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

Form 10-Q

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

For the quarterly period ended September 30, 2015

Commission file number: 1-33818

ENTEROMEDICS INC.

(Exact name of registrant as specified in its charter)

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)

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 October 30, 2015, 106,404,378 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)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,260,989	\$ 11,619,167
Accounts receivable	25,112	2,812
Inventory	1,376,023	980,519
Prepaid expenses and other current assets	232,576	421,673
Total current assets	13,894,700	13,024,171
Property and equipment, net	366,957	481,522
Other assets	748,456	879,905
Total assets	<u>\$ 15,010,113</u>	<u>\$ 14,385,598</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable (net of discount of \$23,836 at December 31, 2014)	\$ —	\$ 2,976,164
Accounts payable	195,821	399,336
Accrued expenses	3,484,521	3,830,766
Accrued interest payable	—	514,937
Total current liabilities	3,680,342	7,721,203
Common stock warrant liability	3,587,489	—
Total liabilities	<u>7,267,831</u>	<u>7,721,203</u>
Commitments and contingencies (note 4)		
Stockholders' equity:		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 106,404,378 and 69,570,444 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	1,064,044	695,704
Additional paid-in capital	277,488,484	258,050,482
Accumulated deficit	(270,810,246)	(252,081,791)
Total stockholders' equity	7,742,282	6,664,395
Total liabilities and stockholders' equity	<u>\$ 15,010,113</u>	<u>\$ 14,385,598</u>

See accompanying notes to condensed consolidated financial statements.

ENTEROMEDICS INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	2015	2014	2015	2014
Sales	\$ 64,000	\$ —	\$ 143,000	\$ —
Cost of goods sold	23,346	—	54,109	—
Gross profit	<u>40,654</u>	<u>—</u>	<u>88,891</u>	<u>—</u>
Operating expenses:				
Selling, general and administrative	4,289,017	3,287,952	13,952,899	11,488,969
Research and development	1,762,013	2,305,952	6,451,406	8,017,249
Total operating expenses	<u>6,051,030</u>	<u>5,593,904</u>	<u>20,404,305</u>	<u>19,506,218</u>
Operating loss	<u>(6,010,376)</u>	<u>(5,593,904)</u>	<u>(20,315,414)</u>	<u>(19,506,218)</u>
Other income (expense):				
Interest income	157	755	1,446	2,505
Interest expense	(565,522)	(120,917)	(840,491)	(435,739)
Change in value of warrant liability	2,416,443	—	2,416,443	—
Other, net	8,628	(176)	9,561	(8,334)
Net loss	<u>\$ (4,150,670)</u>	<u>\$ (5,714,242)</u>	<u>\$ (18,728,455)</u>	<u>\$ (19,947,786)</u>
Net loss per share—basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.08)</u>	<u>\$ (0.22)</u>	<u>\$ (0.30)</u>
Shares used to compute basic and diluted net loss per share	<u>103,969,595</u>	<u>68,885,435</u>	<u>83,817,704</u>	<u>67,414,867</u>

See accompanying notes to condensed consolidated financial statements.

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

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	2015	2014	2015	2014
Net loss	<u>\$ (4,150,670)</u>	<u>\$ (5,714,242)</u>	<u>\$ (18,728,455)</u>	<u>\$ (19,947,786)</u>
Comprehensive loss	<u>\$ (4,150,670)</u>	<u>\$ (5,714,242)</u>	<u>\$ (18,728,455)</u>	<u>\$ (19,947,786)</u>

See accompanying notes to condensed consolidated financial statements.

