amortized to interest expense following the effective interest rate method over the term of the Notes.

The First Closing occurred on November 9, 2015. At the First Closing, the Company issued and sold Notes with an aggregate principal amount of $1.5 million, along with Note Warrants exercisable for 1,679 shares. During the quarter ended September 30, 2016, all remaining principal and interest amounts outstanding under the Notes issued at the First Closing were paid off via conversions to common shares.

The Second Closing occurred on January 11, 2016 after the Company received approval of the offering by the Company's stockholders and the satisfaction of certain customary closing conditions. At the Second Closing, the Company issued and sold Notes with an aggregate principal amount of $11.0 million, along with Note Warrants exercisable for 12,312 shares. The fair value of Note Warrants issued on January 11, 2016 was determined to be $515,000 using a Black-Scholes valuation model. During the quarter ended December 31, 2016, all remaining principal and interest amounts outstanding under Notes issued at the Second Closing were paid off via conversions to common shares.

The Third Closing occurred on May 2, 2016 after the Company entered into the First Amendment and satisfied certain closing conditions. At the Third Closing, the Company issued and sold Notes with an aggregate principal amount of $6.25 million, along with Note Warrants exercisable for 6,995 shares. The fair value of the Note Warrants issued on May 2, 2016 was determined to be $150,195 using a Black-Scholes valuation model. During the quarter ended December 31, 2016, all remaining principal and interest amounts outstanding under Notes issued at the Third Closing were paid off via conversions to common shares.

On December 31, 2015, the fair value of the outstanding Notes was determined to be $1.3 million using a Binomial Lattice model.

The following table summarizes the installment amounts and additional conversions by the holders of the Notes through December 31, 2016:

First Closing:

	Principal	Interest	Total	Common Shares
Installment amount at December 31, 2015	$ 65,217	$ 23,651	$ 88,868	814
Holder conversions during the quarter ended December 31, 2015	18,261	2,375	20,636	189
Total installments and conversions, December 31, 2015	83,478	26,026	109,504	1,003
Installment amount at February 29, 2016	65,217	23,681	88,898	1,314
Installment amount at March 31, 2016	65,217	14,827	80,044	1,271
Holder conversions during the quarter ended March 31, 2016	104,784	12,762	117,546	1,524
Total installments and conversions, March 31, 2016	318,696	77,296	395,992	5,112
Installment amount at April 30, 2016	65,217	13,853	79,070	1,454
Installment amount at May 31, 2016	65,217	13,082	78,299	2,121
Installment amount at June 30, 2016	54,217	11,275	65,492	3,590
Holder conversions during the quarter ended June 30, 2016	1,627	174	1,801	29
Total installments and conversions, June 30, 2016	504,974	115,680	620,654	12,306
Installment amount at July 31, 2016	65,217	10,148	75,365	5,521
Installment amount at August 31, 2016	46,957	5,830	52,787	4,593
Holder conversions during the quarter ended September 30, 2016	882,852	78,634	961,486	72,528
Total installments and conversions, September 30, 2016 and December 31, 2016	$ 1,500,000	$ 210,292	$ 1,710,292	94,948

Second Closing:

	Principal	Interest	Total	Common Shares
Installment amount at March 2, 2016	$ 404,762	$ 149,300	$ 554,062	*
Holder conversions during the quarter ended March 31, 2016	987,000	124,050	1,111,050	14,974
Total installments and conversions, March 31, 2016	1,391,762	273,350	1,665,112	14,974
Installment amount at April 29, 2016	404,762	149,497	554,259	10,190
Installment amount at May 31, 2016	291,428	86,518	377,946	10,238
Installment amount at June 30, 2016	404,762	82,913	487,675	22,842
Holder conversions during the quarter ended June 30, 2016	25,373	2,995	28,368	414
Total installments and conversions, June 30, 2016	2,518,087	595,273	3,113,360	58,658
Installment amount at July 31, 2016	213,429	47,457	260,886	19,113
Installment amount at August 31, 2016	631,429	116,511	747,940	64,810
Installment amount at September 30, 2016	404,762	45,846	450,608	51,698
Holder conversions during the quarter ended September 30, 2016	4,868,679	418,847	5,287,526	418,253
Total installments and conversions, September 30, 2016	8,636,386	1,223,934	9,860,320	612,532
Installment amount at Oct 31, 2016	340,000	24,738	364,738	70,665
Installment amount at Nov 30, 2016	291,429	27,528	318,957	81,952
Installment amount at December 31, 2016	156,867	11,425	168,292	57,453
Holder conversions during the quarter ended December 31, 2016	1,575,318	122,624	1,697,942	450,385
Total installments and conversions, December 31, 2016	$ 11,000,000	$ 1,410,249	$ 12,410,249	1,272,987

Third Closing

	Principal	Interest	Total	Common Shares
Installment amount at June 30, 2016	$ 212,158	$ 90,659	$ 302,817	16,600
Holder conversions during the quarter ended June 30, 2016	—	—	—	—
Total installments and conversions, June 30, 2016	212,158	90,659	302,817	16,600
Installment amount at July 31, 2016	147,368	32,374	179,742	13,168
Cash Payment – July 31, 2016 installment	42,105	6,107	48,212	*
Installment amount at August 31, 2016	336,842	62,059	398,901	34,684
Installment amount at September, 2016	263,158	41,822	304,980	34,523
Holder conversions during the quarter ended September 30, 2016	1,915,698	175,092	2,090,790	155,272
Total installments and conversions, September 30, 2016	2,917,329	408,113	3,325,442	254,247
Installment amount at Oct 31, 2016	221,053	35,004	256,057	48,192
Installment amount at Nov 30, 2016	221,053	31,259	252,312	64,828
Installment amount at December 31, 2016	221,053	14,526	235,579	81,872
Holder conversions during the quarter ended December 31, 2016	2,669,512	170,359	2,839,871	816,707
Total installments and conversions, December 31, 2016	$ 6,250,000	$ 659,261	$ 6,909,261	1,265,846

* Cash payments

Description of the Note Warrants

Each Note Warrant is exercisable immediately and for a period of 60 months from the date of the issuance of the Note Warrant. After completion of the Third Closing, the Note Warrants entitle their holders to purchase, in aggregate, 27,982 shares of the Company's common stock. The Note Warrants were initially exercisable at an exercise price equal to $325.50, subject to adjustment on the eighteen month anniversary of issuance, and certain other adjustments. The exercise price and number of shares of common stock issuable on the exercise of the Note Warrants is subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions. Additionally, the exercise price and number of shares of common stock issuable upon the exercise of the Note Warrants are subject to adjustment in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of each Note Warrant does not have the right to exercise any portion of such Note Warrant if the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Note Warrants. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing notice to the Company.

