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

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**Form 10-Q**

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

For the quarterly period ended March 31, 2016

Commission file number: 1-33818

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**ENTEROMEDICS INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**48-1293684**  
(IRS Employer  
Identification No.)

**2800 Patton Road, St. Paul, Minnesota 55113**  
(Address of principal executive offices, including zip code)

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

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

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

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

Large accelerated filer

Accelerated Filer

Non-accelerated filer  (Do not check if a smaller reporting entity)

Smaller Reporting Company

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

As of April 29, 2016, 9,254,451 shares of the registrant's Common Stock were outstanding.

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**Registered Trademarks and Trademark Applications:** In the United States we have registered trademarks for VBLOC®, ENTEROMEDICS® and MAESTRO®, each registered with the United States Patent and Trademark Office, and trademark applications for VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN. In addition, some or all of the marks VBLOC, ENTEROMEDICS, MAESTRO, MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS, VBLOC POWER TO CHOOSE and VBLOC POWER TO CHOOSE AND DESIGN are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community, India, Kuwait, Mexico, Saudi Arabia, Switzerland and the United Arab Emirates. This Quarterly Report on Form 10-Q contains other trade names and trademarks and service marks of EnteroMedics and of other companies.

## PART I – FINANCIAL INFORMATION

## ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ENTEROMEDICS INC.  
Condensed Consolidated Balance Sheets  
(Unaudited)

	March 31, 2016	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,153,525	\$ 7,927,240
Accounts receivable	55,000	57,928
Inventory	1,868,206	1,686,324
Prepaid expenses and other current assets	873,531	831,495
Total current assets	13,950,262	10,502,987
Property and equipment, net	298,447	326,296
Other assets	606,291	757,802
Total assets	<u>\$ 14,855,000</u>	<u>\$ 11,587,085</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Current portion of convertible notes payable	\$ 5,639,752	\$ 717,391
Accounts payable	261,447	172,050
Accrued expenses	3,483,280	3,595,415
Accrued interest payable	—	1,172
Total current liabilities	9,384,479	4,486,028
Convertible notes payable, less current portion (net of discounts of \$533,110 and \$149,340 at March 31, 2016 and December 31, 2015, respectively)	5,116,248	549,791
Common stock warrant liability	1,613,560	2,877,817
Total liabilities	<u>16,114,287</u>	<u>7,913,636</u>
Commitments and contingencies (note 5)		
Stockholders' equity:		
Common stock, \$0.01 par value; 150,000,000 and 13,333,333 shares authorized at March 31, 2016 and December 31, 2015, respectively; 8,499,651 and 7,163,820 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	84,997	71,638
Additional paid-in capital	283,645,016	281,182,349
Accumulated deficit	<u>(284,989,300)</u>	<u>(277,580,538)</u>
Total stockholders' (deficit) equity	<u>(1,259,287)</u>	<u>3,673,449</u>
Total liabilities and stockholders' equity	<u>\$ 14,855,000</u>	<u>\$ 11,587,085</u>

See accompanying notes to condensed consolidated financial statements.

**ENTEROMEDICS INC.**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Sales	\$ 72,000	\$ —
Cost of goods sold	40,135	—
Gross profit	31,865	—
Operating expenses:		
Selling, general and administrative	6,141,177	4,727,519
Research and development	1,432,381	2,236,606
Total operating expenses	7,573,558	6,964,125
Operating loss	(7,541,693)	(6,964,125)
Other income (expense):		
Interest income	1,691	867
Interest expense	(1,149,294)	(214,546)
Change in value of convertible notes payable	(499,568)	—
Change in value of warrant liability	1,779,414	—
Other, net	688	3,781
Net loss	\$(7,408,762)	\$(7,174,023)
Net loss per share – basic and diluted	\$ (0.94)	\$ (1.48)
Shares used to compute basic and diluted net loss per share	7,840,992	4,849,061

See accompanying notes to condensed consolidated financial statements.

**ENTEROMEDICS INC.**  
**Condensed Consolidated Statements of Comprehensive Loss**  
**(Unaudited)**

	<b>Three months ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
Net loss	\$(7,408,762)	\$(7,174,023)
Comprehensive loss	\$(7,408,762)	\$(7,174,023)

See accompanying notes to condensed consolidated financial statements.

**ENTEROMEDICS INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**

	<b>Three months ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (7,408,762)	\$ (7,174,023)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	39,393	48,651
Stock-based compensation	1,092,488	1,372,076
Amortization of commitment fees, debt issuance costs and original issue discount	815,421	165,291
Change in value of convertible notes payable	499,568	—
Change in value of warrant liability	(1,779,414)	—
Change in operating assets and liabilities:		
Accounts receivable	2,928	1,334
Inventory	(181,882)	(145,778)
Prepaid expenses and other current assets	(42,036)	(41,313)
Other assets	(87,520)	(138,417)
Accounts payable	89,397	(347,163)
Accrued expenses	(112,135)	642,993
Accrued interest payable	174,148	(4,302)
Net cash used in operating activities	<u>(6,898,406)</u>	<u>(5,620,651)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(11,544)	(18,656)
Net cash used in investing activities	<u>(11,544)</u>	<u>(18,656)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from sale of common stock and warrants for purchase of common stock	—	6,651,931
Common stock financing costs	(14,000)	(199,557)
Proceeds from convertible notes payable	11,000,000	—
Repayments on convertible notes payable	(404,762)	—
Repayments on notes payable	—	(1,000,000)
Debt issuance costs	(445,003)	—
Net cash provided by financing activities	<u>10,136,235</u>	<u>5,452,374</u>
Net increase (decrease) in cash and cash equivalents	<u>3,226,285</u>	<u>(186,933)</u>
<b>Cash and cash equivalents:</b>		
Beginning of period	7,927,240	11,619,167
End of period	<u>\$11,153,525</u>	<u>\$11,432,234</u>
<b>Supplemental disclosure:</b>		
Cash paid for interest	\$ 163,152	\$ 53,556
<b>Noncash investing and financing activities:</b>		
Conversion of convertible notes and interest payable	\$ 1,397,538	\$ —

See accompanying notes to condensed consolidated financial statements.

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

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

***Description of Business***

EnteroMedics Inc. (the Company) develops and sells implantable systems to treat obesity, metabolic diseases and other gastrointestinal disorders. The Company was incorporated in the state of Minnesota on December 19, 2002 and was reincorporated in Delaware on July 22, 2004. The Company is headquartered in St. Paul, Minnesota. In January 2006, the Company established EnteroMedics Europe S arl, a wholly-owned subsidiary located in Switzerland.

The Company's board of directors and stockholders approved a 1-for-15 reverse split (the Reverse Stock Split) of the Company's outstanding common stock that became effective after trading on January 6, 2016. The Reverse Stock Split did not change the par value of the Company's stock or the number of preferred shares authorized by the Company's Fifth Amended and Restated Certificate of Incorporation. An amendment to the Certificate of Incorporation was also approved in connection with the Reverse Stock Split to increase the number of shares of the Company's common stock authorized for issuance to 150 million shares, effective immediately after the Reverse Stock Split on January 6, 2016. All share and per share amounts have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

***Risks and Uncertainties***

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

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

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

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

***Basis of Presentation***

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

The accompanying condensed consolidated financial statements and notes thereto are unaudited. In the opinion of the Company's management, these statements include all adjustments, which are of a normal recurring nature, necessary to present a fair presentation. Interim results are not necessarily indicative of results for a full year. The condensed consolidated balance sheet as of December 31, 2015 was derived from audited consolidated financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. The information included in this Form 10-Q should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

***Use of Estimates***

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

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

***Principles of Consolidation***

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

***Fair Value of Financial Instruments***

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, accounts receivable, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. The Company's common stock warrants are required to be reported at fair value and the Company has elected to report its senior amortizing convertible notes at fair value. The fair values of common stock warrants and investments in debt and equity securities, if any, are disclosed in Note 3. The fair value of the Company's senior amortizing convertible notes is disclosed in Notes 3 and 7.

