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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **July 26, 2017**

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

Delaware	**1-33818**	**48-1293684**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

2800 Patton Road **St. Paul, Minnesota**	**55113**
(Address of principal executive offices)	(Zip Code)

(651) 634-3003
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. o

Item 7.01 Regulation FD Disclosure.

Representatives of EnteroMedics Inc. (the "Company") intend to make presentations at investor conferences and in other forums and these presentations may include the information contained in Exhibit 99.1 attached to this Current Report on Form 8-K. A copy of the presentation slides containing such information that may be disclosed by the Company is attached as Exhibit 99.1 to this report and the information set forth therein is incorporated herein by reference and constitutes a part of this report. The Company intends to disclose the information contained in Exhibit 99.1, in whole or in part, and with updates and possibly modifications, in connection with presentations to investors, analysts and others during the remainder of 2017 or until an updated presentation is made available by the Company.

The Company is furnishing the information contained in Exhibit 99.1 pursuant to Regulation FD and Item 7.01 of Form 8-K promulgated by the Securities and Exchange Commission ("SEC"). This information shall not be deemed to be "filed" with the SEC for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

The information contained in Exhibit 99.1 is summary information that is intended to be considered in the context of the Company's SEC filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in Exhibit 99.1, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure. By filing

this report and furnishing this information, the Company makes no admission as to the materiality of any information contained in this report, including Exhibit 99.1.

Item 8.01 Other Events.

The Company is providing certain information as an update to and to supersede the information provide in the Company's previous periodic filings with the SEC in order to reflect recent business developments. An updated description of the Company's business and risk factors are attached hereto as Exhibit 99.2 and 99.3, respectively, and are incorporated herein by reference. The information in this Item 8.01 (including Exhibits 99.2 and 99.3) should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2016, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, and the Company's Current Reports on Form 8-K filed with the SEC since January 1, 2017.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Investor Presentation Slides
99.2	Updated Business Summary
99.3	Updated Risk Factors

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ENTEROMEDICS INC.

By: /s/ Scott P. Youngstrom
Scott P. Youngstrom
Chief Financial Officer and Chief Compliance Officer

Dated: July 26, 2017

Exhibit Index

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EnteroMedics

NASDAQ: ETRM
Company Presentation
2017

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements generally can be identified by the use of words such as expect," "plan," "anticipate," "could," "may," "intend," "will," "continue," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this presentation include statements about the company's total addressable market and annual procedures; competitive companies, technologies and procedures; the company's ability to implement its business model and strategic plan, including its commercialization and reimbursement strategies; expansion of the company's sales team; and implementation and completion of clinical trials.

These forward-looking statements are based on the current expectations of our management and involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others: our limited history of operations; our losses since inception and for the foreseeable future; our limited commercial sales experience with our vBloc® System for the treatment of obesity in the United States or in any foreign market other than Australia and the European Community; the competitive industry in which we operate; our ability to maintain compliance with the Nasdaq continued listing requirements; our ability to commercialize our vBloc® System; our dependence on third parties to initiate and perform our clinical trials; the need to obtain regulatory approval for any modifications to our vBloc® System; physician adoption of our vBloc® System and vBloc® Neurometabolic Therapy; our ability to obtain third party coding, coverage or payment levels; ongoing regulatory compliance; our dependence on third party manufacturers and suppliers; the successful development of our sales and marketing capabilities; our ability to raise additional capital when needed; international commercialization and operation; our ability to attract and retain management and other personnel and to manage our growth effectively; potential product liability claims; the cost and management time of operating a public company; potential healthcare fraud and abuse claims; healthcare legislative reform; our ability to obtain and maintain intellectual property protection for our technology and products; our acquisition of BarioSurg, Inc. may involve unexpected costs or liabilities; the ability to recognize benefits of the acquisition; and risks that the acquisition disrupts current plans and operations.

These and additional risks and uncertainties are described more fully in the Company's filings with the Securities and Exchange Commission, particularly those factors identified as "risk factors" in the annual report on Form 10-K filed March 8, 2017 and quarterly report on Form 10-Q filed May 15, 2017. We are providing this information as of the date of this presentation and do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

EnteroMedics®

Addressing **$1.5 billion/year** surgical device market[1]

Safe, minimally invasive, anatomy preserving solutions with durable outcomes

Growing pipeline via continued acquisition and development

1. Global Bariatric Surgery Devices Market Analysis and Trends, Industry Forecast to 2025, Accuray Research

EnteroMedics

EnteroMedics Company Highlights

Addressing the Continuum of Care in Obesity

Innovative Medical Technologies

- Anatomy friendly solutions
- Minimally invasive (MIS) procedures
- Reversible/removable devices

vBloc® Therapy Gaining Traction

- Strong surgeon relationships and clinical experience
- Commercialization programs converting leads to implants
- Relationship with VA validates vBloc as preferred solution

Large unmet needs in grossly underpenetrated $1.5 billion market[1]

Growing Pipeline + Opportunities

- Acquired Gastric Vest System in Q2 2017
- Establishing strategic partnerships
- Future opportunistic add-ons

Data Supporting Coverage

- More than 700 vBloc patients implanted to date
- Over 25 published clinical papers
- Ongoing clinical trials support marketing and reimbursement

1. Global Bariatric Surgery Devices Market Analysis and Trends, Industry Forecast to 2025, Accuray Research

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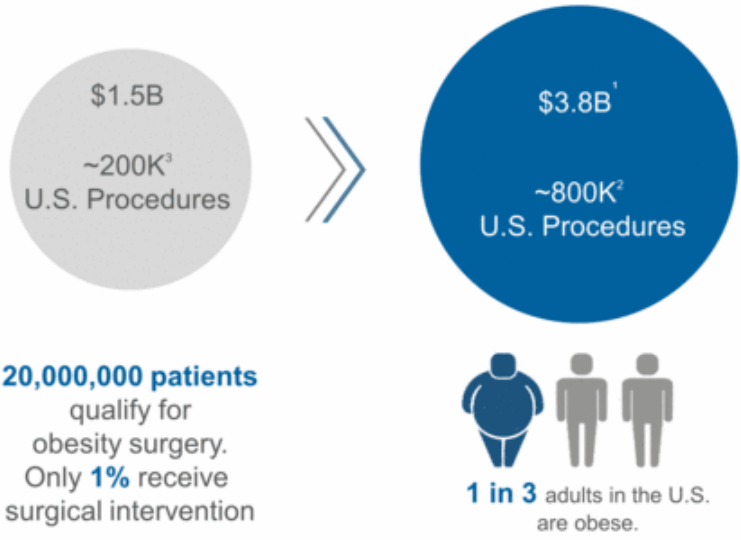
Obesity is Growing in Epidemic Proportions



20,000,000 patients qualify for obesity surgery. Only **1%** receive surgical intervention

1 in 3 adults in the U.S. are obese.