The exercise price of the Note Warrants issued November 9, 2015 was reduced to $76.30 per share on January 29, 2016, the 16 th trading day following the First Reverse Stock Split, per the terms of the Note Warrants. Per the terms of the Note Warrants, the exercise price of each of the Note Warrants issued January 11, 2016 and May 2, 2016 remained $325.50 until January 20, 2017, the 16 th trading day following the Second Reverse Stock Split, at which point the price of all of the Note Warrants was adjusted to $2.18 per share. All of the Note Warrants remain subject to adjustment on the eighteen month anniversary of issuance.

(9) Preferred Stock

The Company's Sixth Amended and Restated Certificate of Incorporation currently authorizes 5,000,000 shares of $0.01 par value preferred stock. As of December 31, 2016 and 2015, there were no shares of preferred stock issued or outstanding.

On January 23, 2017, the Company closed an underwritten public offering that included 12,531 shares of convertible preferred stock. On January 23 and January 24, 2017 all shares of preferred stock issued in conjunction with the offering were converted by their holders into 2,359,894 shares of common stock. See Note 18, Subsequent Events.

(10) Stock Sales

Sales Agreement—July 2015

On July 8, 2015, the Company closed a public offering, where it sold 30,476 units at an aggregate price of $525.00 per unit, for gross proceeds of $16.0 million before deducting estimated offering expenses of approximately $1.4 million, of which $532,000 was assigned to the warrants issued with each unit sold and was recognized immediately as interest expense in the consolidated statements of operations as the warrants are exercisable upon issuance. Each unit consisted of: (A)(i) one share of common stock or (ii) one pre-funded Series C warrant to purchase one share of common stock at an exercise price equal to $525.00 per share (Series C Warrant); and (B) one Series A Warrant with an exercise price initially equal to $630.00 per share (Series A Warrant). Each purchaser of a unit could elect to receive a Series C Warrant in lieu of a share of common stock. No Series C Warrants were issued.

The Series A Warrants are exercisable for a period of 42 months from the closing date of the public offering. The exercise price and number of shares of common stock issuable on the exercise of the Series A Warrants are subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of the Series A Warrant does not have the right to exercise any portion of the Series A Warrant if the holder, together with its affiliates, would, subject to certain limited exceptions, beneficially own in excess of 9.99% of the Company's common stock outstanding immediately after the exercise or 4.99% as may be elected by the purchaser.

The exercise price of the Series A Warrants issued July 8, 2015 was reduced to $168.00 per share on November 9, 2015 as a result of the issuance of the Notes and was further reduced to $67.90 per share on January 29, 2016, the 16 th trading day following the First Reverse Stock Split, per the terms of the Series A Warrants and was further reduced at various times during the year ended December 31, 2016 as a result of installment and acceleration payments made on the Notes. As of December 31, 2016, the exercise price of the warrants was $2.80 per share and on January 20, 2017, the 16 th trading day following the Second Reverse Stock Split, the exercise price of the Series A Warrants was adjusted to $2.18 per share, per the terms of the Series A Warrants.

Sales Agreement—June 2014

On June 13, 2014, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of the Company's common stock having aggregate gross sales proceeds of up to $25.0 million, from time to time, through an at-the-market (ATM) facility under which Cowen will act as the Company's sales agent (the Cowen ATM). The Company will determine, at its sole discretion, the timing and number of shares to be sold under the Cowen ATM. The Company will pay Cowen a commission for its services in acting as agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of December 31, 2015, the Company had sold 5,256 shares under the Cowen ATM at a weighted-average selling price of $1,442.00 per share for gross proceeds of $7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM subsequent to December 31, 2015 through March 6, 2017. The Company can direct Cowen to sell up to $17.4 million in common stock, provided we remain in compliance with all of the conditions under the Cowen ATM.

(11) Income Taxes

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

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

	2016	2015	2014
Computed 'expected' tax benefit	34 %	34 %	34 %
Other permanent adjustments	3.1 %	1.6 %	(2.3)%
Research and development credit	0.6 %	0.9 %	0.3 %
Federal valuation allowance	(37.7)%	(36.5)%	(32)%
	— %	— %	— %

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

	2016	2015
Deferred tax assets (liabilities):		
Start-up costs	$ 6,662,000	$ 8,886,000
Capitalized research and development costs	23,012,000	29,781,000
Reserves and accruals	8,933,000	8,121,000
Property and equipment	83,000	107,000
Research and development credit	2,198,000	1,972,000
Net operating loss carryforwards	41,657,000	25,695,000
Total gross deferred tax assets	82,545,000	74,562,000
Valuation allowance	(82,545,000)	(74,562,000)
Net deferred tax assets	$ —	$ —

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. In addition, certain limitations imposed under the Internal Revenue Code (IRC) could further limit the Company's realization of these deferred tax assets in the event of changes in ownership of the Company, as defined by IRC Section 382. Based on the level of historical taxable losses and projections of future taxable income (losses) over the periods in which the deferred tax assets can be realized, management currently believes that it is more likely than not that the Company will not realize the benefits of these deductible differences. Accordingly, the Company has provided a valuation allowance against the gross deferred tax assets as of December 31, 2016 and 2015.