***Common Stock Warrant Liability***

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

***Cash and Cash Equivalents***

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

***Short-Term Investments***

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

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

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

***Inventory***

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

***Property and Equipment, Net***

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

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

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

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

***Income Taxes***

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

***Medical Device Excise Tax***

On January 14, 2015, the Company received FDA approval for vBloc Therapy, delivered via the Maestro Rechargeable System, and starting in the second quarter of 2015 revenues were generated from sales in the United States. As a result, the Company is now required to pay a quarterly Medical Device Tax which is a part of the Affordable Care Act, which imposes a 2.3% excise tax on the sale of certain medical devices by device manufacturers, producers or importers. The excise tax was effective on sales of devices made after December 31, 2012. The Company records the Medical Device Tax as an operating expense in the condensed consolidated statements of operations. A moratorium was placed on the Medical Device Tax for 2016 and 2017.

***Comprehensive Loss***

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

***Revenue Recognition***

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

***Research and Development Expenses***

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

***Net Loss Per Share***

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

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

The following table sets forth the computation of basic and diluted net loss per share for the three months ended March 31, 2016 and 2015:

	Three months ended	
	March 31,	
	2016	2015
Numerator:		
Net loss	\$(7,408,762)	\$(7,174,023)
Denominator for basic and diluted net loss per share:		
Weighted-average common shares outstanding	7,840,992	4,849,061
Net loss per share—basic and diluted	\$ (0.94)	\$ (1.48)

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

	March 31,	
	2016	2015
Stock options outstanding	1,953,859	948,675
Warrants to purchase common stock	4,476,839	1,613,133

### **Recently Issued or Adopted Accounting Standards**

In March 2016, the Financial Accounting Standards Board (FASB) issued *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (Accounting Standards Update No. 2016-09 (ASU 2016-09))*. ASU 2016-09 modifies several aspects of the accounting for share-based payment awards, including income tax consequences, and classification on the statement of cash flows. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2016. The Company is currently evaluating the impact of adopting ASU 2016-09 on its consolidated financial statements.

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))*, which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2017. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

There have been no other significant changes in recent accounting pronouncements during the three months ended March 31, 2016 as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2015.

### **(2) Liquidity and Management's Plans**

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. The Company has financed its operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of March 31, 2016, the Company had \$11.2 million of cash and cash equivalents to fund its anticipated operations through 2016. On November 4, 2015, the Company entered into a securities purchase agreement (the Purchase Agreement) with institutional investors to issue \$25.0 million of senior amortizing convertible notes (the Notes) along with the accompanying warrants. \$1.5 million of the Notes was funded at the first closing on November 9, 2015. An additional \$11.0 million of the Notes was funded at the second closing on January 11, 2016. Pursuant to an amendment to the Purchase Agreement (the Amendment) entered into on May 2, 2016, the remaining \$12.5 million will be funded at two separate closings, with \$6.25 million of

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

the Notes funded on May 2, 2016 and the remaining \$6.25 million to be funded at a later date. Additionally, the Company has agreed that it will not, for a period of one year after the first closing, issue any further securities, other than certain excluded securities. The Company's anticipated operations include plans that consider the controlled commercial launch of vBloc Therapy, delivered via the Maestro Rechargeable System, which was approved by the FDA on January 14, 2015. The Company believes that it has the flexibility to manage the growth of its expenditures and operations.

**(3) Short-term Investments and Fair Value Measurements**

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

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

The Company's assets that are measured at fair value on a recurring basis are classified within Level 1 or Level 2 of the fair value hierarchy. The Company does not hold any assets that are measured at fair value using Level 3 inputs. The types of instruments the Company invests in that are valued based on quoted market prices in active markets may include U.S. treasury securities and money market funds. Such instruments are classified by the company within Level 1 of the fair value hierarchy. U.S. treasuries are valued using unadjusted quoted prices for identical assets in active markets that the Company can access.

The types of instruments the Company invests in that are valued based on quoted prices in less active markets, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency include the Company's U.S. agency securities, commercial paper, U.S. corporate bonds and municipal obligations. Such instruments are classified by the Company within Level 2 of the fair value hierarchy. The Company values these types of assets using consensus pricing or a weighted average price, which is based on multiple pricing sources received from a variety of industry standard data providers (e.g. Bloomberg), security master files from large financial institutions, and other third-party sources. The multiple prices obtained are then used as inputs into a distribution-curve-based algorithm to determine the daily market price.

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

The fair value of the Company's common stock warrant liability is calculated using a Black-Scholes valuation model and is classified as Level 2 in the fair value hierarchy. The common stock warrants issued July 8, 2015 had a fair value of \$1,198,689 and \$2,759,583 on March 31, 2016 and December 31, 2015, respectively. The common stock warrants issued November 9, 2015 had a fair value of \$75,670 and \$118,234 on March 31, 2016 and December 31, 2015, respectively. The common stock warrants issued January 11, 2016 had a fair value of \$339,201 and \$515,157 on March 31, 2016 and January 11, 2016, respectively. The fair value was calculated using the following assumptions:

	July 2015 Warrants		November 2015 Warrants		January 2016 Warrants	
	March 31, 2016	December 31, 2015	March 31, 2016	December 31, 2015	March 31, 2016	January 11, 2016
Risk-free interest rates	0.87%	1.31%	1.21%	1.76%	1.21%	1.58%
Expected life	33 months	36 months	55 months	58 months	57 months	60 months
Expected dividends	0%	0%	0%	0%	0%	0%
Expected volatility	91.15%	97.94%	91.42%	86.27%	90.04%	85.90%

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

The following table summarizes fair value measurements of the senior amortizing convertible notes and the common stock warrants issued in 2015 and during the three months ended March 31, 2016 by level at March 31, 2016:

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Senior amortizing convertible notes	\$ —	\$ —	\$10,756,000	\$10,756,000
Common stock warrants	—	1,613,560	—	1,613,560
<b>Total</b>	<u>\$ —</u>	<u>\$1,613,560</u>	<u>\$10,756,000</u>	<u>\$12,369,560</u>

As of March 31, 2016, the Company converted \$1,507,042 of senior amortizing convertible notes principal and interest into shares of common stock. There was a \$499,568 loss resulting from the senior amortizing convertible notes recognized in the condensed consolidated statements of operations for the three months ended March 31, 2016.

#### (4) Inventory

From the Company's inception, inventory related purchases had been used for research and development related activities and had accordingly been expensed as incurred. In December 2011, the Company began receiving ARTG listings for components of the Maestro Rechargeable System from the Australian Therapeutic Goods Administration, with the final components being listed on the ARTG in January 2012. As a result, the Company determined certain assets were recoverable as inventory beginning in December 2011. The Company accounts for inventory at the lower of cost or market and records any long-term inventory as other assets in the condensed consolidated balance sheets. There was approximately \$606,000 and \$519,000 of long-term inventory, primarily consisting of raw materials, as of March 31, 2016 and December 31, 2015, respectively.