2015 – 2025 Projected Growth Drivers

- Coverage by payers
  - Less invasive therapies proven to save costs and address comorbidities
- Cost efficiencies vs. drugs
- Increase in interventions with new procedures and therapies
  - Anatomy friendly
  - Out-patient procedures

1. Global Bariatric Surgery Devices Market Analysis and Trends, Industry Forecast to 2025, Accuray Research
2. Canaccord Genuity Equity Research 2014
3. Estimate of Bariatric Surgery Numbers, 2011-2015, ASMBS.org

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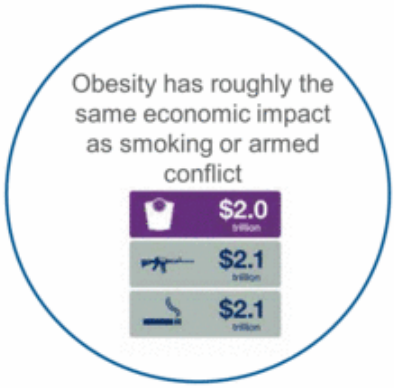
High Healthcare Costs of Obesity

Obesity is one of the biggest drivers of preventable chronic diseases and healthcare costs in the United States

- Obesity is the **#1** cause of preventable death in the U.S.A.
- **70 million adults** in the U.S. and **545 million adults** worldwide struggle with obesity
- Global economic impact of obesity was estimated at **$2.0 trillion** in 2014
- Obese adults spend **42% more** on healthcare than those at a healthy weight
- Obesity contributes to more than **$210 billion** in preventable healthcare spending
- Obesity is a **leading cause** for Type 2 Diabetes



5. Finkelstein, Trogdon, Cohen, et al. Annual Medical Spending Attributable to Obesity. Health Affairs, 2009.
6. Cawley J and Meyerhoefer C. The Medical Care Costs of Obesity: An Instrumental Variables Approach. Journal of Health Economics, 31(1): 219-230, 2012.
7. McKinsey Report, 2014. Grand View Research, Bariatric Surgery Market Analysis, 2016.

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The Challenge of Today's Surgical Solutions for Obesity

There is a significant unmet need for a better weight-loss solution

Only ~1% of obese people seek treatment due to significant shortcomings of existing solutions…

SAFETY	INVASIVENESS	DURATION
Are there safety concerns?	Does it significantly alter anatomy?	Is weight loss sustainable over long term?
Long and short-term safety profiles of many procedures are of concern	Many current procedures are highly invasive and/or anatomy altering	Patients and physicians require durable long-term weight loss

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Meeting Customer and Patient Needs

Patient **needs drive** procedural **volumes**

DESIRABLE SOLUTION

A minimally invasive solution that **does not cut or remove portions of the stomach** and is **removable** or **reversible**

INCREASE QUALITY OF LIFE

An obesity treatment that provides the feeling of fullness with smaller amounts of food, enabling weight loss and **reducing the co-morbidities** of excess weight

A SAFE SOLUTION

A **safe** solution that patients find desirable and can commit to long term

DURABLE WEIGHT LOSS

A **sustainable solution** that helps patients work toward accomplishing their weight loss goals

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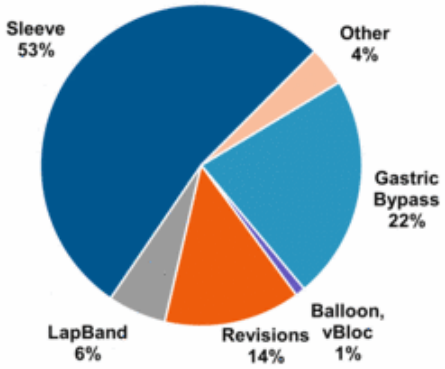
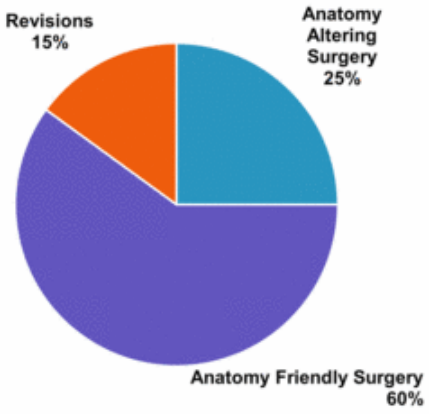
U.S. Obesity Procedures 2015 & Beyond

2015



~198,000 Procedures
$1.5 Billion

2025E



~800,000 Procedures
$3.8 Billion

2025 Procedure Mix Projections

- Sleeve procedures lose market share due to weight regain and non-responders
- Gastric bypass procedures fall due to invasiveness and high complication rates
- Revision surgery market will convert to less invasive anatomy friendly alternatives

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EnteroMedics' Current Portfolio

vBloc℠ neurometabolic therapy

- Minimally invasive
- Durable, sustainable, long-term weight loss solution
- Manages co-morbidities
- Non anatomy changing; reversible
- Safe with low complication rates
- FDA approved

- In-house 24/7 Customer service component
- Lifestyle and nutritional advice for our patients

vBloc Achieve | complete support

GastricVest SYSTEM

- Immediate, high volume weight loss solution
- For morbidly obese, high BMI patients
- Shorter term, minimally invasive treatment
- Removable
- Currently for Investigational Use Only

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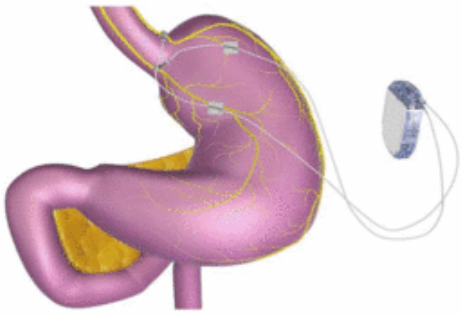
vBloc® Neurometabolic Therapy

Proprietary **bioelectronic neuroblocking technology** designed to help patients feel full and eat less by intermittently blocking hunger signals on the vagus nerve.

vBloc℠
neurometabolic therapy



- More than **700 patients** implanted to date
- **16 centers** currently implanting
- Patient can maintain **diet choices**
- **Non-anatomy-altering** and improved **quality of life**
- **Safe and effective** minimally invasive outpatient procedure