The Company's ability to utilize its net operating loss carryforwards and built-in items of deduction, including capitalized start-up costs and research and development costs, may be substantially limited due to ownership changes that may have occurred or that could occur in the future. These ownership changes may limit the amount of net operating loss carryforwards and built-in items of deduction that can be utilized annually to offset future taxable income. In general, an ownership change, as defined in IRC Section 382, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders or public groups. During 2011, the Company completed an IRC Section 382 review and the results of the review indicated that ownership changes had occurred. While the Company has not completed an IRC Section 382 review since 2011, it believes that it is likely that additional ownership changes have occurred since then. Since the Company has experienced an ownership change, utilization of carryforward attributes are subject to an annual limitation, which is determined by first multiplying the value of the Company's common stock at the time of the ownership change by the applicable long-term, tax-exempt rate, and then could be subject to additional adjustments, as required. Any such limitation may result in the expiration of a significant portion of the carryforward attributes before utilization and the permanent loss of built-in items of deduction. Any carryforward attributes that expire prior to utilization or permanent loss of built-in items of deduction as a result of such limitations will be removed from deferred tax assets with a corresponding adjustment to the valuation allowance.

As of December 31, 2016, the Company has generated U.S. federal net operating loss carryforwards of approximately $161.4 million. Of the total federal net operating loss, $48.0 million will expire unused as a result of the 2011 Section 382 limitation and $221,000 are generated from excess tax benefits not yet recorded to the income tax payable, such that they are not reflected in the deferred tax asset balance. The federal net operating loss carryforwards expire in the years 2022 through 2036. The Company's research and development credit carryforwards, if not used, begin to expire in 2024.

Net operating loss carryforwards of the Company are subject to review and possible adjustment by the taxing authorities. With certain exceptions (e.g. the net operating loss carryforwards), the Company is no longer subject to U.S. federal, state or local examinations by tax authorities for years prior to 2013. There are no tax examinations currently in progress.

(12) Stock Options

The Company has adopted the Second Amended and Restated 2003 Stock Incentive Plan (the Plan) that includes both incentive stock options and nonqualified stock options to be granted to employees, officers, consultants, independent contractors, directors and affiliates of the Company. At December 31, 2016 and 2015, according to the Plan 40,000,000 and 18,857 shares, respectively, were authorized and reserved. Pursuant to the terms of the Plan, the shares authorized under the Plan were not adjusted automatically as part of the Second Reverse Stock Split. Instead, pursuant to the terms of the Plan, the board of directors exercised its power to adjust the number of shares authorized under the Plan as it determines is necessary after a stock split or other similar event to prevent dilution or enlargement of the benefits intended to be made available under the Plan. On February 8, 2017, pursuant to the terms of the Plan, the board of directors adjusted the number of shares authorized under the Plan to 3,000,000 shares as a result of the recapitalization of the Company consisting of the Second Reverse Stock Split and the public offering of the Company's stock which closed on January 23, 2017. Pursuant to the terms of the Plan, the board of directors is required to adjust the number of shares authorized under the Plan as it determines necessary after a recapitalization or other similar corporate transaction to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan.

The board of directors establishes the terms and conditions of all stock option grants, subject to the Plan and applicable provisions of the IRC. Incentive stock options must be granted at an exercise price not less than the fair market value of the common stock on the grant date. The options granted to participants owning more than 10% of the Company's outstanding voting stock must be granted at an exercise price not less than 110% of fair market value of the common stock on the grant date. The options expire on the date determined by the board of directors, but may not extend more than 10 years from the grant date, while incentive stock options granted to participants owning more than 10% of the Company's outstanding voting stock expire five years from the grant date. The vesting period for employees is generally over four years. The vesting period for nonemployees is determined based on the services being provided.

Stock option activity for the Plan is as follows:

	Shares Available For Grant	Outstanding Options: Number of Shares	Outstanding Options: Weighted-Average Exercise Price	Outstanding Options: Aggregate Intrinsic Value
Balance, December 31, 2013	519	11,129	$ 2,660.00	
Shares reserved	7,143	—	—	
Options granted	(1,197)	1,197	1,712.00	
Options exercised	—	—	—	
Options cancelled	275	(275)	2,528.00	
Balance, December 31, 2014	6,740	12,051	2,597.00	$ 519,546
Shares reserved	—	—		
Options granted	(3,238)	3,238	1,104.00	
Options exercised	—	—		
Options cancelled	735	(735)	1,942.00	
Balance, December 31, 2015	4,237	14,554	2,298.00	
Shares reserved (1)	2,976,486	—	—	
Options granted	(2,174)	2,174	45.35	
Options exercised	—	—	—	
Options cancelled	9,694	(9,694)	2,134.47	
Balance, December 31, 2016	2,988,243	7,034	$ **1,824.87**	$ —

(1) Reflects the board of directors' February 8, 2017 adjustment of number of shares reserved under the Plan from 40,000,000 to 3,000,000.

On June 27, 2016 the Company completed an option exchange offer to its employees whereby certain outstanding options to purchase shares of the Company's common stock were tendered by employees in exchange for new options with the exercise price to be set at the then current market price of the Company's common stock. Options to purchase 6,424 shares of the Company's common stock, which included all the options eligible for exchange, were tendered by employees and cancelled by the Company. On the same date, options to purchase 1,083 shares of the Company's common stock were issued with an exercise price of $23.28 per share, which was the Company's closing stock price on June 27, 2016. Because the fair value of the tendered options immediately before the exchange approximated the fair value of the new options granted, no additional compensation expense was recognized.