Current inventory consists of the following as of:

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
Raw materials	\$ 527,471	\$ 576,898
Work-in-process	1,296,525	1,066,345
Finished goods	44,210	43,081
<b>Inventory</b>	<u>\$1,868,206</u>	<u>\$ 1,686,324</u>

#### (5) Commitments and Contingencies

##### *Operating Lease*

The Company rents its office, warehouse and laboratory facilities under an operating lease, which was originally set to expire on September 30, 2015. On August 25, 2015, the Company entered into an amendment extending the term of the operating lease for three years until September 30, 2018, with monthly base rent ranging from \$18,925 to \$20,345. Total rent expense recognized for each of the three month periods ended March 31, 2016 and 2015 was \$58,905 and \$67,718, respectively. At March 31, 2016, future minimum payments under the lease are as follows:

<u>Year ending December 31:</u>	
Remaining nine months in 2016	\$172,457
2017	237,749
2018	183,103
	<u>\$593,309</u>

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

***Product Liability Claims***

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

***Clinical Trials***

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

**(6) Notes Payable**

On April 16, 2012, the Company entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank (SVB) pursuant to which SVB agreed to make term loans in an aggregate principal amount of up to \$20.0 million (\$10.0 million of which was not available as the Company did not meet the predefined primary efficacy measures of the ReCharge trial and did not meet certain financial objectives for 2012), on the terms and conditions set forth in the Loan Agreement.

Pursuant to the Loan Agreement, a term loan was funded in the aggregate principal amount of \$10.0 million on April 23, 2012, a portion of which was used to repay in full outstanding debt of approximately \$4.7 million. The term loan required interest only payments monthly through March 31, 2013 followed by 30 equal payments of principal in the amount of \$333,333 plus accrued interest beginning on April 1, 2013 and ending on September 1, 2015, payable monthly. Amounts borrowed under the Loan Agreement bore interest at a fixed annual rate equal to 8.0%. The Company entered into a First Amendment (the First Amendment) to the Loan Agreement on May 9, 2013 pursuant to which the Company and SVB agreed to new financial covenants.

The First Amendment eliminated the financial covenants that required the Company to generate certain minimum amounts of revenue from the sale of its Maestro Rechargeable System and to implant certain minimum numbers of Maestro Rechargeable Systems during cumulative quarterly measurement periods beginning with the period ended March 31, 2013 and ending with the period ended June 30, 2015. It also removed SVB's ability to require the Company to maintain a restricted cash balance of \$7.5 million in an SVB account as a result of the Company not meeting the predefined primary efficacy measures of the ReCharge trial.

The First Amendment added two new financial covenants, one of which required the Company to receive cumulative aggregate net proceeds of at least \$5.0 million by November 15, 2013 and \$10.0 million by April 15, 2014 from new capital transactions, both of which were fulfilled. The second financial covenant required the Company to maintain a liquidity ratio (unrestricted cash divided by outstanding debt) of at least 1.25:1.00 until it received FDA approval for the Maestro Rechargeable System on January 14, 2015, at which point it was reduced to 0.75:1.00. The First Amendment did not change the interest rate or the amortization structure. A 5.0% final payment fee of \$500,000 was due and paid on September 1, 2015. The Company also paid SVB a \$187,000 success fee as a result of receiving FDA approval for the Maestro Rechargeable System.

The Company had granted SVB a security interest in all of the Company's assets, excluding intellectual property except with respect to all license, royalty fees and other revenues and income arising out of or relating to any of the intellectual property and all proceeds of the intellectual property. The Company also had entered into a negative pledge arrangement with SVB pursuant to which it had agreed not to encumber any of its intellectual property without SVB's prior written consent.

Pursuant to the Loan Agreement, on April 16, 2012, the Company issued SVB a warrant to purchase 7,116 shares of common stock, exercisable for ten years from the date of grant, at an exercise price of \$35.10 per share.

The final payment related to the Loan Agreement, as amended, was paid on September 1, 2015.

**(7) Senior Amortizing Convertible Notes**

On November 4, 2015, the Company entered into the Purchase Agreement to issue and sell to four institutional investors 7% senior amortizing convertible notes due 2017 that are convertible into shares of the Company's common stock at a price equal to \$4.35 per share with an aggregate principal amount of \$25.0 million. Each Note was sold with a warrant to purchase a share of common stock (the

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

Warrants) with an exercise price of \$4.65 per share. The Company issued and sold Notes and Warrants for aggregate total proceeds of \$12.5 million in two separate closings through March 31, 2016 and pursuant to the Amendment, issued and sold Notes and Warrants for aggregate total proceeds of \$6.25 million in the third closing, which occurred on May 2, 2016. The Company will issue and sell Notes and Warrants for aggregate total proceeds of \$6.25 million in the fourth and final closing.

**Description of the Notes**

The Notes are payable in monthly installments, accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the First Closing (defined below), unless converted or redeemed earlier. The Notes may be repaid, at the Company's election, in either cash or shares of the Company's common stock at a discount to the then-current market price. The Notes are also convertible from time to time, at the election of the holders, into shares of the Company's common stock at an initial conversion price of \$4.35 per share. The conversion price was adjusted to \$1.09 per share on January 29, 2016, the 16th trading day following the Reverse Stock Split, per the terms of the Notes.

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

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

The first of the four closings (the First Closing) occurred on November 9, 2015. At the First Closing, the Company issued and sold Notes with an aggregate principal amount of \$1.5 million, along with Warrants exercisable for 117,520 shares. The fair value of the Warrants issued on November 9, 2015 was determined to be \$169,000 using a Black-Scholes valuation model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 84.85%; (3) weighted average risk-free interest rate of 1.75%; and (4) expected life of 5.0 years.

The second of the four closings (the Second Closing) occurred on January 11, 2016 after the Company received approval of the offering by the Company's stockholders and the satisfaction of certain customary closing conditions. At the Second Closing, the Company issued and sold Notes with an aggregate principal amount of \$11.0 million, along with Warrants exercisable for 861,842 shares. The fair value of the Warrants issued on January 11, 2016 was determined to be \$515,000 using a Black-Scholes valuation model and the following assumptions: (1) dividend yield of 0%; (2) expected volatility of 85.90%; (3) weighted average risk-free interest rate of 1.58%; and (4) expected life of 5.0 years.

The third of the four closings (the Third Closing) occurred on May 2, 2016 after the Company entered into the Amendment. At the Third Closing, the Company issued and sold Notes with an aggregate principal amount of \$6.25 million, along with Warrants exercisable for 489,684 shares.

At the final of the four closings (the Fourth Closing) the Company will issue and sell Notes with an aggregate principal amount of \$6.25 million, along with Warrants exercisable for 489,682 shares.