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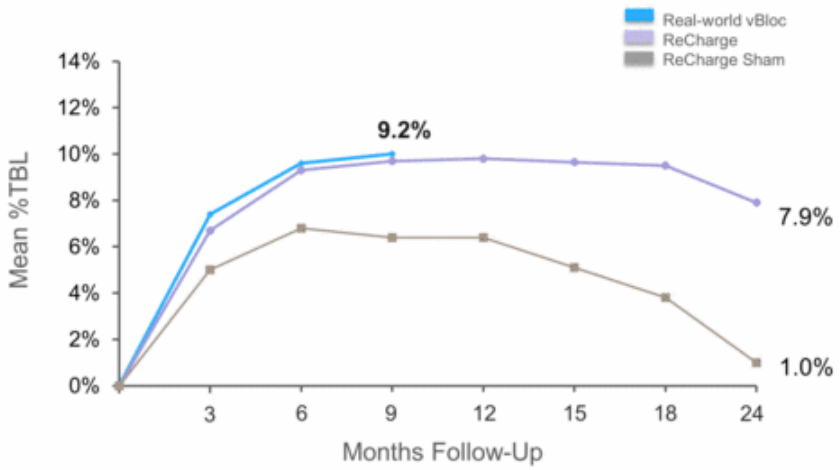
vBloc Clinical Data

Results of vBloc ReCharge FDA Trial
% Total Body Weight Loss (%TBL)



With ReCharge, the sham patients lost more than expected, but regained nearly all weight by 24 months.

8. Caroline M. Apovian & Sajani N. Shah & Bruce M. Wolfe & Sayeed Ikramuddin & Christopher J. Miller & Katherine S. Tweden & Charles J. Billington & Scott A. Shikora., *Two-Year Outcomes of Vagal Nerve Blocking (vBloc) for the Treatment of Obesity in the ReCharge Trial*. OBES SURG, DOI: 10.1007/s11695-016-2325-7
9. Short-Term Results for Intermittent Vagal Nerve Blocking (vBloc) in the Real World, Nonresearch Environment, ASMBS Abstract, Accepted for 2017 Fall Meeting

Efficacious

- Achieves meaningful and sustainable weight loss

Safe

- Low complication rate (3.7%) is significantly safer than any other surgical treatment.

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vBloc Clinical Evidence: Reduction in Comorbidities

vBloc Therapy patients experienced a **reduction in comorbidities** and improvements in overall cardiovascular health at **1 and 2 years**

CLINICAL STUDY PATIENTS AT 1 YEAR

- HbA1c (%) reduction of 1.0 point
  - Highly competitive with leading diabetes drugs
- Waist circumference reduced by 7" (~18 cm)
- Drop in "bad" cholesterol

CLINICAL STUDY PATIENTS AT 2 YEARS

- 50% remittance of pre-diabetes
- 50% remittance of metabolic syndrome

Reductions in co-morbidities yield significant savings to the health care system

11. Shikora, Scott, et al. "Vagal Blocking Improves Glycemic Control and Elevated Blood Pressure in Obese Subjects with Type 2 Diabetes Mellitus." *Journal of Obesity*. (2013) Article ID 245683. DOI: 10.1155/2013/245683.

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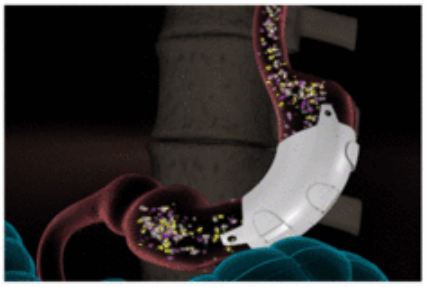
GastricVest SYSTEM



- EnteroMedics acquired the Gastric Vest in May 2017
- Minimally invasive
- No stapling, cutting, or removing the stomach
- Device is removable / reversible
- Studies show rapid sustainable weight loss in 12 months
- Currently for investigational use only

The Gastric Vest is a thin, implantable-grade silicon device that wraps around the stomach emulating the effect of conventional weight-loss surgery.

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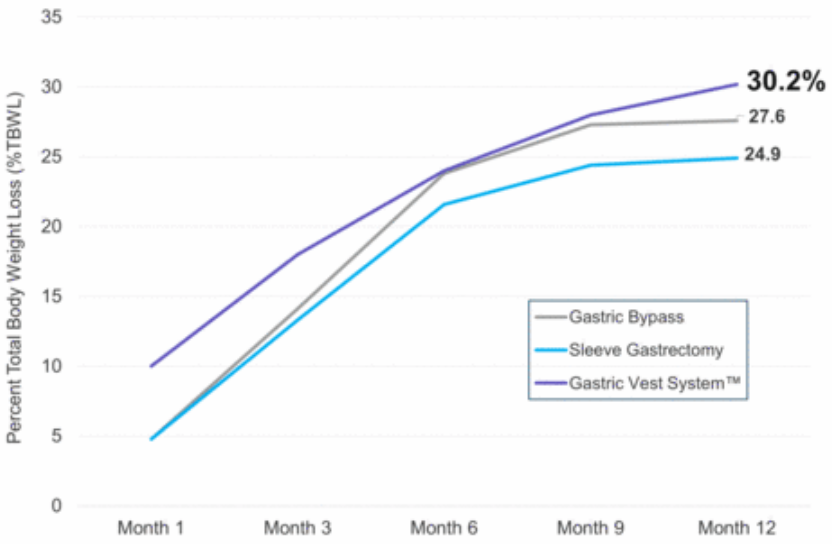
Gastric Vest System Pilot Study Outcomes



12. Schauer et al. N.E.J.M. 366: 1567, 2012.

Efficacious

- Pilot study patients achieve gold standard of weight loss at 12 months.