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

	<u>Nine months ended September 30,</u>	
	<u>2015</u>	<u>2014</u>
Cash flows from operating activities:		
Net loss	\$(18,728,455)	\$(19,947,786)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	146,292	141,890
Loss on sale of equipment	885	—
Stock-based compensation	4,357,742	4,781,299
Amortization of commitment fees, debt issuance costs and original issue discount	754,242	99,928
Change in value of warrant liability	(2,416,443)	—
Change in operating assets and liabilities:		
Accounts receivable	(22,300)	17,742
Inventory	(395,504)	212,443
Prepaid expenses and other current assets	189,097	305,108
Other assets	(66,643)	(187,980)
Accounts payable	(198,864)	(75,768)
Accrued expenses	(346,245)	(292,743)
Accrued interest payable	(514,937)	(8,931)
Net cash used in operating activities	<u>(17,241,133)</u>	<u>(14,954,798)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(37,263)	(27,066)
Net cash used in investing activities	<u>(37,263)</u>	<u>(27,066)</u>
Cash flows from financing activities:		
Proceeds from warrants exercised	—	2,242,265
Proceeds from sale of common stock and warrants for purchase of common stock	22,651,932	8,909,383
Common stock financing costs	(1,731,714)	(197,685)
Repayments on notes payable	(3,000,000)	(3,000,000)
Net cash provided by financing activities	<u>17,920,218</u>	<u>7,953,963</u>
Net increase (decrease) in cash and cash equivalents	641,822	(7,027,901)
Cash and cash equivalents:		
Beginning of period	11,619,167	23,297,479
End of period	<u>\$ 12,260,989</u>	<u>\$ 16,269,578</u>
Supplemental disclosure:		
Interest paid	\$ 601,185	\$ 344,741

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) is developing and selling 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 Sàrl, a wholly-owned subsidiary located in Switzerland.

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 bariatric centers of excellence in the United States. The Maestro Rechargeable System has also received CE Mark and is listed on the Australian Register of Therapeutic Goods.

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, 2014 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, 2014.

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 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 had a fair value of \$3,587,489 and \$6,003,932 on September 30, 2015 and July 8, 2015, respectively. The fair value was calculated using the following assumptions:

	September 30, 2015	July 8, 2015
Risk-free interest rates	0.92%	0.91%
Expected life	39 months	42 months
Expected dividends	0%	0%
Expected volatility	92.78%	89.89%

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 include U.S. treasury securities. 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 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 as of September 30, 2015 and December 31, 2014.

Common Stock Warrant Liability

Common stock warrants that were issued in connection with the July 8, 2015 public offering 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.

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.

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

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 manufactures, 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.

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 and nine months ended September 30, 2015 and 2014.

Revenue Recognition

Revenue is recognized when persuasive evidence of an arrangement exists, title or risk of loss has passed, the selling price is fixed or determinable and collection is reasonably assured. Products are sold through direct sales or medical device distributors and revenue is recognized upon sale to a bariatric center of excellence or a medical device distributor when no right of return or price protection exists. Terms of sales to international distributors are generally EXW, reflecting that goods are shipped "ex works," in which risk of loss is assumed by the distributor at the shipping point. A provision for returns is recorded only if product sales provide for a right of return. No provision for returns was recorded for the three and nine months ended September 30, 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 and nine months ended September 30, 2015 and 2014:

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Numerator:				
Net loss	\$ (4,150,670)	\$ (5,714,242)	\$ (18,728,455)	\$ (19,947,786)
Denominator for basic and diluted net loss per share:				
Weighted-average common shares outstanding	103,969,595	68,885,435	83,817,704	67,414,867
Net loss per share—basic and diluted	\$ (0.04)	\$ (0.08)	\$ (0.22)	\$ (0.30)

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:

	September 30,	
	2015	2014
Stock options outstanding	15,450,499	12,336,783
Warrants to purchase common stock	56,199,705	24,199,705

Recently Issued Accounting Standards

In May 2014, the Financial Accounting Standards Board (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 nine months ended September 30, 2015 as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

(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 September 30, 2015, the Company had \$12.3 million of cash and cash equivalents to fund its anticipated operations into 2016. The Company also announced on November 5, 2015 that it had entered into a securities 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 will be funded at the initial closing of around November 9, 2015, and the balance will be funded in two tranches of \$11.0 million and \$12.5 million which are subject to the shareholders of the Company approving a reverse stock split of the Company's common stock and the terms of the issuance. 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 (further described in Note 8). 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) Inventory

From inception, inventory related purchases had been used for research and development related activities and had accordingly been expensed as incurred. In December 2011, the Company began receiving Australian Register of Therapeutic Goods (ARTG) listings for components of the 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

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

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 \$748,000 and \$825,000 of long-term inventory, primarily consisting of raw materials, as of September 30, 2015 and December 31, 2014, respectively.

Current inventory consists of the following as of:

	<u>September 30,</u> <u>2015</u>	<u>December 31,</u> <u>2014</u>
Raw materials	\$ 429,710	\$ 322,157
Work-in-process	917,138	632,615
Finished goods	29,175	25,747
Inventory	<u>\$ 1,376,023</u>	<u>\$ 980,519</u>

(4) 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 September 30, 2015 and 2014 was \$67,718, and for each of the nine month periods ended September 30, 2015 and 2014 was \$203,154. At September 30, 2015, future minimum payments under the lease are as follows:

<u>Year ending December 31:</u>	
Remaining three months in 2015	\$ 56,776
2016	229,233
2017	237,749
2018	183,103
	<u>\$706,861</u>

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.