On March 31, 2016 and December 31, 2015, the fair value of the outstanding Notes from the First Closing was determined to be \$1.2 million and \$1.3 million, respectively. On March 31, 2016 and January 11, 2016, the fair value of the outstanding Notes from the Second Closing was determined to be \$9.5 million and \$9.9 million, respectively. The fair values were calculated using a Binomial Lattice model and the following assumptions:

	November 2015 Notes		January 2016 Notes	
	March 31, 2016	December 31, 2015	March 31, 2016	January 11, 2016
Risk-free interest rates	0.68%	1.11%	0.68%	1.01%
Expected life	1.61 years	1.86 years	1.61 years	1.83 years
Expected dividends	0%	0%	0%	0%
Expected volatility	65.0%	57.5%	65.0%	60.0%
Fair value per share of common stock	\$ 0.97	\$ 1.95	\$ 0.97	\$ 1.33

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the First Closing through March 31, 2016:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>	<u>Common Shares</u>
Installment amount at December 31, 2015	\$ 65,217	\$23,651	\$ 88,868	56,967
Holder conversions during the quarter ended December 31, 2015	18,261	2,375	20,636	13,228
<b>Balance December 31, 2015</b>	<b>83,478</b>	<b>26,026</b>	<b>109,504</b>	<b>70,195</b>
Installment amount at February 29, 2016	65,217	23,681	88,898	91,953
Installment amount at March 31, 2016	65,217	14,827	80,044	88,960
Holder conversions during the quarter ended March 31, 2016	104,784	12,762	117,546	106,684
<b>Balance, March 31, 2016</b>	<b>\$318,696</b>	<b>\$77,296</b>	<b>\$395,992</b>	<b>357,792</b>

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the Second Closing through March 31, 2016:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>	<u>Common Shares</u>
Installment amount at March 2, 2016	\$ 404,762	\$149,300	\$ 554,062	*
Holder conversions during the quarter ended March 31, 2016	987,000	124,050	1,111,050	1,048,167
<b>Balance, March 31, 2016</b>	<b>\$1,391,762</b>	<b>\$273,350</b>	<b>\$1,665,112</b>	<b>1,048,167</b>

\* Cash payments

**Description of the Warrants**

Each Warrant is exercisable immediately and for a period of 60 months from the date of the issuance of the Warrant. The Warrants entitle the holders of the Warrants to purchase, in aggregate, 1,958,728 shares of the Company's common stock upon the completion of the Fourth Closing, subject to certain adjustments. The Warrants are initially exercisable at an exercise price equal to \$4.65, subject to adjustment on the eighteen month anniversary of issuance, and certain other adjustments. The exercise price and number of shares of common stock issuable on the exercise of the Warrants is subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of each Warrant does not have the right to exercise any portion of such Warrant if the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing notice to the Company.

The exercise price of the Warrants issued November 9, 2015 was reduced to \$1.09 per share on January 29, 2016, the 16<sup>th</sup> trading day following the Reverse Stock Split, per the terms of the Warrants. The exercise price of the Warrants issued January 11, 2016 and May 2, 2016 remains \$4.65 per share per the terms of the Warrants. All of the Warrants issued with the Notes remain subject to adjustment on the eighteen month anniversary of issuance.

**(8) Stock-based Compensation**

The fair value method of accounting for share-based payments is applied to all share-based payment awards issued to employees and where appropriate, nonemployees, unless another source of literature applies. When determining the measurement date of a

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

nonemployee's share-based payment award, the Company measures the stock options at fair value and remeasures such stock options to the current fair value until the performance date has been reached.

Based on the application of these standards, stock-based compensation expense for stock-based awards under the Company's Amended and Restated 2003 Stock Incentive Plan (the Plan) and inducement grants for the three months ended March 31, 2016 and 2015 was allocated to operating expenses and employees and nonemployees as follows:

	Three months ended March 31,	
	2016	2015
Selling, general and administrative	\$ 839,777	\$1,036,446
Research and development	252,711	335,630
<b>Total</b>	<b>\$1,092,488</b>	<b>\$1,372,076</b>

	Three months ended March 31,	
	2016	2015
Employees	\$1,090,192	\$1,387,924
Nonemployees	2,296	(15,848)
<b>Total</b>	<b>\$1,092,488</b>	<b>\$1,372,076</b>

As of March 31, 2016 there was approximately \$5.1 million of total unrecognized compensation costs, net of estimated forfeitures, related to employee unvested stock option awards, which are expected to be recognized over a weighted-average period of 2.57 years.

The estimated grant-date fair values of the stock options were calculated using the Black-Scholes valuation model, based on the following assumptions for the three months ended March 31, 2016 and 2015:

	Employees	
	Three months ended March 31,	
	2016	2015
Risk-free interest rates	1.16%-1.64%	1.65%-1.80%
Expected life	5.00-6.25 years	6.25 years
Expected dividends	0%	0%
Expected volatility	88.43%-92.24%	110.32%-111.77%

  

	Nonemployees	
	Three months ended March 31,	
	2016	2015
Risk-free interest rates	1.11%	0.03%-1.77%
Expected life	4.39 years	0.25-8.51 years
Expected dividends	0%	0%
Expected volatility	92.41%	37.36%-131.49%

Option activity under the Plan for the three months ended March 31, 2016 was as follows:

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
**(Unaudited)**

	Shares Available For Grant	Outstanding Options	
		Number of Shares	Weighted-Average Exercise Price
<b>Balance, December 31, 2015</b>	296,579	1,018,752	\$ 32.83
Shares reserved	—	—	—
Options granted	(53,333)	53,333	1.07
Options exercised	—	—	—
Options cancelled	14,893	(14,893)	5.10
<b>Balance, March 31, 2016</b>	<u>258,139</u>	<u>1,057,192</u>	\$ 31.62

In addition to the stock options granted pursuant to the Plan, the Company has also granted inducement stock options in connection with the appointments of Mr. Gladney to the position of President and Chief Executive Officer on October 28, 2015, Mr. Ansari to the position of Senior Vice President (SVP) of Sales on January 6, 2016, Mr. Delange to the position of SVP of Operations and Business Development on January 18, 2016 and Mr. Hickey to the position of SVP of Marketing and Reimbursement on January 18, 2016. Mr. Gladney was granted an option to purchase 516,666 shares of the Company's common stock as an inducement grant, with an exercise price of \$3.75 per share, the closing price of the Company's common stock on October 28, 2015. Mr. Delange was granted an option to purchase 166,667 shares of the Company's common stock as an inducement grant, with an exercise price of \$1.38 per share, the closing price of the Company's common stock on January 18, 2016. Mr. Ansari was granted an option to purchase 106,667 shares of the Company's common stock as an inducement grant, with an exercise price of \$1.31 per share, the closing price of the Company's common stock on January 19, 2016. Mr. Hickey was granted an option to purchase 106,667 shares of the Company's common stock as an inducement grant, with an exercise price of \$1.32 per share, the closing price of the Company's common stock on January 22, 2016. Each of the inducement grants will vest as follows: 25% of the shares will vest as of one year from the date of the officer's employment agreement, and the remaining 75% of the shares will then vest in equal 2.0833% installments each month thereafter for 36 months.

#### (9) Stock Sales

##### *Sales Agreement—July 2015*

On July 8, 2015, the Company closed a public offering, where it sold 2,133,333 units at an aggregate price of \$7.50 per unit, for gross proceeds of \$16.0 million before deducting estimated offering expenses of approximately \$1.4 million, of which \$532,000 was assigned to the warrants issued with each unit sold and was recognized immediately as interest expense in the condensed consolidated statements of operations as the warrants are exercisable upon issuance. Each unit consisted of: (A)(i) one share of common stock or (ii) one pre-funded Series C warrant to purchase one share of common stock at an exercise price equal to \$7.50 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price initially equal to \$9.00 per share (Series A Warrant). Each purchaser of a unit could elect to receive a Series C Warrant in lieu of a share of common stock. No Series C Warrants were issued.