Minimally Invasive

- Vest surgery is laparoscopic and a reversible, anatomy friendly procedure

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Gastric Vest Clinical Evidence: Reduction in Comorbidities

Patients in the Gastric Vest pilot study demonstrated **significant improvements in comorbidities**

PILOT STUDY PATIENTS AT 1 YEAR

- HbA1c (%) reduction of 2.1 points
- Systolic blood pressure decreased 13 mmHg
- Waist circumference reduced by 15"
- Increase in HDL “good cholesterol” of 29 mg/dL

Improvements in co-morbidities yield significant savings to the health care system

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vBloc Commercial Strategy

Multi-tiered strategy converts leads to implants and gains payer attention driving coverage decisions

vBloc Now Program

- Establishes commercial demand and traction at low cost to patient
- Generates outcomes and comorbidity data to support coverage
- Unit and demand focus

vBloc Institutes

- **16** centers in U.S. trained and credentialed on vBloc
- Partners in data collection/publication
- Payer and employer engagement
- Employee coverage (where applicable)

Veterans Affairs

- Sole source agreement covers vBloc System
  - Procedures at VA facilities are reimbursed
- Facilities Trained
  - **4** VA Hospitals
    9 VA Choice

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Strategy to Collect vBloc Outcomes Data for Reimbursement

Three initiatives underway supporting coverage and reimbursement decisions with payers

- vBloc Now Program (June 2017)
  - Real-world outcomes on over 125 patients from select vBloc institutes
  - Will include co-morbidity improvement data
  - Data to be utilized to support reimbursement
- ReNew FDA Post-Market Study (August 2017)
  - Five year, 200 patient trial with vBloc Therapy and vBloc Achieve aftercare program
  - Up to 15 sites
- Kaiser Diabetic Study (September 2017)
  - Partnered with Kaiser Permanente on a 3 year, 60 patient study
  - Full enrollment expected mid-2018
  - Goal to demonstrate advantage of vBloc Therapy over non-surgical Rx treatment of diabetes

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Gastric Vest Clinical and Regulatory Path

- US FDA Study
  - PMA. 200-250 patient pivotal trial with a 12-month weight loss and safety endpoint. Minimum of 2-year follow-up
  - First US PMA implants expected in Q2 2018 with approval estimated Q4 2020, pending FDA review times
- EU Study:
  - CE Mark trial of 50-100 patients with a 6-month weight loss and safety endpoint. Minimum 12-month follow-up
  - First EU implants will start in Q1 2018 with CE mark estimated Q2 2019

All study designs will include metrics requested by payers (e.g. safety, efficacy, health economics)

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Driving Coverage and Reimbursement

MULTI-FACETED REIMBURSEMENT STRATEGY TO DRIVE LONG-TERM COVERAGE

Society Support

Leverage clinical data through strength of societies, including ASMBS and TOS

Cost Analysis

Study and publish economic savings and complication reduction

Physician Demand

Surgeons engage commercial payers and MACs

Data

Continue to collect and publish efficacy and safety data

Patient Demand

vBloc Access program supports patients during prior authorization and appeals

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Intellectual Property

Bioelectronic Medicine (vBloc)

- Broad claim coverage for bioelectronic systems and methods related to neuroblocking, neuromodulation, and neurostimulation technology
- IP covers indications including obesity, bulimia, pancreatitis, heart rate regulation, and glucose regulation
- 45 granted U.S. patents
- 45 granted foreign patents in Australia, Europe, China and Japan
- Additional U.S. and 22 OUS patents pending

Gastric Vest

- Intellectual property for gastric restriction device to treat obesity
- 4 granted U.S. patents
- 4 granted foreign patents in China, Israel, Canada and Australia

Strategic Partnership

Collaboration Agreement

(for pre-clinical research)

- Funded co-development of new modified EnteroMedics' products
- Future opportunities (continued IP + technology platform co-development)
- Intellectual property licensing
- EnteroMedics will receive payments for its development work and supply under this agreement

EnteroMedics Milestones and Objectives

1. **Focus on Commercial Use and Outcomes**
   - Unit placements
   - Co-morbidity and clinical support
2. **Establish vBloc Reimbursement**
   - Commercial coverage
   - Publish real-world outcomes and co-morbidity data
3. **Grow Pipeline**
   - Complete CE Mark trial for Gastric Vest
   - Complete US PMA trial for Gastric Vest
   - Strategic partnerships and acquisitions

Financial Snapshot

Commercial Unit Placements	
Full year 2016	63
Six months ended June 30, 2017	50

Key Balance Sheet Metrics	
Cash as of June 30, 2017	$11.0 M
Debt as of June 30, 2017	$0.0

Capitalization (as of June 30, 2017, in millions)	
Common Shares Outstanding	8.3
To be issued (BarioSurg)	5.0
Issued (and to be issued) and outstanding	13.3
Warrants (January 2017 cash warrants at $5.84)	3.0
Fully Diluted	16.3

Investment Summary

Large, underserved and rapidly expanding market with multiple sub-segments

FDA approved vBloc technology gaining commercial traction

Growing minimally invasive pipeline for the treatment of obesity via continued acquisition and development

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EnteroMedics

EnteroMedics Inc. (NASDAQ:ETRM)
2800 Patton Road
St. Paul, MN 55113

Dan Gladney
President, Chief Executive Officer & Chairman of the Board
651-634-3089
dwgladney@enteromedics.com

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APPENDIX

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Positioning Gastric Vest and vBloc in the Market

	Alter Anatomy?	Diet Restrictions	Procedure Type	Safety Risks	Weight Loss %EWL	**Procedure Cost**
By-Pass	Yes	Severe	Laparoscopic	Potential for serious complications	65-80%	~$24,000
Sleeve	Yes	Severe	Laparoscopic	Potential for serious complications	50-65%	~$19,000
Gastric Vest	Restrict	None	Laparoscopic	Low	+85%	~$8,000-$11,000
Band	Restrict	None	Laparoscopic	Erosion, Infection, Leakage	30-50%	~15,000
vBloc	No	None	Laparoscopic	Low	25% (durable)	~$20,000
Balloon	No	None	Endoscopic	Low- erosion, obstruction	25-35% (temporary)	~$8,000
Aspire	No	None	Endoscopic	Infection, leakage	30-35%	~$10,000

GastricVest SYSTEM

vBloc neurometabolic therapy

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Our Company

We are a medical device company focused on the development and commercialization of technology to treat obesity and metabolic diseases.

The vBloc®System, our initial product, is a U.S. Food and Drug Administration (FDA)-approved pacemaker-like device that delivers vBloc® Neurometabolic Therapy (vBloc Therapy) to help patients feel full and eat less by intermittently blocking hunger signals on the vagus nerve. Our therapy limits the expansion of the stomach, helps control hunger sensations between meals, reduces the frequency and intensity of stomach contractions and produces a feeling of early and prolonged fullness. 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 have a limited operating history and only recently received FDA approval to sell the vBloc System in the United States. In addition, we have regulatory approval to sell the vBloc System 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.

On May 22, 2017, we acquired the Gastric Vest System™ through our acquisition of BarioSurg. The Gastric Vest System is an investigational, minimally invasive, laparoscopically implanted medical device being studied for weight loss in morbidly obese patients. The device wraps around the stomach, emulating the effect of conventional weight-loss surgery, and is intended to enable gastric volume reduction without permanently changing patient anatomy. The acquisition was completed under the terms of a merger agreement pursuant to which BarioSurg became a wholly-owned subsidiary of our company. The aggregate merger consideration we paid for all of the outstanding shares of capital stock and outstanding options of BarioSurg was: (i) 1.38 million shares of our common stock, (ii) 1.0 million shares of our newly created conditional convertible preferred stock, which shares will convert into 5.0 million shares of our common stock subject to and contingent upon the post-closing approval of our stockholders in accordance with the NASDAQ Stock Market Rules, and (iii) $2 million in cash.