In addition to the stock options granted pursuant to the Plan, the Company from time to time grants options to individuals as an inducement to accepting management positions (Inducement Grants). These Inducement Grants are made at the discretion of the board of directors and our issued outside of the Plan. Inducement Grants are summarized below:

	Shares Available For Grant	Outstanding Options: Number of Shares	Outstanding Options: Weighted-Average Exercise Price	Outstanding Options: Aggregate Intrinsic Value
Balance, December 31, 2014	—	—	—	
Shares reserved	7,380	—		
Options granted	(7,380)	7,380	$ 262.50	
Options exercised	—	—		
Options cancelled	—	—	—	
Balance, December 31, 2015	—	7,380	262.50	$ —
Shares reserved	5,426	—	—	
Options granted	(5,426)	5,426	94.05	
Options exercised	—	—	—	
Options cancelled	—	—	—	
Balance, December 31, 2016	—	12,806	$ **191.12**	$ —

Each of the Inducement Grants will vest as follows: 25% of the shares will vest as of one year from the date of the officer's employment agreement, and the remaining 75% of the shares will then vest in equal 2.0833% installments each month thereafter for 36 months. The options awarded as Inducement Grants were not eligible for the option exchange program

The options outstanding, vested and currently exercisable for the Plan and Inducement Grants are set forth by exercise price at December 31, 2016 in the following table:

	Outstanding Options and Expected to Vest			Options Exercisable and Vested		
Exercise Price	Number of Shares Outstanding	Weighted-Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value
$0.01 to $25.00	829	9.5	$ —	498	$ 23.12	$ —
$25.01 to $175.00	6,416	9.1	—	846	72.56	—
$175.01 to $350.00	7,644	8.8	—	2,407	260.78	—
$350.01 to $1,475.00	2,073	7.2	—	2,041	1,321.12	—
> $1,475.00	2,878	5.1	—	2,870	3,460.40	—
	19,840		$ —	8,662	$ 1,538.71	$ —

Stock-Based Compensation for Nonemployees

Stock-based compensation expenses related to stock options granted to nonemployees is recognized as the stock options are earned. The Company believes that the fair value of the stock options is more reliably measurable than the fair value of the services received. The fair value of the stock options granted is calculated at each reporting date, using the Black-Scholes option-pricing model, until the award vests or there is a substantial disincentive for the nonemployee not to perform the required services. The fair value for the years ended December 31, 2015 and 2014 was calculated using the following assumptions, defined below:

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rates	N/A	0.02%–2.10%	0.08%–2.63%
Expected life	N/A	0.08 years–8.51 years	0.50 years–9.51 years
Expected dividends	N/A	0%	0%
Expected volatility	N/A	37.36%–132.01%	56.54%–139.65%

Stock-based compensation expense charged to operations on options granted to nonemployees for the years ended December 31, 2016, 2015 and 2014 was $3,535, $(34,712) and $181,323, respectively.

Employee Stock-Based Awards

Compensation cost for employee stock-based awards is based on the estimated grant-date fair value and is recognized over the vesting period of the applicable award on a straight-line basis. The weighted average estimated fair value of the employee stock options granted for the years ended December 31, 2016, 2015 and 2014 was $60.00, $426.30, and $1,486.00 per share, respectively.

The Company uses the Black-Scholes pricing model to determine the fair value of stock options. The determination of the fair value of stock-based payment awards on the date of grant is affected by the Company's stock price as well as assumptions regarding a number of complex and subjective variables. These variables include the Company's expected stock price volatility over the term of the awards, actual and projected employee stock option exercise behaviors, risk-free interest rates and expected dividends. The estimated grant-date fair values of the employee stock options were calculated using the Black-Scholes valuation model, based on the following assumptions for the years ended December 31, 2016, 2015 and 2014:

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rates	0.87%–1.64%	1.49%–1.80%	1.73%–1.96%
Expected life	4.0 years–6.25 years	5.50 years–6.25 years	6.00 years–6.25 years
Expected dividends	0%	0%	0%
Expected volatility	88.43%–114.38%	83.36%–111.77%	118.64%–120.70%

Expected Life. The expected life is based on the "simplified" method described in the SEC Staff Accounting Bulletin, Topic 14: *Share-Based Payment* .

Volatility. The expected volatility was based on the Company's historical volatility.

Risk-Free Interest Rate. The risk-free rate is based on the daily yield curve rate from the U.S. Treasury with remaining terms similar to the expected term on the options.

Dividend Yield. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and, therefore, used an expected dividend yield of zero in the valuation model.

Forfeitures. The Company is required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods. If the Company's actual forfeiture rate is materially different from its estimate, the stock-based compensation expense could be significantly different from what the Company has recorded in the current period.

As of December 31, 2016 there was approximately $2.8 million of total unrecognized compensation costs, net of estimated forfeitures, related to employee unvested stock option awards, which are expected to be recognized over a weighted-average period of 2.2 years.

There were no stock option exercises for the years ended December 31, 2016, 2015 and 2014.

(13) Warrants

Stock warrant activity is as follows:

	Common Shares	Weighted Average Exercise Price
Balance, December 31, 2013	24,331	$ 1,964.90
Granted	—	—
Exercised	(1,265)	1,772.40
Cancelled	(22)	50,988.00
Balance, December 31, 2014	23,044	1,929.20
Granted (1)	32,155	116.20
Exercised	—	—
Cancelled	(324)	2,299.50
Balance, December 31, 2015	54,875	1,929.20
Granted (1)	19,308	325.50
Exercised	(1,428)	3.50
Cancelled	(17,706)	2,257.50
Balance, December 31, 2016	55,049	$ 238.90

(1) See Notes 8 and 10 for discussions relating to the issuance of warrants in 2016 and 2015.

At December 31, 2016 and 2015, the weighted-average remaining contractual life of outstanding warrants was 2.76 and 2.18 years, respectively. All of the warrants outstanding are currently exercisable at the option of the holder into the equivalent number of shares of common stock.

(14) Related Party Transactions

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Consulting Agreement—Anthony Jansz

The Company entered into a consulting agreement with Anthony Jansz, who is a former member of the board of directors, for the period from June 1, 2011 through April 30, 2015. In exchange for consulting services provided, Mr. Jansz was entitled to receive consulting fees and options to purchase 16,663 shares of common stock at a weighted average exercise price of $29.78. Total stock-based compensation expense recorded was approximately $600 and $40,000 for the years ended December 31, 2015 and 2014, respectively. Due to a failure to meet certain performance conditions, 471 shares of the options granted to Mr. Jansz did not vest. In addition to the option grants, the Company paid Mr. Jansz approximately $75,000 and $196,000 in fees and expenses for consulting services provided during the years ended December 31, 2015 and 2014, respectively. No consulting fees or expenses were paid to Mr. Jansz in 2016.