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

The exercise price of the Series A Warrants issued July 8, 2015 was reduced to \$2.40 per share on November 9, 2015 as a result of the issuance of the Notes and was further reduced to \$1.50 per share on December 31, 2015, \$0.97 per share on January 29, 2016 and \$0.88 on March 30, 2016 after installment payments on the Notes were made.

##### *Sales Agreement—June 2014*

On June 13, 2014, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of the Company's common stock having aggregate gross sales proceeds of up to \$25.0 million, from time to time, through an ATM under which Cowen will act as the Company's sales agent (the Cowen ATM). The Company will determine, at its sole discretion, the timing and number of shares to be sold under the Cowen ATM. The Company will pay Cowen a commission for its services in acting as

**EnteroMedics Inc.**  
**Notes to Condensed Consolidated Financial Statements (Continued)**  
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agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of March 31, 2016, the Company had sold 367,903 shares under the Cowen ATM at a weighted-average selling price of \$20.60 per share for gross proceeds of \$7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM subsequent to March 31, 2016 through May 10, 2016. The Company is restricted from issuing shares under the Cowen ATM until November 9, 2016 per the terms of the Notes (see Notes 2 and 7).

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion should be read in conjunction with the condensed consolidated financial statements and notes thereto appearing elsewhere in this Quarterly Report on Form 10-Q.*

*Except for the historical information contained herein, the matters discussed in this "Management's Discussion and Analysis of Financial Condition and Results of Operations," are forward-looking statements that involve risks and uncertainties. In some cases, these statements may be identified by terminology such as "may," "will," "should," "expects," "could," "intends," "might," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue," or the negative of such terms and other comparable terminology. These statements involve known and unknown risks and uncertainties that may cause our results, level of activity, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Factors that may cause or contribute to such differences include, among others, those discussed in Part I, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2015. Except as may be required by law, we undertake no obligation to update any forward-looking statement to reflect events after the date of this report.*

### Overview

We are a medical device company with approvals to commercially launch our product, the Maestro Rechargeable System, in the United States, Australia, the European Economic Area and other countries that recognize the European CE Mark. We are focused on the design and development of devices that use neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders. Our proprietary neuroblocking technology, which we refer to as vBloc Therapy, is designed to intermittently block the vagus nerve using high frequency, low energy, electrical impulses. We have a limited operating history and only recently received U.S. Food and Drug Administration (FDA) approval to sell our product in the United States. In addition, we have regulatory approval to sell our product in Australia, 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 Maestro Rechargeable System.

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

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, for the treatment of adult patients with obesity who have a Body Mass Index (BMI) of at least 40 to 45 kg/m<sup>2</sup>, or a BMI of at least 35 to 39.9 kg/m<sup>2</sup> 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. We have begun a controlled commercial launch at select centers in the United States and had our first commercial sales in 2015. During 2015, we began a controlled expansion of our commercial operations and started the process of building a sales force. In January 2016, we hired three new executives to oversee this expansion. The direct sales force is supported by field technical managers who provide training, technical and other support services to our customers. Throughout 2015, our sales force called directly on key opinion leaders and bariatric surgeons at commercially-driven centers that met our certification criteria, which led to the training and certification of over 50 centers and 75 surgeons in implanting and administering vBloc Therapy. We have continued these efforts in the first three months of 2016 and plan to build on these efforts during the remainder of 2016 through geography and self-pay patient focused direct-to-patient marketing, key opinion leader and center specific partnering, and a multi-faceted reimbursement strategy. To date, we have relied on, and anticipate that we will continue to rely on, third-party manufacturers and suppliers for the production of the Maestro Rechargeable System.

Data from our ReCharge trial was used to support the premarket approval (PMA) application for the Maestro Rechargeable System, submitted to the FDA in June 2013. The ReCharge trial is a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial testing the effectiveness and safety of vBloc Therapy utilizing our Maestro Rechargeable 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.

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Although the trial did not meet its predefined co-primary efficacy endpoints, it did demonstrate 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. 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.

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.

<u>Risk Factor</u>	<u>10% TBL</u>
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 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.

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

To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in our human clinical trials. We have also not observed any long-term problematic clinical side effects in any patients. In addition, data from our VBLOC-DM2 ENABLE trial outside the United States demonstrate that vBloc Therapy may hold promise in improving obesity-related comorbidities such as diabetes and hypertension. We are conducting, or plan to conduct, further studies in each of these comorbidities to assess vBloc Therapy's potential in addressing multiple indications.

We recently commenced commercial operations in the United States, deriving revenues from our primary business activity in 2015. We expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our selling, general and administrative expenses to increase as we continue to add the infrastructure necessary to support our initial commercial sales, operate as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur operating losses for the next several years. We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments.

Our board of directors and stockholders approved a 1-for-15 reverse split of the Company's outstanding common stock that became effective after trading on January 6, 2016 (the Reverse Stock Split). The Reverse Stock Split did not change the par value of our stock or the number of preferred shares authorized by our Fifth Amended and Restated Certificate of Incorporation. An amendment to the Certificate of Incorporation was also approved in connection with the Reverse Stock Split to increase the number of shares of our common stock authorized for issuance to 150 million shares, effective immediately after the Reverse Stock Split on January 6, 2016. All share and per share amounts have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented.

## Financial Overview

### *Revenue*

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, and have begun a controlled commercial launch at select centers in the United States. In 2015 we trained and certified over 50 centers and 75 surgeons in implanting and administering vBloc Therapy. We had our first commercial sales within the United States in 2015 and for the year ended December 31, 2015 we recognized \$292,000 in revenue. For the three months ended March 31, 2016 we recognized \$72,000 in revenue. We have not generated revenue from commercial sales outside of the United States since 2012.

Any revenue from initial sales of a new product in the United States or internationally is difficult to predict and in any event will only modestly reduce our continued losses resulting from our research and development and other activities.

### *Selling, General and Administrative Expenses*

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

### *Research and Development Expenses*

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

## Results of Operations

### *Comparison of the Three Months Ended March 31, 2016 and 2015*

*Sales.* Sales were \$72,000 for the three months ended March 31, 2016, compared to no sales for the three months ended March 31, 2015. The increase of \$72,000 is the result of receiving FDA approval on January 14, 2015 and commencing a controlled commercial launch of the Maestro Rechargeable System at select centers in the United States.

*Cost of Goods Sold.* Cost of goods sold were \$40,000 for the three months ended March 31, 2016, compared to no cost of goods sold for the three months ended March 31, 2015. Gross margin was 44.3% for the three months ended March 31, 2016.

*Selling, General and Administrative Expenses.* Selling, general and administrative expenses were \$6.1 million for the three months ended March 31, 2016, compared to \$4.7 million for the three months ended March 31, 2015. The increase of \$1.4 million, or 29.9%, was primarily due to increases of \$1.1 million and \$469,000 in professional services and payroll-related expenses, respectively. The increase in both professional services and payroll-related expenses are the result of increasing commercialization efforts after receiving FDA approval on January 14, 2015 and beginning a controlled commercial launch at select centers in the United States, including the hiring of three new executives in January 2016 to oversee our commercialization efforts.

*Research and Development Expenses.* Research and development expenses were \$1.4 million for the three months ended March 31, 2016, compared to \$2.2 million for the three months ended March 31, 2015. The decrease of \$804,000, or 36.0%, was primarily due to decreases of \$396,000 and \$175,000 in payroll-related expenses and professional services, respectively. The decreases are the result of a shift away from a research and development focus towards commercialization following FDA approval on January 14, 2015.