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. Our vBloc Therapy is a covered benefit for over 21 million U.S. veterans. The VA estimates that 78% of U.S. veterans are overweight or obese and nearly 25% of VA patients have diabetes. 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

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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.

Our goal for the vBloc System remains broad coverage and reimbursement for vBloc Therapy. We believe that the most significant barrier to adoption for patients who want vBloc Therapy has been cost and lack of payer coverage. In June 2017, we launched our vBloc Now program. The vBloc Now program provides qualified patients battling obesity the opportunity to receive vBloc Therapy, including the device, procedure, and vBloc Achieve follow up program, at an affordable price in exchange for sharing detailed health data with EnteroMedics. The program is available for a limited time, will reduce patient total out-of-pocket costs, and compete with leading covered bariatric surgery procedures as well as other low-cost weight loss devices

In addition, the vBloc Now program provides us with additional commercial data concerning vBloc Therapy in order to enhance our case with third-party payers that the vBloc System can have a clinically meaningful level of effectiveness in reducing the incidence of diabetes and other comorbidities in certain patients. While we do not expect to recognize any revenues in conjunction with the vBloc Now program, the Company anticipates that vBloc Now program expenses will be offset by a reduction in marketing and advertising expenses and will not increase the Company's overall operating expenses.

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 was 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 the vBloc System 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.

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 obese and more than 1.9 billion adults are 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, and according to a 2014 McKinsey Report is the leading cause of preventable death in the U.S. Currently, the Center for Disease Control (the CDC) estimates that 35.7% of U.S. adults (or approximately 73 million 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 comorbidity, 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. An estimated approximately $1.5 billion was spent in 2015 alone on bariatric surgical procedures to treat 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 traditional bariatric surgical approaches, we believe there is a substantial need for a patient-friendly, safer, effective and durable solution that:

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

Our Products

The vBloc System

The vBloc System, our initial product, uses vBloc Therapy to block the gastrointestinal effects of the vagus nerve using high-frequency, low-energy electrical impulses to intermittently interrupt naturally occurring neural

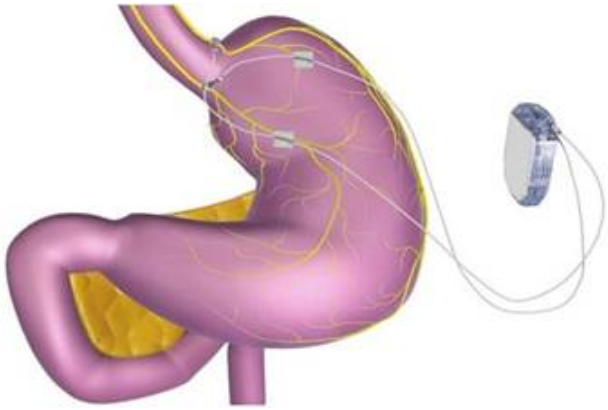
impulses on the vagus nerve between the brain and the digestive system. Our therapy controls hunger sensations between meals, limits the expansion of the stomach and reduces the frequency and intensity of stomach contractions, leading to earlier fullness. The resulting physiologic effects of vBloc Therapy 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.

Benefits. 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 conventional 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 clinical trials to demonstrate the safety of the vBloc System. In our clinical trials to date, including the ReCharge trial, 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.

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 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 loss.

The Gastric Vest System

The Gastric Vest System, which we acquired in May 2017 in connection with our acquisition of BarioSurg, is an investigational, minimally invasive, laparoscopically implanted medical device being studied for weight loss in morbidly obese patients with a BMI of at least 35. This device is designed to restrict the intake of food and provide the feeling of fullness without cutting or permanently removing portions of the stomach, or bypassing, any portion of the gastrointestinal tract. The implantation of the device mimics a traditional weight-loss surgery without permanently altering the anatomy and does not appear to require vitamin supplementation.

In a small pilot study conducted outside the U.S., at 12 months, Gastric Vest patients demonstrated a mean percent excess weight loss (%EWL) of 85%, an average drop in HbA1c (Hemoglobin A1c) of 2.1 points, and an average waist circumference reduction of 38 centimeters, or approximately 15 inches.

Benefits. The Gastric Vest System, if approved for sale, would allow us to offer an additional weight loss solution that emulates the effect of conventional weight loss surgery through a procedure that is minimally invasive. The Gastric Vest System potentially offers the following benefits:

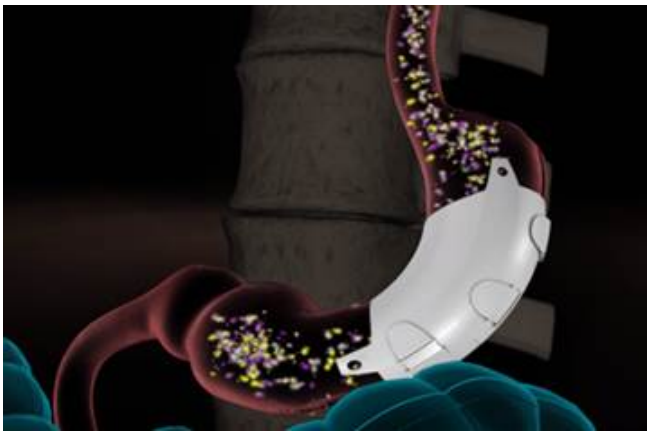
- **Minimizes Changes to Normal Anatomy.** The Gastric Vest System emulates the effects of conventional weight-loss surgery without stapling, cutting or removing any portion of the stomach.

- **Minimally Invasive Procedure**. Unlike conventional weight loss surgery, which typically is performed in a hospital setting under general anesthesia and requires a hospital stay of up to four days, the Gastric Vest System is inserted laparoscopically in an outpatient procedure.

  Removable/Reversible. The Gastric Vest System is designed to be removed laparoscopically, permitting the removal of the device at a later time, if that is desired.

- **Allows Continued Ingestion and Digestion of Foods Found in a Typical, Healthy Diet**. Because the Gastric Vest System also leaves the digestive anatomy largely unaltered, patients are able to maintain a more consistent nutritional balance compared to conventional surgical approaches, thus allowing them to effect positive changes in their eating behavior in a non-forced and potentially more consistent way.