(5) 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.

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

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%. 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 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 106,746 shares of common stock, exercisable for ten years from the date of grant, at an exercise price of \$2.34 per share.

The final payment related to the Loan Agreement, as amended, was paid on September 1, 2015. As of September 30, 2015 the Company does not have any outstanding notes payable.

(6) 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 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 for the three and nine months ended September 30, 2015 and 2014 was allocated to operating expenses and employees and nonemployees as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Selling, general and administrative	\$1,107,526	\$1,176,465	\$3,349,417	\$3,655,314
Research and development	329,431	329,772	1,008,325	1,125,985
Total	\$1,436,957	\$1,506,237	\$4,357,742	\$4,781,299
	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Employees	\$1,452,709	\$1,536,465	\$4,392,741	\$4,637,556
Nonemployees	(15,752)	(30,228)	(34,999)	143,743
Total	\$1,436,957	\$1,506,237	\$4,357,742	\$4,781,299

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

As of September 30, 2015 there was approximately \$7.1 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 2.03 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 and nine months ended September 30, 2015 and 2014:

	Employees		Employees	
	Three months ended September 30, 2015		Nine months ended September 30, 2015	
Risk-free interest rates	1.65%-1.67%		1.49%-1.80%	
Expected life	6.00-6.25 years		5.50-6.25 years	
Expected dividends	0%		0%	
Expected volatility	110.72%-111.61%		83.36%-111.77%	

There were no new employee grants for the three months ended September 30, 2014.

	Nonemployees		Nonemployees	
	Three months ended September 30, 2015		Nine months ended September 30, 2015	
Risk-free interest rates	1.34%-1.79%		0.02%-2.10%	
Expected life	4.89-8.01 years		0.08-8.51 years	
Expected dividends	0%		0%	
Expected volatility	83.98%-114.89%		22.42%-132.01%	

Option activity under the Company's Amended and Restated 2003 Stock Incentive Plan for the nine months ended September 30, 2015 was as follows:

	Outstanding Options		
	Shares Available For Grant	Number of Shares	Weighted-Average Exercise Price
Balance, December 31, 2014	7,073,726	12,655,792	\$ 2.47
Shares reserved	—	—	—
Options granted	(3,157,000)	3,157,000	1.04
Options exercised	—	—	—
Options cancelled	362,293	(362,293)	2.47
Balance, September 30, 2015	<u>4,279,019</u>	<u>15,450,499</u>	\$ 2.18

(7) Stock Sales

Sales Agreement—July 2015

On July 8, 2015, the Company closed a public offering, where it sold 32,000,000 units at an aggregate price of \$0.50 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 consists 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 \$0.50 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price equal to \$0.60 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

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

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 will 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.

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 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 September 30, 2015, the Company had sold 5,518,536 shares under the Cowen ATM at a weighted-average selling price of \$1.37 per share for gross proceeds of \$7.6 million before deducting offering expenses. There have been no shares sold under the Cowen ATM during the three months ended September 30, 2015 and subsequent to September 30, 2015 through November 9, 2015. The Company may be restricted from issuing shares under the Cowen ATM per the terms of the Senior Amortizing Convertible Notes (see Note 8).

Equity Distribution Agreement—July 2013

On July 31, 2013, the Company entered into an equity distribution agreement with Canaccord Genuity Inc. (Canaccord) to sell shares of the Company's common stock having aggregate gross sales proceeds of up to \$20.0 million, from time to time, through an ATM under which Canaccord acted as the Company's sales agent (the Canaccord ATM). The Company determined, at its sole discretion, the timing and number of shares sold under the Canaccord ATM. The Company paid Canaccord a commission for its services in acting as agent in the sale of common stock equal to 2.0% of the gross sales price per share of all shares sold through it as agent under the equity distribution agreement. The equity distribution agreement with Canaccord was terminated effective June 10, 2014. As of the termination date, the Company had sold a total of 11,923,977 shares under the Canaccord ATM at a weighted-average selling price of \$1.67 per share for gross proceeds of \$19.9 million before deducting offering expenses.