*Interest Expense.* Interest expense was \$1.1 million for the three months ended March 31, 2016, compared to \$215,000 for the three months ended March 31, 2015. The increase of \$935,000, or 435.7%, is primarily due to the interest expense recognized for both the senior amortizing convertible notes issued November 9, 2015 and January 11, 2016, including \$684,000 of debt issuance costs being recognized immediately as interest expense as we elected the fair value alternative for the senior amortizing convertible notes. The interest expense recognized for the three months ended March 31, 2015 included a \$187,000 success fee paid to Silicon Valley Bank required by the Loan and Security Agreement as a result of achieving FDA approval on January 14, 2015 as well as the remaining interest expense associated with the long-term debt that was decreasing as a result of the declining principal balance through monthly principal and interest loan payments that began on April 1, 2013 and ended on September 1, 2015.

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*Change in Value of Convertible Notes Payable.* The value of the senior amortizing convertible notes payable increased \$500,000 for the three months ended March 31, 2016. There were no senior amortizing convertible notes outstanding for the three months ended March 31, 2015 as the senior amortizing convertible notes were issued on November 9, 2015 and January 11, 2016. The fair market value was calculated using a Binomial Lattice model, which resulted in \$146,000 and \$354,000 increases for the three months ended March 31, 2016 for the November 9, 2015 senior amortizing convertible notes and the January 11, 2016 senior amortizing convertible notes, respectively.

*Change in Value of Warrant Liability.* The value of the common stock warrant liability decreased \$1.8 million for the three months ended March 31, 2016. There were no warrants outstanding that were required to be measured at fair value for the three months ended March 31, 2015. Common stock warrant liabilities were recorded on July 8, 2015, November 9, 2015 and January 11, 2016 as the common stock warrants issued with the July 8, 2015 public offering and with the senior amortizing convertible notes provide for certain anti-dilution protections in the event shares of common stock or securities convertible into shares of common stock are issued below the then-existing exercise price. The fair market value was calculated using the Black-Scholes valuation model, which resulted in \$1.6 million, \$43,000 and \$176,000 decreases for the three months ended March 31, 2016 for the common stock warrants issued with the July 8, 2015 public offering, November 9, 2015 senior amortizing convertible notes and the January 11, 2016 senior amortizing convertible notes, respectively, as our stock price decreased from \$1.95 on December 31, 2015 and \$1.33 on January 11, 2016 to \$0.97 on March 31, 2016.

### **Liquidity and Capital Resources**

As of March 31, 2016, we had \$11.2 million in cash and cash equivalents. Of this amount \$2.8 million was invested in short-term money market funds that are not considered to be bank deposits and are not insured or guaranteed by the Federal Deposit Insurance Company or other government agency. These money market funds seek to preserve the value of the investment at \$1.00 per share; however, it is possible to lose money investing in these funds. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. At times, such deposits may be in excess of insured limits. We have not experienced any losses on our deposits of cash and cash equivalents.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of March 31, 2016, we had \$11.2 million of cash and cash equivalents to fund our anticipated operations through 2016. On November 4, 2015, we entered into a securities purchase agreement (the Purchase Agreement) with institutional investors to issue \$25.0 million of senior amortizing convertible notes (the Notes) along with the accompanying warrants. \$1.5 million of the Notes was funded at the initial closing on November 9, 2015. An additional \$11.0 million of the Notes was funded at the second closing on January 11, 2016. Pursuant to an amendment to the Purchase Agreement (the Amendment) entered into on May 2, 2016, the remaining \$12.5 million will be funded at two separate closings, with \$6.25 million of the Notes funded on May 2, 2016 and the remaining \$6.25 million to be funded at a later date. Additionally, we have agreed that we will not, for a period of one year after the first closing, issue any further securities, other than certain excluded securities. Our anticipated operations include plans that consider the controlled commercial launch of vBloc Therapy, delivered via the Maestro Rechargeable System, which was approved by the FDA on January 14, 2015. We believe that we have the flexibility to manage the growth of our expenditures and operations. In order to accelerate the execution of our business plans we may need to raise additional funds.

### **Loan and Security Agreement**

On April 16, 2012, we entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank (SVB) pursuant to which SVB agreed to make term loans in an aggregate principal amount of up to \$20.0 million (\$10.0 million of which was not available as we did not meet the predefined primary efficacy measures of the ReCharge trial and did not meet certain financial objectives for 2012), on the terms and conditions set forth in the Loan Agreement.

Pursuant to the Loan Agreement, a term loan was funded in the aggregate principal amount of \$10.0 million on April 23, 2012, a portion of which was used to repay in full outstanding debt of approximately \$4.7 million. The term loan required interest only payments monthly through March 31, 2013, followed by 30 equal payments of principal in the amount of \$333,333 plus accrued interest beginning on April 1, 2013 and ending on September 1, 2015, payable monthly. Amounts borrowed under the Loan Agreement bear interest at a fixed annual rate equal to 8.0%. We entered into a First Amendment (the First Amendment) to the Loan Agreement on May 9, 2013 pursuant to which we agreed to new financial covenants.

The First Amendment eliminated the financial covenants that required us to generate certain minimum amounts of revenue from the sale of our Maestro Rechargeable System and to implant certain minimum numbers of Maestro Rechargeable Systems during cumulative quarterly measurement periods beginning with the period ended March 31, 2013 and ending with the period ended June 30, 2015. It also removed SVB's ability to require us to maintain a restricted cash balance of \$7.5 million in an SVB account as a result of not meeting the predefined primary efficacy measures of the ReCharge trial.

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The First Amendment added two new financial covenants, one of which required us to receive cumulative aggregate proceeds of at least \$5.0 million by November 15, 2013 and \$10.0 million by April 15, 2014 from new capital transactions, both of which were fulfilled. The second financial covenant required us to maintain a liquidity ratio (unrestricted cash divided by outstanding debt) of at least 1.25:1.00 until we received FDA approval for the Maestro Rechargeable System on January 14, 2015, at which point it was reduced to 0.75:1.00. The First Amendment did not change the interest rate or the amortization structure. A 5.0% final payment fee of \$500,000 was due and paid on September 1, 2015. We also paid SVB a \$187,000 success fee as a result of receiving FDA approval for the Maestro Rechargeable System. The final payment related to the Loan Agreement, as amended, was paid on September 1, 2015.

### ***Sales Agreement—June 2014***

On June 13, 2014, we entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of our common stock having aggregate gross sales proceeds of up to \$25.0 million, from time to time, through an ATM under which Cowen will act as our sales agent (the Cowen ATM). We will determine, at our sole discretion, the timing and number of shares to be sold under the Cowen ATM. We will pay Cowen a commission for its services in acting as agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of March 31, 2016, we have sold 367,903 shares under the Cowen ATM at a weighted-average selling price of \$20.60 per share for gross proceeds of \$7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM subsequent to March 31, 2016 through May 10, 2016. We are restricted from issuing shares under the Cowen ATM until November 9, 2016 per the terms of the Notes (further described below).

### ***Sales Agreement—July 2015***

On July 8, 2015, we closed a public offering, where we sold 2,133,333 units at an aggregate price of \$7.50 per unit, for gross proceeds of \$16.0 million, before deducting estimated offering expenses of approximately \$1.4 million, of which \$532,000 was assigned to the warrants. Each unit consisted of: (A)(i) one share of common stock or (ii) one pre-funded Series C warrant to purchase one share of common stock at an exercise price equal to \$7.50 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price equal initially to \$9.00 per share (Series A Warrant). Each purchaser of a unit could elect to receive a Series C Warrant in lieu of a share of common stock. No Series C Warrants were issued.