Consulting Agreement—Jon Tremmel

Effective August 10, 2015, the Company entered into a one year consulting agreement with Jon Tremmel & Associates, LLC, which is wholly-owned by Jon Tremmel, a member of the board of directors. In exchange for consulting services provided, Mr. Tremmel was entitled to receive consulting fees and an option to purchase 16,666 shares of common stock at $3.45 per share. Total stock-based compensation expense recorded was approximately $3,000 and $13,000 for the years ended December 31, 2016 and 2015, respectively. In addition to the option grant, the Company paid Mr. Tremmel approximately $50,000 in fees and expenses for consulting services provided during the year ended December 31, 2015. No consulting fees or expenses were paid to Mr. Tremmel in 2016.

Other

The Company entered into an agreement with an advisory firm to provide various consulting services. The advisory firm is partially owned by a company with whom a member of our board of directors is a partner. The Company recognized $253,000 in selling, general and administrative expense for the year ended December 31, 2014 for consulting services provided by the advisory firm.

(15) Commitments and Contingencies

Operating Lease

The Company rents its office, warehouse and laboratory facilities under an operating lease, which was originally set to expire on September 30, 2015. On August 25, 2015, the Company entered into an amendment extending the term of the operating lease for three years until September 30, 2018, with monthly base rent ranging from $18,925 to $20,345. Total rent expense recognized for the years ended December 31, 2016, 2015 and 2014, respectively, was $229,000, $262,000 and $271,000. Facility related expenses are included as general and administrative costs on the consolidated statements of operations.

The following is a schedule of total future minimum lease payments due as of December 31, 2016:

Year ending December 31,	
2017	$ 237,749
2018	183,103
	$ 420,852

Product Liability Claims

The Company is exposed to product liability claims that are inherent in the testing, production, marketing and sale of medical devices. Management believes any losses that may occur from these matters are adequately covered by insurance, and the ultimate outcome of these matters will not have a material effect on the Company's financial position or results of operations. The Company is not currently a party to any litigation and is not aware of any pending or threatened litigation that could have a material adverse effect on the Company's business, operating results or financial condition.

Clinical Trials

The Company is evaluating the vBloc System in human clinical trials, including the EMPOWER trial and ReCharge trial. Both of these clinical trials require patients to be followed out to 60 months. The Company is required to pay for patient follow up visits only to the extent they occur. In the event a patient does not attend a follow up visit, the Company has no financial obligation. The Company is also required to pay for explants or revisions, including potential conversions of ReCharge control devices to active devices, should a patient request or be required to have one during the course of the clinical trials. The Company has no financial obligation unless an explant, revision or conversion is requested or required. Clinical trial costs are expensed as incurred.

Litigation

On February 28, 2017, the Company received a class action and derivative complaint filed on February 24, 2017 in U. S. District Court for the District of Delaware by Vinh Du, one of the Company's shareholders. The complaint names as defendants EnteroMedics, the board of directors and four members of our senior management, namely, Scott Youngstrom, Nick Ansari, Peter DeLange and Paul Hickey, and contains a purported class action claim for breach of fiduciary duty against the board of directors and derivative claims for breach of fiduciary duty against the board of directors and unjust enrichment against our senior management. The allegations in the complaint relate to the increase in the number of shares authorized for grant under our Second Amended and Restated 2003 Stock Incentive Plan (the "Plan"), which was approved by our shareholders at the Special Meeting of Shareholders held on December 12, 2016 (the "Special Meeting"), and to our subsequent grant of stock options on February 8, 2017, to the Company's Directors and senior management to purchase an aggregate of 1,093,450 shares of our common stock (the "Option Grants"). In the complaint, the plaintiff contends that (i) the number of shares authorized for grant under the Plan, as adjusted by the board of directors after the Special Meeting for the subsequent recapitalization of the Company, resulted from an alleged breach of fiduciary duties by the board of directors, and (ii) our senior management was allegedly unjustly enriched by the subsequent Option Grants. The plaintiff seeks relief in the form of an order rescinding the Plan as approved by the shareholders at the Special Meeting, an order cancelling the Option Grants, and an award to plaintiff for his costs, including fees and disbursements of attorneys, experts and accountants. We believe the allegations in the complaint are without merit, and intend to defend the action vigorously.

Except as disclosed in the foregoing paragraph, the Company is not currently a party to any litigation and the Company is not aware of any pending or threatened litigation against it that could have a material adverse effect on the Company's business, operating results or financial condition. The medical device industry in which the Company operates is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, the Company may be involved in various legal proceedings from time to time.

(16) Retirement Plan

The Company has a 401(k) profit-sharing plan that provides retirement benefits to employees. Eligible employees may contribute a percentage of their annual compensation, subject to Internal Revenue Service limitations. The Company's matching is at the discretion of the Company's board of directors. For the years ended December 31, 2016, 2015 and 2014, the Company did not provide any matching of employees' contributions.

(17) Quarterly Data (unaudited)

The following table represents certain unaudited quarterly information for each of the eight quarters in the period ended December 31, 2016. In management's opinion, this information has been prepared on the same basis as the audited consolidated financial statements and includes all the adjustments necessary to fairly state the unaudited quarterly results of operations (in thousands, except per share data).

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter (1)
2016:				
Revenue	$ 72	$ 276	$ 297	$ 142
Net loss	$ (7,409)	$ (4,995)	$ (6,522)	$ (4,434)
Basic and diluted net loss per share	$ (66.14)	$ (33.96)	$ (11.77)	$ (2.65)
2015:				
Revenue	$ —	$ 79	$ 64	$ 149
Net loss	$ (7,174)	$ (7,404)	$ (4,151)	$ (6,770)
Basic and diluted net loss per share	$ (103.56)	$ (104.48)	$ (41.92)	$ (66.70)

(1) The $2.4 million reduction in the 2016 fourth quarter net loss compared with the 2015 fourth quarter net loss reflects a $3.5 mllion decrease in operating expenses partially offset by a $0.6 million increase in interest expense and a $0.5 million increase in expenses from net changes in warrant liability and convertible note liability valuations.