(8) Subsequent Events

Senior Amortizing Convertible Notes

The Company announced on November 5, 2015 that it had entered into a securities purchase agreement with institutional investors to issue \$25.0 million of Senior Amortizing Convertible Notes (the Notes) that are convertible into shares of the Company's common stock at a price equal to \$0.29 per share. Each Note will be sold with a warrant (the Warrants) with an exercise price of \$0.31 per share that are initially exercisable for shares of the Company's common stock equal to approximately 30% of the principal amount of the Notes, for a total of 29,381,039 warrants. The Notes and Warrants will be issued and sold for aggregate total proceeds of \$25.0 million in three separate closings, with the second and third closing subject to approval by the Company's stockholders.

The first of the three closings will occur on or about November 9, 2015. At the first closing, the Company will issue and sell Notes with an aggregate principal amount of \$1.5 million, along with the accompanying Warrants initially exercisable for 1,762,862 shares, for aggregate proceeds of \$1.5 million. The second of the three closings will occur on the third trading day after the approval of the offering by the Company's stockholders and the satisfaction of certain customary closing conditions, but in no case shall the second closing occur later than June 15, 2016. At the second closing, the Company will issue and sell Notes with an aggregate principal amount of \$11.0 million, along with the accompanying Warrants initially exercisable for 12,927,657 shares, for aggregate proceeds of \$11.0 million. The second closing is required to occur no later than June 15, 2016. The final of the three closings will occur forty-five days after the second closing upon satisfaction of customary closing conditions. At the third closing, the Company will issue and sell Notes with an aggregate principal amount of \$12.5 million, along with the accompanying Warrants initially exercisable for 14,690,520 shares, for aggregate proceeds of \$12.5 million. 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 Notes will be payable in monthly installments, will accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the initial closing, 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

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Notes to Condensed Consolidated Financial Statements (Continued)
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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 \$0.29 per share. The holder of each Note will not have the right to convert any portion of such Note if the holder, together with its affiliates, beneficially own 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 Warrants to be issued are 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, 29,381,039 shares of the Company's common stock, subject to certain adjustments. The Warrants are initially exercisable at an exercise price equal to \$0.31, 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 shall be 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 will not have the right to exercise any portion of such Warrant if the holder, together with its affiliates, beneficially own 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.

Stock Option Grant

On November 2, 2015, the Company announced that Dan W. Gladney would become the Company's President and Chief Executive Officer (CEO) effective November 16, 2015, and would join the Company on November 2, 2015 as President-Elect and a member of the Board of Directors. In connection with the appointment of Mr. Gladney to the position of President and CEO, on October 28, 2015, Mr. Gladney was also granted an option to purchase 7,750,000 shares of the Company's common stock as an inducement grant, with an exercise price of \$0.25 per share, the closing price of the Company's common stock on October 28, 2015. Mr. Gladney's option will vest as follows: 25% of the shares will vest as of one year from the date of his employment agreement, and the remaining 75% of the shares will then vest in equal 2.0833% installments each month thereafter over the following 36 months.

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, 2014. 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 our 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 will offer 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/m², or a BMI of at least 35 to 39.9 kg/m² with a related health condition such as high blood pressure or high cholesterol levels, and who have tried to lose weight in a supervised weight management program and failed within the past five years. We have begun a controlled commercial launch at select bariatric centers of excellence in the United States and had our first commercial sales within the United States during the three months ended June 30, 2015. We have started to build a sales force in the United States that will call directly on key opinion leaders and bariatric surgeons at commercially-driven bariatric centers of excellence that meet our certification criteria. The direct sales force is supported by field technical managers who provide training, technical and other support services to our customers. As of August 6, 2015, 51 centers have been certified and 77 surgeons have been trained in implanting and administering vBloc Therapy, exceeding our goal of training 20-25 vBloc Therapy centers and surgeons by the end of 2015. To date, we have relied on, and anticipate that we will continue to rely on, third-party manufacturers and suppliers for the production of our 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.

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

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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.

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

We 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.

An Advisory Panel meeting was held on June 17, 2014 to review this data and our entire PMA application for approval of the Maestro Rechargeable System. The Advisory Panel voted 8 to 1 in favor that the Maestro Rechargeable System is safe when used as designed and voted 4 to 5 against on the issue of a reasonable assurance of efficacy. The final vote, on whether the relative benefits outweighed the relative risk, was 6 to 2 in favor, with 1 abstention. On January 14, 2015, the FDA agreed with the Advisory Panel that the benefits of vBloc Therapy outweigh the risks when it approved vBloc Therapy, delivered via the Maestro Rechargeable System, for the treatment of obesity as indicated.