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

The exercise price of the Series A Warrants issued July 8, 2015 was reduced to \$2.40 per share on November 9, 2015 as a result of the issuance of the Notes and was further reduced to \$1.50 per share on December 31, 2015, \$0.97 per share on January 29, 2016 and \$0.88 on March 30, 2016 after installment payments on the Notes were made.

### ***Senior Amortizing Convertible Notes***

On November 4, 2015, we entered into the Purchase Agreement to issue and sell to four institutional investors 7% senior amortizing convertible notes due 2017 that are convertible into shares of our common stock at a price equal to \$4.35 per share with an aggregate principal amount of \$25.0 million. Each Note was sold with a warrant to purchase a share of common stock (the Warrants) with an exercise price of \$4.65 per share. We issued and sold Notes and Warrants for aggregate total proceeds of \$12.5 million in two separate closings through March 31, 2016, and pursuant to the Amendment, issued and sold Notes and Warrants for aggregate total proceeds of \$6.25 million in the third closing, which occurred on May 2, 2016. We will issue and sell Notes and Warrants for aggregate total proceeds of \$6.25 million in the fourth and final closing.

### ***Description of the Notes***

The Notes are payable in monthly installments, accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the First Closing (defined below), unless converted or redeemed earlier. The Notes may be repaid, at our election, in either cash or shares of our common stock at a discount to the then-current market price. The Notes are also convertible from time to time, at the election of the holders, into shares of our common stock at an initial conversion price of \$4.35 per share. The conversion price was adjusted to \$1.09 per share on January 29, 2016, the 16th trading day following the Reverse Stock Split, per the terms of the Notes.

The holder of each Note has the right to convert any portion of such Note unless the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the

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conversion, as such percentage ownership is determined in accordance with the terms of the Notes. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing us notice.

The first of the four closings (the First Closing) occurred on November 9, 2015. At the First Closing, we issued and sold Notes with an aggregate principal amount of \$1.5 million, along with Warrants exercisable for 117,520 shares.

The second of the four closings (the Second Closing) occurred on January 11, 2016 after we received approval of the offering by our stockholders and the satisfaction of certain customary closing conditions. At the Second Closing, we issued and sold Notes with an aggregate principal amount of \$11.0 million, along with Warrants exercisable for 861,842 shares.

The third of the four closings (the Third Closing) occurred on May 2, 2016 after we entered into the Amendment. At the Third Closing, we issued and sold Notes with an aggregate principal amount of \$6.25 million, along with Warrants exercisable for 489,684 shares.

At the final of the four closings (the Fourth Closing) we will issue and sell Notes with an aggregate principal amount of \$6.25 million, along with Warrants exercisable for 489,682 shares.

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the First Closing through March 31, 2016:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>	<u>Common Shares</u>
Installment amount at December 31, 2015	\$ 65,217	\$23,651	\$ 88,868	56,967
Holder conversions during the quarter ended December 31, 2015	18,261	2,375	20,636	13,228
<b>Balance December 31, 2015</b>	<b>83,478</b>	<b>26,026</b>	<b>109,504</b>	<b>70,195</b>
Installment amount at February 29, 2016	65,217	23,681	88,898	91,953
Installment amount at March 31, 2016	65,217	14,827	80,044	88,960
Holder conversions during the quarter ended March 31, 2016	104,784	12,762	117,546	106,684
<b>Balance, March 31, 2016</b>	<b>\$318,696</b>	<b>\$77,296</b>	<b>\$395,992</b>	<b>357,792</b>

The following table summarizes the installment amounts and additional conversions by the holders of the Notes issued at the Second Closing through March 31, 2016:

	<u>Principal</u>	<u>Interest</u>	<u>Total</u>	<u>Common Shares</u>
Installment amount at March 2, 2016	\$ 404,762	\$149,300	\$ 554,062	*
Holder conversions during the quarter ended March 31, 2016	987,000	124,050	1,111,050	1,048,167
<b>Balance, March 31, 2016</b>	<b>\$1,391,762</b>	<b>\$273,350</b>	<b>\$1,665,112</b>	<b>1,048,167</b>

\* Cash payments

### **Description of the Warrants**

Each Warrant is exercisable immediately and for a period of 60 months from the date of the issuance of the Warrant. The Warrants entitle the holders of the Warrants to purchase, in aggregate, 1,958,728 shares of our common stock upon the completion of the Fourth Closing, subject to certain adjustments. The Warrants are initially exercisable at an exercise price equal to \$4.65, subject to adjustment on the eighteen month anniversary of issuance, and certain other adjustments. The exercise price and number of shares of common stock issuable on the exercise of the Warrants is subject to adjustment upon the issuance of any shares of common stock or securities convertible into shares of common stock below the then-existing exercise price, with certain exceptions, and in the event of any stock split, reverse stock split, recapitalization, reorganization or similar transaction. The holder of each Warrant does not have the right to exercise any portion of such Warrant if the holder, together with its affiliates, beneficially owns in excess of 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Warrants. However, any holder may increase or decrease such percentage to any other percentage, but in no event above 9.99%, provided that any increase of such percentage will not be effective until 61 days after providing us notice.

The exercise price of the Warrants issued November 9, 2015 was reduced to \$1.09 per share on January 29, 2016, the 16th trading day following the Reverse Stock Split, per the terms of the Warrants. The exercise price of the Warrants issued January 11,

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2016 and May 2, 2016 remains \$4.65 per share per the terms of the Warrants. All of the Warrants issued with the Notes remain subject to adjustment on the eighteen month anniversary of issuance.

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

Net cash used in operating activities was \$6.9 million and \$5.6 million for the three months ended March 31, 2016 and 2015, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, less noncash expenses for stock-based compensation, depreciation and amortization, change in value of convertible notes payable, change in value of warrant liability, and partially offset by changes in operating assets and liabilities.

### ***Net Cash Used in Investing Activities***

Net cash used in investing activities was \$12,000 and \$19,000 for the three months ended March 31, 2016 and 2015, respectively. Net cash used in investing activities for the three months ended March 31, 2016 and 2015 is attributable to the purchase of property and equipment.

### ***Net Cash Provided by Financing Activities***

Net cash provided by financing activities was \$10.1 million and \$5.5 million for the three months ended March 31, 2016 and 2015, respectively. Net cash provided by financing activities for the three months ended March 31, 2016 was due to \$11.0 million in gross proceeds from the issuance of the Notes on January 11, 2016, offset by \$445,000 of debt issuance costs and principal repayments of \$405,000 on the Notes. Net cash provided by financing activities for the three months ended March 31, 2015 was due to gross proceeds from ATM draws of \$6.7 million, offset by \$1.0 million in principal repayments on our long-term debt and \$200,000 in financing costs.