System. The Gastric Vest System is a thin, implantable-grade silicon device that wraps around the stomach, as shown below. Following stomach plication, the device wraps around the stomach, emulating the effect of conventional weight-loss surgery, and is intended to enable gastric volume reduction without permanently changing patient anatomy. By decreasing the cross-sectional area of the stomach, food travels faster through the stomach, resulting in faster gastric emptying. The smaller amount of food in the stomach coupled with restriction is intended to stimulate the stretch receptors along the stomach, which send signals to the brain that the patient should stop eating.



Alternative Weight Loss Solutions

If we are able to commercialize the Gastric Vest System, we believe we will be able to offer three distinct approaches as weight loss solutions for obesity and its related comorbidities: the vBloc System; the Gastric Vest System; and a combination of both the vBloc System and the Gastric Vest System.

Our Commercialization Strategy

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 the vBloc System 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 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.

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$\pm$5% ($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.

ReNew Trial

The ReNew Trial is a Post Approval Study required by the FDA as a condition of approval. ReNew is a five-year, single arm, multi-center trial to evaluate the long-term safety and efficacy of the Maestro Rechargeable System in treating obesity in 200 patients at 10 to 15 sites. We expect enrollment for the ReNew trial to begin in the second half of 2017.

Kaiser Diabetes Trial

On April 26, 2017, we entered into a Clinical Trial Agreement with Southern California Permanente Medical Group ("Southern"), a division of Kaiser Permanente, with an effective date of June 1, 2017. Under the agreement, we are sponsoring an investigator-initiated study with Southern to study vBloc Therapy as a treatment for Type 2 diabetic patients with obesity. As sponsor of the study, we are obligated to pay Southern approximately $3.4 million over three years to fund the study. We expect enrollment to begin in the fourth quarter of 2017.

All clinical data generated during the study will be disclosed to us and may be used for any purpose stated in the informed consent form or otherwise in compliance with applicable law. We will have the right to publish, present or use any final results arising out of the study.

Gastric Vest System ENDURE Trial

The Gastric Vest System was studied internationally in the ENDURE trial, which was designed to evaluate the safety and efficacy of the Gastric Vest System. Of the 17 patients enrolled, 14 have completed their 12-month follow-up visit. Results from these 14 patients show that the Gastric Vest System demonstrated a mean excess weight loss (%EWL) of 85.5% compared to approximately 75% and 65% for gastric bypass and sleeve gastrectomy. The patients also experienced an average HgA1c decrease of 2.1%, and an average waist circumference reduction of

38 cm, or 15 inches. The Gastric Vest System will continue to be studied in upcoming trials in the US and internationally.

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;

- testing and developing the Gastric Vest System;
- developing the next-generation vBloc System;
- identifying the effect of vagal blocking on nerve and organ function; and
- investigating the vBloc and Gastric Vest 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 and Gastric Vest System 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. vBloc Therapy for patients with Type 2 diabetes will continue to be studied primarily in our Kaiser Diabeties Trial.
- ***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 patients from an earlier clinical trial 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 or Gastric Vest System for these indications in the United States or internationally.

Medical Advisors

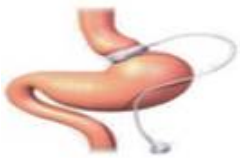
In addition to our collaboration with Mayo Clinic, we also have medical advisors who provide strategic guidance to our development programs, consult with us on clinical investigational plans and individual study protocols, and advise on clinical investigational site selection. Members of our medical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

Our vBloc System competes, and we expect that our Gastric Vest System will compete, with surgical obesity procedures, including gastric bypass, gastric balloon, gastric banding, sleeve gastrectomy and the endoscopic sleeve. 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,ORBERA Intragastric Balloon System, and OverStitch Endoscopic Suturing System), ReShape Medical, Inc. (ReShape Integrated Dual Balloon System), Obalon Therapeutics, Inc. (Obalon Balloon System) and Johnson & Johnson (Realize Adjustable Gastric Band).

In June 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. Our acquisition of the Gastric Vest System included four U.S. patents, one pending U.S. patent application, four foreign patents, and five pending foreign patent applications. The patents we acquired related to the Gastric Vest System will expire between 2028 and 2034. 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. The applications that we acquired related to the Gastric Vest System primarily pertain to methods of gastric restriction for treating obesity.

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. While the Company believes that it has common law trademark rights to GASTRIC VEST, it has not applied for the registration of this mark.

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 for the vBloc System 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 and our proposed Gastric Vest System are regulated by the FDA as medical devices 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.

The Gastric Vest System will likely be considered a Class III Long Term Implantable (LTI) product by the FDA requiring the premarket approval (PMA) path. A PMA is required to establish the safety and effectiveness of the device and a key component of a PMA submission is the pivotal clinical trial data, as discussed in more detail below. A pivotal trial for the Gastric Vest System will likely include 200 to 250 implanted patients monitored up to three years. Other implantable devices for the treatment of obesity relied on 12 month endpoints for the PMA submission with annual follow-up visits up to five years and we expect the pivotal trial for the Gastric Vest System to be similar. A US pivotal trial requires FDA Investigational Device Exemption (IDE) submission and approval. We expect to submit our IDE application to the FDA in the first quarter of 2018 and expect the first U.S. PMA implants of the Gastric Vest System to take place in the second quarter of 2018. Our goal is to obtain PMA approval by the end of 2020. We intend to initiate a CE Mark trial in the European Union of 50 to 100 patients with a six-month weight loss and safety endpoint with a minimum 12-month follow up. We expect the first EU implants will start in the first quarter of 2018. Our goal is to obtain CE mark approval by the second quarter of 2019.

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 June 30, 2017, we had a total of 41 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 June 30, 2017:

Name	Age	Position
Dan W. Gladney	64	President and Chief Executive Officer
Scott P. Youngstrom	57	Chief Financial Officer and Chief Compliance Officer
Rajesh Nihalani, M.D.	47	Chief Technology Officer
Naqeeb (Nick) A. Ansari	56	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 Compex 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.

Rajesh Nihalani, M.D. has served as our Chief Technology Officer since May 22, 2017, the date we completed our acquisition of BarioSurg, Inc. From August 2008 to May 2017, Dr. Nihalani served as the Chief Executive Officer of BarioSurg, Inc., a privately held medical device company that developed a minimally invasive and reversible device to treat obesity and glycemic control. Dr. Nihalani holds a medical degree from the University of Nagpur, India.

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 we 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 Current Report on Form 8-K and should not be considered a part of this Current Report on Form 8-K.