(18) Subsequent Events

On January 23, 2017, the Company closed an underwritten public offering consisting of units of common stock, convertible preferred stock and warrants to purchase common stock. Gross proceeds of the offering were $19.0 million, prior to deducting underwriting discounts and commissions and offering expenses of approximately $2.5 million.

The offering was comprised of Class A Units, priced at a public offering price of $5.31 per unit, with each unit consisting of one share of common stock and one five-year warrant (each, a "2017 Warrant") to purchase one share of common stock with an exercise price of $5.84 per share, and Class B Units, priced at a public offering price of $1,000 per unit, with each unit comprised of one share of Series A Preferred Stock (the Preferred Stock), which was convertible into 188 shares of common stock, and 2017 Warrants to purchase 188 shares of common stock. The conversion price of the Preferred Stock issued in the transaction as well as the exercise price of the 2017 Warrants are fixed priced and do not contain any variable pricing features nor any price based anti-dilutive features apart from customary adjustments for splits and reverse splits of common stock. The Preferred Stock included a beneficial ownership limitation of 4.99%, but had no dividend preference (except to extent dividends are also paid on the common stock), liquidation preference or other preferences over common stock. The securities comprising the units were immediately separable were issued separately.

A total of 1,218,107 shares of common stock, 12,531 shares of Preferred Stock convertible into 2,359,894 shares of common stock, and 2017 Warrants to purchase 3,577,994 shares of common stock were issued in the offering

including the underwriters' exercise of their over-allotment option to purchase 466,695 shares of common stock and 2017 Warrants to purchase an additional 466,695 shares of common stock.

On January 23 and January 24, 2017 all shares of Preferred Stock issued in conjunction with the offering were converted by their holders into 2,359,894 shares of common stock.

Between January 1, 2017 and March 6, 2017, common stock warrants for 559,256 shares of common stock were exercised by warrant holders with proceeds to the Company of $3.1 million.

ITEM 9. *CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*

None.

ITEM 9A. *CONTROLS AND PROCEDURE S*

Evaluation of Disclosure Controls and Procedures

We have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act)), as of the end of the period covered by this report (the Evaluation Date). Our management, including the Chief Executive Officer and the Chief Financial Officer, supervised and participated in the evaluation. Based on the evaluation, we concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's forms and rules, and the material information relating to the Company is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Control systems, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that control objectives are met. Because of inherent limitations in all control systems, no evaluation of controls can provide assurance that all control issues and instances of fraud, if any, within a company will be detected. Additionally, controls can be circumvented by individuals, by collusion of two or more people or by management override. Over time, controls can become inadequate because of changes in conditions or the degree of compliance may deteriorate. Further, the design of any system of controls is based in part upon assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Because of the inherent limitations in any cost-effective control system, misstatements due to errors or fraud may occur and not be detected.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the quarter ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company as defined in Rules 13a-15(c) and 15d-15(c) of the Exchange Act. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. The Company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding prevention or timely detection of

unauthorized acquisition, use, or disposition of the Company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has evaluated the design and operating effectiveness of our internal control over financial reporting as of December 31, 2016 utilizing the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework (2013)* . Based upon the evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2016.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to permanent exemption rules of the Dodd-Frank Wall Street Reform and Consumer Protection Act that permit the Company to provide only management's report in this annual report.

ITEM 9B. ***OTHER INFORMATION***

None.

PART III.

Certain information required by Part III is omitted from this report, and is incorporated by reference to our Definitive Proxy Statement to be filed with the SEC pursuant to Regulation 14A (the Proxy Statement) in connection with our 2017 Annual Meeting of Stockholders.

ITEM 10. *DIRECTORS, EXECUTIVE OFFICER S AND CORPORATE GOVERNANCE*

The information required by this Item concerning our directors and executive officers is hereby incorporated by reference to the sections of our Proxy Statement under the headings "Nominees," "Executive Officers," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Board Meetings and Committees—Audit Committee."

We have adopted a code of business conduct and ethics, which applies to all directors and employees, including executive officers, including, without limitation, our principal executive officer, principal financial officer, principal accounting officer and persons performing similar functions. A copy of this code of business conduct and ethics is available on our website at *www.enteromedics.com* (under "Investors," "Corporate Governance") and we intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding any waivers from or amendments to any provision of the code of business conduct and ethics by disclosing such information on the same website.

In addition, we intend to promptly disclose (1) the nature of any amendment to our code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of business conduct and ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

ITEM 11. *EXECUTIVE COMPENSATIO N*

The information required by this Item is hereby incorporated by reference to the sections of our Proxy Statement entitled "Director Compensation," "Executive Compensation," "Compensation Committee Interlocks and Insider Participation" and "Compensation Committee Report."

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNER S AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS*

(a) Equity Compensation Plans

The following table sets forth information as of December 31, 2016 with respect to our equity compensation plans:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Second Column)
Equity compensation plans approved by security holders	7,034 (1)	$ 1,824.87	2,988,243 (2)
Equity compensation plans not approved by security holders	12,806 (3)	191.12	—
Total	19,840	$ 770.35	2,988,243

(1) Consists of options awarded under the Amended and Restated 2003 Stock Incentive Plan, which was amended and restated as the Second Amended and Restated 2003 Stock Incentive Plan (the "Plan) on December 12, 2016.

(2) Represents the maximum number of shares of common stock available to be awarded under the Plan as of December 31, 2016 adjusted to reflect the Company's board of directors' February 8, 2017 action to adjust the number of shares reserved under the Plan from 40,000,000 to 3,000,000 in connection with the Company's recapitalization.

(3) Consists of the inducement grants awarded in 2015 and 2016 to four executives in connection with their hiring.

(b) Security Ownership

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled "Security Ownership of Certain Beneficial Owners and Management."

ITEM 13. ***CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE***

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled "Certain Relationships and Related Transactions, and Director Independence."

ITEM 14. ***PRINCIPAL ACCOUNTANT FEES AND SERVICES***

The information required by this Item is hereby incorporated by reference to the section of our Proxy Statement entitled "Principal Accountant Fees and Services" and "Administration of Engagement of Independent Auditor."

PART IV.