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

We received FDA approval on January 14, 2015 for vBloc Therapy, delivered via the Maestro Rechargeable System, and have begun a controlled commercial launch at select centers in the United States. We had our first commercial sales within the United States in 2015 and for the year ended December 31, 2015 we recognized \$292,000 in revenue. For the three months ended March 31, 2016 we recognized \$72,000 in revenue. We anticipate that we will continue to incur net losses for the next several years as we develop our products, commercialize our Maestro Rechargeable System, develop the corporate infrastructure required to sell our products, operate as a publicly-traded company and pursue additional applications for our technology platform.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of March 31, 2016, we had \$11.2 million of cash and cash equivalents to fund our anticipated operations through 2016. On November 4, 2015 we entered into a securities purchase agreement with institutional investors to issue \$25.0 million of Notes along with the accompanying warrants. \$1.5 million of the Notes was funded at the First Closing on November 9, 2015. An additional \$11.0 million of the Notes was funded at the Second Closing on January 11, 2016 and \$6.25 million more of the Notes was funded at the Third Closing on May 2, 2016, with the remaining \$6.25 million to be funded at the Fourth Closing. Additionally, we have agreed that we will not, for a period of one year after the first closing, issue any further securities, other than certain excluded securities. Our anticipated operations include plans that consider the controlled commercial launch of vBloc Therapy, delivered via the Maestro Rechargeable System, which was approved by the FDA on January 14, 2015. We believe that we have the flexibility to manage the growth of our expenditures and operations. In order to accelerate the execution of our business plans we may need to raise additional funds. Obtaining funds through the sale of additional equity and debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt securities, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. The sale of additional equity may require us to obtain approval from our stockholders to increase the number of shares of common stock we have authorized under our certificate of incorporation. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to products or proprietary technologies, or grant licenses on terms that are not favorable.

Our forecast of the period of time through which our financial resources will be adequate to support our operations, the costs to complete development of products and the cost to commercialize our products are forward-looking statements and involve risks and uncertainties, and actual results could vary materially and negatively as a result of a number of factors, including the factors discussed in Part I, Item 1A, *Risk Factors*, of our Annual Report on Form 10-K for the year ended December 31, 2015. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

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

- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our Maestro Rechargeable System and any products that we may develop;
- the rate of market acceptance of our Maestro Rechargeable System and vBloc Therapy and any other product candidates;
- the cost and timing of obtaining adequate coding, coverage or payment levels for our Maestro Rechargeable System and vBloc Therapy by government healthcare programs and other third-party payors;
- 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 Maestro Rechargeable System or our future products;
- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals;
- the cost of any recalls or other field actions required either by us or by regulatory bodies in those countries in which we market our products; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

### **Critical Accounting Policies and Estimates**

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States. In doing so, we have to make estimates and assumptions that affect our reported amounts of assets, liabilities and expenses, as well as related disclosure of contingent assets and liabilities. In many cases, we could reasonably have used different accounting policies and estimates. In some cases, changes in the accounting estimates are reasonably likely to occur from period to period. Accordingly, actual results could differ materially from our estimates. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations will be affected. We base our estimates on past experiences and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis.

During the three months ended March 31, 2016, there were no material changes to our significant accounting policies which are fully described in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015.

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### Contractual Obligations

During the three months ended March 31, 2016, there were no material changes to our contractual obligation disclosures as set forth under the caption, “Contractual Obligations” in Part II, Item 7, *Management’s Discussion and Analysis of Financial Condition and Results of Operations*, of our Annual Report on Form 10-K for the year ended December 31, 2015.

The following table summarizes our contractual obligations as of March 31, 2016 and the effect those obligations are expected to have on our financial condition and liquidity position in future periods:

Contractual Obligations	Payments Due By Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease	\$593,309	\$ 231,362	\$361,947	\$ —	\$ —
Total contractual cash obligations	<u>\$593,309</u>	<u>\$ 231,362</u>	<u>\$361,947</u>	<u>\$ —</u>	<u>\$ —</u>

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

### Off-Balance Sheet Arrangements

As of March 31, 2016, we did not have any off-balance sheet arrangements.

### Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting (Accounting Standards Update No. 2016-09 (ASU 2016-09))*. ASU 2016-09 modifies several aspects of the accounting for share-based payment awards, including income tax consequences, and classification on the statement of cash flows. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2016. We are currently evaluating the impact of adopting ASU 2016-09 on our consolidated financial statements.

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))*, which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2017. We are currently evaluating the impact of adopting ASU 2014-09 on our consolidated financial statements.

There have been no other significant changes in recent accounting pronouncements during the three months ended March 31, 2016 as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the year ended December 31, 2015.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our exposure to market risk is confined to our cash and cash equivalents. As of March 31, 2016, we had \$11.2 million in cash and cash equivalents. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio, if any, are not leveraged, are classified as either available for sale or held-to-maturity and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk.

**ITEM 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures*

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), defines the term “disclosure controls and procedures” as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation as of March 31, 2016, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

*Changes in Internal Control Over Financial Reporting*

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

### ITEM 1A. RISK FACTORS

Other than the risk factor identified below, there have been no material changes during the three months ended March 31, 2016 to the risk factors set forth in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the year ended December 31, 2015.

***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 having stockholders' equity of at least \$2.5 million and a minimum closing bid price of \$1.00 per share for our common stock) to maintain the listing of our common stock on 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.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

#### *Unregistered Sales of Equity Securities*

None.

#### *Uses of Proceeds from Sale of Registered Securities*

None.

#### *Purchases of Equity Securities*

None.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

### ITEM 5. OTHER INFORMATION

None.

### ITEM 6. EXHIBITS

The list of exhibits on the accompanying Exhibit Index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.



**EXHIBIT INDEX**

<b><u>Exhibit Number</u></b>	<b><u>Description of Document</u></b>
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Company's Registration Statement on Form S-3 filed on May 9, 2014 (File No. 333-195855)).
3.2	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on January 8, 2016 (File No. 1-33818)).
3.3	Certificate of Amendment to Fifth Amended and Restated Certificate of Incorporation. (Incorporated herein by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed on January 8, 2016 (File No. 1-33818)).
3.4	Amended and Restated Bylaws of the Company, as currently in effect. (Incorporated herein by reference to Exhibit 3.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).
10.1†	Inducement Option Plan. (Incorporated herein by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.2†	Amendment No. 2 to Executive Employment Agreement, dated May 21, 2007, by and between the Company and Greg S. Lea, dated January 27, 2016. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 3, 2016 (File No. 1-33818)).
10.3†	Separation Agreement, by and between the Company and Brad Hancock, dated February 24, 2016. (Incorporated herein by reference to Exhibit 10.45 to the Company's Annual Report on Form 10-K filed on March 28, 2016 (File No. 1-33818)).
10.4†	Executive Employment Agreement, dated January 19, 2016, by and between the Company and Naqeeb "Nick" Ansari. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.5†	Executive Employment Agreement, dated January 18, 2016, by and between the Company and Peter DeLange. (Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
10.6†	Executive Employment Agreement, dated January 22, 2016, by and between the Company and Paul Hickey. (Incorporated herein by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed on January 22, 2016 (File No. 1-33818)).
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2016, formatted in Extensible Business Reporting Language: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash flows and (v) the Notes to Condensed Consolidated Financial Statements.

\* Filed herewith.

† Indicates management contract or compensation plan or agreement.

## CERTIFICATION

I, Dan W. Gladney, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of EnteroMedics Inc.;

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

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

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

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

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

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

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

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

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

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

/s/ DAN W. GLADNEY

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**Dan W. Gladney**  
**President and Chief Executive Officer**

Date: May 10, 2016

## CERTIFICATION

I, Greg S. Lea, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of EnteroMedics Inc.;

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

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

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

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

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

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

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

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

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

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

/s/ GREG S. LEA

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**Greg S. Lea**  
**Chief Financial Officer**  
**and Chief Compliance Officer**

Date: May 10, 2016