RISK FACTORS

Risks Related to Our Recently Completed Acquisition of BarioSurg

Our acquisition of BarioSurg in May 2017 could adversely affect our operations, financial results and financial condition.

In May 2017, we acquired BarioSurg, a privately held medical device company that developed the proprietary, minimally invasive and reversible device, the Gastric Vest System, to treat obesity and related comorbidities. In addition, we may pursue additional acquisitions of other companies or product lines. A successful acquisition depends on our ability to identify, negotiate, complete and integrate such acquisition and to obtain any necessary financing. With respect to our acquisition of BarioSurg and any future acquisitions, we may experience:

- difficulties in integrating the acquired businesses and their respective personnel and products into our existing business;
- difficulties in integrating commercial organizations;
- difficulties or delays in realizing the anticipated benefits of the acquisition;
- diversion of our management's time and attention from other business concerns;
- challenges due to limited or no direct prior experience in new markets or countries we may enter;
- inability to successfully develop new products and services on a timely basis that address our new market opportunities post-acquisition;
- inability to compete effectively against companies already serving the broader market opportunities expected to be available to us post-acquisition;
- unanticipated costs and other contingent liabilities; and
- any unforeseen compliance risks and accompanying financial and reputational exposure or loss not uncovered in the due diligence process and which are imputed to our company, such as compliance with federal laws and regulations, the advertising and promotion regulations under the federal Food, Drug and Cosmetic Act, the Anti-kickback Statute, the False Claims Act, the Physician Sunshine Payments Act and other applicable laws.

We have invested, and expect to continue to invest, significant cash and other resources in connection with our acquisition of BarioSurg and our development of the Gastric Vest System. The consideration we paid to acquire BarioSurg included $2 million in cash and our efforts to continue the development of, and to successfully commercialize, the Gastric Vest System will require significant cash expenditures. There can be no assurance that we will be successful in our efforts. Should we be unable to obtain adequate financing or generate sufficient revenue in the future, our business, result of operations, liquidity and financial condition could be materially and adversely harmed.

If we do not achieve the contemplated benefits of our acquisition of BarioSurg, our business and financial condition may be materially impaired.

We may not achieve the desired benefits from our acquisition of BarioSurg. For any of the reasons described above and elsewhere in this report and even if we are able to successfully operate BarioSurg within our company, we may not be able to realize the revenue and other growth that we anticipate from the acquisition in the time frame that we currently expect, and the costs of achieving these benefits may be higher than what we currently expect, because of a number of risks, including, but not limited to:

- the possibility that the acquisition may not further our business strategy as we expected;

- the possibility that we may not be able to obtain the required regulatory approvals for the Gastric Vest System; and
- the possibility that we may not be able to commercialize the Gastric Vest System.

As a result of these risks, we may not achieve the anticipated strategic and financial benefits of the BarioSurg acquisition.

Our proposed Gastric Vest System product is in the early stages of development. If the development of this product is not successfully completed or any required regulatory approvals are not obtained, the Gastric Vest System may not be commercialized and our business prospects may suffer.

The Gastric Vest System that we acquired as part of acquisition of BarioSurg is in the early stages of development and has not yet reached the clinical trial stage. Our ability to market the Gastric Vest System in the United States and abroad depends upon our ability to demonstrate the safety, and in the case of the United States, efficacy, of the product with clinical data to support our requests for regulatory approval. The Gastric Vest System may not be found to be safe and, where required, effective in clinical trials and may not ultimately be approved for marketing by U.S. or foreign regulatory authorities, which would have a negative impact on our net sales.

There is no assurance that we will be successful in achieving the desired results in our anticipated clinical trials for the Gastric Vest System or, if we do, that the FDA or other regulatory agencies will approve the product for sale without the need for additional clinical trial data to demonstrate safety and efficacy. We continually evaluate the potential financial benefits and costs of clinical trials and the products being evaluated in them. If we determine that the costs associated with obtaining regulatory approval of a product exceed the potential financial benefits of that product or if the projected development timeline is inconsistent with our investment horizon, we may choose to stop a clinical trial and/or the development of a product.

Our Board of Directors and executive officers are able to influence matters requiring stockholder approval and could discourage the purchase of our outstanding shares at a premium.

As of June 30, 2017, Dr. Raj Nihalani, the founder and former Chief Executive Officer of BarioSurg and our Chief Technology Officer, beneficially owned approximately 35% of our outstanding common stock (assuming the conversion of the shares of non-voting conditional convertible preferred stock issued in the merger into shares of voting common stock). Under a voting agreement entered into in connection with our acquisition of BarioSurg, Dr. Nihalani agreed to vote all shares of our common stock he owns in accordance with the recommendation of our Board of Directors and granted an irrevocable proxy to our Board of Directors to vote his shares in accordance with the terms of the voting agreement. Collectively, our directors and executive officers as a group beneficially own approximately 40% of our outstanding common stock. As a result of Dr. Nihalani's share ownership and the voting agreement and irrevocable proxy, our Board of Directors and executive officers are able to influence matters requiring stockholder approval, such as the election of directors and approval of significant corporate transactions. The interests of our Board of Directors and executive officers may differ from the interests of our other stockholders. For example, our Board of Directors and executive officers could oppose a third party offer to acquire us that the other stockholders might consider attractive. In such case and in similar situations, our other stockholders may disagree with our Board of Directors and executive officers as to whether the action opposed or supported by our Board of Directors and executive officers is in the best interest of our stockholders.

Under the terms of the merger agreement, we are required to seek stockholder approval of the conversion of the conditional convertible preferred stock issued in the merger into shares of common stock, which we may not be able to obtain.

In connection with the merger, we issued approximately 1.0 million shares of newly created non-voting conditional convertible preferred stock, which shares will convert into approximately 5.0 million shares of voting common stock subject to and contingent upon the post-closing approval of our stockholders in accordance with the NASDAQ Stock Market Rules. If our stockholders do not approve the conversion of the conditional convertible preferred stock into shares of common stock, under the terms of the merger agreement with BarioSurg, we will be required to continue to seek the requisite stockholder approval at subsequent annual or special meetings to be held at

least every six months until such approval is obtained, which would be time consuming and costly. Until we obtain the requisite stockholder approval, the convertible preferred stock will remain outstanding in accordance with its terms. In general, the convertible preferred stock is entitled to receive dividends (on an as-if-converted-to-common stock basis) actually paid on shares of common stock when, as and if such dividends are paid on shares of common stock. No other dividends will be paid on shares of convertible preferred stock. While the convertible preferred stock generally does not have voting rights, as long as any shares of convertible preferred stock remain outstanding, we cannot, without the affirmative vote of holders of a majority of the then-outstanding shares of convertible preferred stock, (a) alter or change adversely the powers, preferences or rights given to the convertible preferred stock or alter or amend the certificate of designation, (b) amend our certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of convertible preferred stock, (c) increase the number of authorized shares of convertible preferred stock or (d) enter into any agreement with respect to any of the foregoing. In the event of a liquidation, the holders of shares of convertible preferred stock are entitled to participate on an as-converted-to-common stock basis with holders of the common stock in any distribution of our assets to the holders of common stock. In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common shares are converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock, then following such event, the holders of the convertible preferred stock will be entitled to receive upon conversion of the convertible preferred stock the same kind and amount of securities, cash or property which the holders would have received had they converted the convertible preferred stock immediately prior to such fundamental transaction.