ITEM 15. ***EXHIBITS, FINANCIAL STATEMENTS AND FINANCIAL STATEMENT SCHEDULES***

(a) *Financial Statements and Schedules:* Consolidated Financial Statements for the three years ended December 31, 2016 are included in Part II, Item 8 of this Annual Report on Form 10-K. All schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

(b) *Exhibits:* The list of exhibits on the Exhibit Index on page 89 of this report is incorporated herein by reference.

ITEM 16. ***FORM 10-K SUMMARY***

Not applicable

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ENTEROMEDICS INC.

By: /S/ DAN W. GLADNEY
Dan W. Gladney
Chairman, President and Chief Executive Officer

Dated: March 8, 2017

POWERS OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Dan W. Gladney and Scott P. Youngstrom, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them or their substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ DAN W. GLADNEY **Dan W. Gladney**	Chairman of the Board, President, and Chief Executive Officer (principal executive officer)	March 8, 2017
/S/ SCOTT P. YOUNGSTROM **Scott P. Youngstrom**	Chief Financial Officer and Chief Compliance Officer (principal financial and accounting officer)	March 8, 2017
/S/ GARY D. BLACKFORD **Gary D. Blackford**	Director	March 8, 2017
/S/ CARL GOLDFISCHER, M.D. **Carl Goldfischer, M.D.**	Director	March 8, 2017
/S/ BOBBY I. GRIFFIN **Bobby I. Griffin**	Director	March 8, 2017
/S/ LORI MCDOUGAL **Lori McDougal**	Director	March 8, 2017
/S/ NICHOLAS L. TETI, JR. **Nicholas L. Teti, Jr.**	Director	March 8, 2017
/S/ JON T. TREMMEL **Jon T. Tremmel**	Director	March 8, 2017

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Sixth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on December 28, 2016 (File No. 1-33818)).
3.2	Form of Certificate of Designation of Series A Preferred Stock. (Incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed on January 11, 2017 (File No. 333-213704)).
3.3	Form of Series A Preferred Stock Certificate. (Incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1 filed on January 11, 2017 (File No. 333-213704)).
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)).
10.1	Form of Warrant to purchase stock under Loan and Security Agreement, dated April 16, 2012, between the Company and Silicon Valley Bank. (Incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 10, 2012 (File No. 1-33818)).
10.2	Securities Purchase Agreement, dated as of February 22, 2013, by and between Craig-Hallum Capital Group LLC and the Company. (Incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on February 22, 2013 (File No. 1-33818)).
10.3	Form of Common Stock Warrant, dated as of February 22, 2013, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on February 22, 2013 (File No. 1-33818)).
10.4	Sales Agreement, dated as of June 13, 2014, by and between Cowen and Company, LLC and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 13, 2014 (File No. 1-33818)).
10.5	Amendment No. 1 to the Sales Agreement, dated as of August 25, 2015, by and between Cowen and Company, LLC and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 1, 2015 (File No. 1-33818)).
10.6	Underwriting Agreement, dated as of July 7, 2015, by and between Canaccord Genuity Inc. and the Company. (Incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on July 7, 2015 (File No. 1-33818)).
10.7	Form of Series A Warrant, dated as of July 8, 2015, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on July 7, 2015 (File No. 1-33818)).
10.8	Form of Series C Warrant, dated as of July 8, 2015, by and between the Company and several accredited investors. (Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on July 7, 2015 (File No. 1-33818)).
10.9	Form of Securities Purchase Agreement. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
10.10	Form of Amendment No. 1 to the Securities Purchase Agreement dated November 4, 2015, between the Company and the buyers listed therein. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 6, 2016 (File No. 1-33818)).
10.11	Form of Amendment No. 2 to the Securities Purchase Agreement dated November 4, 2015, as amended by Amendment No.1 thereto dated May 2, 2016, among the Company and the buyers listed therein. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 15, 2016 (File No. 1-33818)).

Exhibit Number	Description of Document
10.12	Form of Senior Convertible Note. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
10.13	Form of Warrant. (Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
10.14	Form of Underwriting Agreement. (Incorporated herein by reference to Exhibit 1.1 to the Company's Registration Statement on Form S-1 filed on January 11, 2017 (File No. 333-213704)).
10.15	Form of Warrant to purchase shares of Common Stock. (Incorporated herein by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1 filed on January 11, 2017 (File No. 333-213704)).
10.16	Warrant Agency Agreement, by and between the Company and Wells Fargo Bank, National Association, dated January 20, 2017. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 24, 2017 (File No. 1-33818)).
10.17†	Second Amended and Restated 2003 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 14, 2017 (File No. 1-33818)).
10.18†	Standard form of Incentive Stock Option Agreement pursuant to the Amended and Restated 2003 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.13 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.19†	Standard form of Non-Incentive Stock Option Agreement pursuant to the Amended and Restated 2003 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.14 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.20†	Form of Non-Incentive Stock Option Agreement for the new options granted October 29, 2010 pursuant to the option exchange program. (Incorporated herein by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q filed on November 8, 2010 (File No. 1-33818)).
10.21†	Form of 2012 Senior Management Non-Incentive Stock Option Agreement pursuant to the Amended and Restated 2003 Stock Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on July 13, 2012 (File No. 1-33818)).
10.22†	Standard form of Restricted Stock Agreement. (Incorporated herein by reference to Exhibit 10.15 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.23†	Form of Indemnification Agreement entered into by and between the Company and each of its executive officers and directors. (Incorporated herein by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).
10.24†	Form of Tandem Stock Purchase Right and Bonus Share Agreement. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 13, 2015 (File No. 1-33818)).
10.25†	Inducement Option Plan. (Incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.26†	Form of Non-Incentive Stock Option Agreement pursuant to the Inducement Option Plan. (Incorporated herein by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K filed on March 28, 2016 (File No. 1-33818)).
10.27†	Form of Non-Incentive Stock Option Agreement for New Options granted June 27, 2016 pursuant to the option exchange offer. (Incorporated herein by reference to Exhibit (d)(6) to the Company's Tender Offer Statement under Section 14(d)(1) on Schedule TO filed on May 27, 2016).
10.28†	Consulting Agreement, dated as of August 21, 2015, by and between Jon Tremmel & Associates, LLC and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 25, 2015 (File No. 1-33818)).

Exhibit Number	Description of Document
10.29†	Executive Employment Agreement, dated May 21, 2007, by and between the Company and Greg S. Lea. (Incorporated herein by reference to Exhibit 10.9 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.30†	Amendment No. 1 to Executive Employment Agreement, dated May 21, 2007, by and between the Company and Greg S. Lea. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on April 19, 2010 (File No. 1-33818)).
10.31†	Amendment No. 2 to Executive Employment Agreement, dated May 21, 2007, by and between the Company and Greg S. Lea, dated January 27, 2016. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 3, 2016 (File No. 1-33818)).
10.32†	Executive Employment Agreement, dated August 5, 2008, by and between the Company and Katherine S. Tweden. (Incorporated herein by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on May 7, 2009 (File No. 1-33818)).
10.33†	Executive Employment Agreement, by and between the Company and Brad Hancock, dated November 17, 2014. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 12, 2015 (File No. 1-33818)).
10.34†	Separation Agreement, by and between the Company and Brad Hancock, dated February 24, 2016. (Incorporated herein by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed on March 28, 2016 (File No. 1-33818)).
10.35†	Executive Employment Agreement, dated October 28, 2015, by and between the Company and Dan W. Gladney. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 2, 2015 (File No. 1-33818)).
10.36†	Form of Non-Incentive Stock Option Agreement for non-plan executive inducement option grants. (Incorporated herein by reference to Exhibit 10.47 to the Company's Annual Report on Form 10-K filed on March 28, 2016 (File No. 1-33818)).
10.37†	Executive Employment Agreement, dated January 19, 2016, by and between the Company and Naqeeb "Nick" Ansari. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.38†	Executive Employment Agreement, dated January 18, 2016, by and between the Company and Peter DeLange. (Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.39†	Executive Employment Agreement, dated January 22, 2016, by and between the Company and Paul Hickey. (Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.40†	Executive Employment Agreement, dated October 3, 2016, by and between the Company and Scott Youngstrom. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 6, 2016 (File No. 1-33818)).
10.41†	Management Incentive Plan. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 12, 2008 (File No. 1-33818)).
10.42†	Amendments to the Management Incentive Plan described in Item 5.02(e). (Incorporated herein by reference to Item 5.02(e) of the Company's Current Report on Form 8-K filed on May 10, 2016 (File No. 1-33818)).
10.43†	Amendments to the Management Incentive Plan described in Item 5.02(e). (Incorporated herein by reference to Item 5.02(e) of the Company's Current Report on Form 8-K filed on September 20, 2016 (File No. 1-33818)).
10.44	Lease Agreement, effective October 1, 2008, by and between the Company and Roseville Properties Management Company. (Incorporated herein by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on March 12, 2009 (File No. 1-33818)).

Exhibit Number	Description of Document
10.45	First Amendment to Lease Agreement, entered into August 25, 2015, by and between the Company and Roseville Properties Management Company. (Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 1, 2015 (File No. 1-33818)).
10.46	Distribution Agreement, dated as of March 28, 2011, by and between Device Technologies Australia Pty Limited and the Company. (Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 6, 2011 (File No. 1-33818)).
10.47	Amendment No. 1, effective as of July 10, 2012, to Distribution Agreement by and between Device Technologies Australia Pty Limited and the Company. (Incorporated herein by reference to Exhibit 10.6 to the Company's Quarterly Report on Form 10-Q filed on August 8, 2012 (File No. 1-33818)).
10.48	Distribution Agreement, dated as of February 21, 2012, by and between Bader Sultan & Brothers Co. W.L.L. and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 10, 2012 (File No. 1-33818)).
10.49	Exclusive Federal Government Business Channel Sales Agreement, effective April 25, 2016, by and between the Company and Academy Medical, LLC, as amended July 26, 2016. (Incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on August 12, 2016 (File No. 1-33818)).
14.1	Code of Conduct and Ethics of the Company. (Incorporated herein by reference to Exhibit 14.1 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
23.1*	Consent of Deloitte & Touche LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on signature page to this Form 10-K).
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Annual Report on Form 10-K of the Company for the year ended December 31, 2016, formatted in Extensible Business Reporting Language: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Stockholders' Equity; (iv) the Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements.

* Filed herewith.

† Indicates management contract or compensation plan or agreement.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-211940, 333-196646, 333-184181, 333-176174, 333-171244, 333-159592, and 333-149662 on Form S-8, Registration Statement Nos.333-205353, 333-195855, 333-183313, 333-171944, 333-170503, 333-171052, 333-166011, and 333-158516 on Form S-3, and Registration Statement Nos. 333-215590 and 333-123704 on Form S-1 of our report dated March 8, 2017, relating to the consolidated financial statements of EnteroMedics Inc. and subsidiary, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2016.

/s/ DELOITTE & TOUCHE LLP
Minneapolis, MN
March 8, 2017

EXHIBIT 31.1

CERTIFICATIONS

I, Dan W. Gladney, certify that:

1. I have reviewed this Annual Report on Form 10-K of EnteroMedics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ DAN W. GLADNEY
Dan W. Gladney
Chairman, President and Chief Executive Officer

Date: March 8, 2017

EXHIBIT 31.2

CERTIFICATIONS

I, Scott P. Youngstrom, certify that:

1. I have reviewed this Annual Report on Form 10-K of EnteroMedics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/S/ SCOTT P. YOUNGSTROM

Scott P. Youngstrom
Chief Financial Officer
and Chief Compliance Officer

Date: March 8, 2017

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of EnteroMedics Inc. (the Company) on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Dan W. Gladney, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ DAN W. GLADNEY
Dan W. Gladney
Chairman, President and Chief Executive Officer

March 8, 2017

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. §1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of EnteroMedics Inc. (the Company) on Form 10-K for the period ended December 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the Report), I, Scott P. Youngstrom, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/S/ SCOTT P. YOUNGSTROM
Scott P. Youngstrom
Chief Financial Officer
and Chief Compliance Officer

March 8, 2017