Risks Related to Our Business and Industry

If we are unsuccessful in our pursuit of various funding options, we will be unable to continue as a going concern.

Management is currently pursuing various funding options, including seeking additional equity financing, to continue the development of, and to successfully commercialize, the vBloc System and the Gastric Vest System. There can be no assurance that we will be successful in our efforts. Should we be unable to obtain adequate financing or generate sufficient revenue in the future, our business, result of operations, liquidity and financial condition would be materially and adversely harmed, and we would be unable to continue as a going concern. Additionally, there can be no assurance that, assuming we are able to strengthen our cash position, we will achieve sufficient revenue or profitable operations to continue as a going concern.

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 vBloc System in the United States on January 14, 2015 and we have had commercial sales within the United States since 2015. We have also completed the regulatory process required to sell our vBloc System 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 or regulatory approvals needed to market our recently acquired Gastric Vest 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 or develop and commercialize the Gastric Vest System, 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, develop the Gastric Vest System, 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 development and commercialization of our products and on research and development, including conducting current and future clinical trials for our vBloc System, Gastric Vest System and subsequent versions of our products. 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 the vBloc System, to develop the Gastric Vest System, 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, our Gastric Vest System and any products that we may develop;
- the rate of market acceptance of our vBloc System and vBloc Therapy, our Gastric Vest System 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, our Gastric Vest 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.

Congress is considering 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 and Gastric Vest System

Our efforts to commercialize our vBloc System and our Gastric Vest 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 and our Gastric Vest System. Our efforts to commercialize these products may not succeed for a number of reasons, including:

- we may not be able to obtain the regulatory approvals required for our Gastric Vest System or for any future modifications to our vBloc System;
- our products may not be accepted in the marketplace by physicians, patients and third-party payers;
- the price of our our products, 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 products 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 products;
- physicians and potential patients may not be aware of the perceived effectiveness and sustainability of the results of our products;

- we, or the investigators of our products, 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 products obsolete;
- we may not be able to have our products 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 products or to develop sales and marketing capabilities for our products; 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 products will depend on successfully communicating the benefits of our products to three additional constituencies involved in deciding whether to treat a particular patient using our products: (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 and Gastric Vest System. 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 products to be successful.

If our products, or any other therapy or products for other gastrointestinal diseases and disorders that we may develop, do 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 for our vBloc System 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 may not be able to obtain required regulatory approvals for our Gastric Vest System in a cost-effective manner or at all, which could adversely affect our business and operating results.

The production and marketing of our Gastric Vest System and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U.S. and foreign regulations applicable to medical devices are wide-ranging and govern, among other things, the development, testing, marketing and premarket review of new medical devices, in addition to regulating manufacturing practices, reporting, advertising, exporting, labeling and record keeping procedures. We are required to obtain FDA approval or clearance before we can market our Gastric Vest System in the United States and certain foreign countries. The regulatory process requires significant time, effort and expenditures to bring products to market, and it is possible that our Gastric Vest System will not be approved for sale. Even if regulatory approval or clearance of a product is granted, it may not be granted within the timeframe that we expect, which could have an adverse effect on our operating results and financial condition. In addition, even if regulatory approval or clearance of a product is granted, the approval or clearance could limit the uses for which the product may be labeled and promoted, which may limit the market for our Gastric Vest System. Even after a product is approved or cleared by the FDA, we may have ongoing responsibilities under FDA regulations, non-compliance of which could result in the subsequent withdrawal of such approvals or clearances, or such approvals or clearances could be withdrawn due to the occurrence of unforeseen problems following initial approval. We also are subject to medical device reporting

regulations that require us to report to the FDA if any of our products causes or contributes to a death or serious injury or if a malfunction were it to occur might cause or contribute to a death or serious injury. Any failure to obtain regulatory approvals or clearances on a timely basis or the subsequent withdrawal of such approvals or clearances could prevent us from successfully marketing our products, which could adversely affect our business and operating results.

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 products 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 products 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 and the development of our Gastric Vest 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 develop our Gastric Vest System, 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 products cause, or appear 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 products 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 products and to perform the related therapy. If these medical personnel are not properly trained or are negligent, the therapeutic effect of our products 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 and our Gastric Vest System 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 and the treatment of obesity. We have also received or applied for patents in

Europe, Australia, China, India, Japan, Israel and Canada. 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 or our Gastric Vest 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 June 30, 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 products 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 and shares received by the former BarioSurg equity holders in connection with the merger, which may be subject to holding period, volume and other limitations under Rule 144. 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.

Offers or availability for sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.

The shares of common stock issued to the former BarioSurg equity holders in connection with the merger were issued in a transaction intended to be exempt from registration under the Securities Act of 1933. Therefore, those shares are not currently freely tradable under the federal securities laws. We may also issue additional registered or unregistered shares of our common stock in conection with acquisitions or corporate alliances. If our stockholders sell substantial amounts of our common stock in the public market upon the expiration of any statutory holding period under Rule 144, it could create a circumstance commonly referred to as an "overhang" and in anticipation of which the market price of our common stock could fall. The existence of an overhang, whether or not sales have occurred or are occurring, also could make more difficult our ability to raise additional financing through the sale of equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate.

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.

In addition, we issued approximately 1.0 million shares of newly created non-voting conditional convertible preferred stock, which shares will convert into approximately 5.0 million shares of voting common stock subject to and contingent upon the post-closing approval of our stockholders in accordance with the NASDAQ Stock Market Rules. If our stockholders do not approve the conversion of the conditional convertible preferred stock into shares of common stock, under the terms of the merger agreement with BarioSurg, we will be required to continue to seek the requisite stockholder approval at subsequent annual or special meetings to be held at least every six months until such approval is obtained, which would be time consuming and costly. Until we obtain the requisite stockholder approval, the convertible preferred stock will remain outstanding in accordance with its terms.

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.