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). We continue to explore select international markets to commercialize the Maestro Rechargeable System, including Australia, Europe and the Middle East. Outside the United States, we intend to use direct, dealer and distributor sales models as the targeted geography 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.

On November 2, 2015, we announced that Dan W. Gladney would become our President and Chief Executive Officer (CEO) effective November 16, 2015, and would join the Company on November 2, 2015 as President-Elect and a member of the Board of Directors. As part of the transition process, Mark B. Knudson, Ph.D., our current President and CEO, will serve as Executive Chairman starting on November 16, 2015 until December 31, 2015, after which he will retire from his executive position at the Company while continuing to serve as non-executive Chairman of the Board of Directors.

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 bariatric centers of excellence in the United States. As of August 6, 2015, 51 centers have been certified and 77 surgeons have been trained in implanting and administering vBloc Therapy, exceeding our goal of training 20-25 vBloc Therapy centers and surgeons by the end of 2015. We had our first commercial sales within the United States in 2015 and for the three and nine months ended September 30, 2015 we recognized \$64,000 and \$143,000 in revenue, respectively.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011 for the treatment of obesity, which enables commercialization in the European Economic Area and other countries that recognize the European CE Mark. The CE Mark approval for our 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 ARTG by the Australian TGA. We have entered into exclusive, multi-year agreements with Device Technologies Australia Pty Limited and Bader Sultan & Brothers Co. W.L.L., for commercialization and distribution of the Maestro Rechargeable System in Australia and the Gulf Coast Countries of the Middle East, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates, respectively. We made our first commercial shipments to Device Technologies Australia Pty Limited and Bader Sultan & Brothers Co. W.L.L. during the year ended December 31, 2012 and recognized \$311,000 in revenue. We did not recognize any revenue subsequent to December 31, 2012 through September 30, 2015, primarily due to focusing our resources on the United States regulatory approval process.

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 sales and marketing, research and development and other activities.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of compensation for executive, finance, sales, marketing and administrative personnel, including stock-based compensation. Other significant expenses include costs associated with attending medical conferences, training and certifying centers and surgeons, marketing and reimbursement programs, 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 September 30, 2015 and 2014

Sales. Sales were \$64,000 for the three months ended September 30, 2015, compared to no sales for the three months ended September 30, 2014. The increase of \$64,000 is the result of receiving FDA approval on January 14, 2015 and commencing a controlled commercial launch of the Maestro Rechargeable System at select bariatric centers of excellence in the United States.

Cost of Goods Sold. Cost of goods sold were \$23,000 for the three months ended September 30, 2015, compared to no cost of goods sold for the three months ended September 30, 2014. Gross margin was 63.5% for the three months ended September 30, 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$4.3 million for the three months ended September 30, 2015, compared to \$3.3 million for the three months ended September 30, 2014. The increase of \$1.0 million, or 30.4%, was primarily due to increases of \$595,000 and \$295,000 in professional services and payroll-related expenses, respectively. The increases in professional services and payroll-related expenses are primarily the result of receiving FDA approval on January 14, 2015 and beginning a controlled commercial launch at select bariatric centers of excellence in the United States.

Research and Development Expenses. Research and development expenses were \$1.8 million for the three months ended September 30, 2015, compared to \$2.3 million for the three months ended September 30, 2014. The decrease of \$544,000, or 23.6%,

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was primarily due to a decrease of \$468,000 in professional services. The decrease in professional services expenses is primarily related to a change of focus from research and development to commercialization following FDA approval on January 14, 2015.

Interest Expense. Interest expense was \$566,000 for the three months ended September 30, 2015, compared to \$121,000 for the three months ended September 30, 2014. The increase of \$445,000 is primarily due to \$532,000 of financing costs that were assigned to the common stock warrants issued with the July 8, 2015 financing being recognized immediately as interest expense as the warrants are exercisable upon issuance, offset by a reduction of interest expense due to the declining principal balance through monthly principal and interest loan payments that began on April 1, 2013.

Change in Value of Warrant Liability. The value of the common stock warrant liability decreased \$2.4 million for the three months ended September 30, 2015, compared to no change for the three months ended September 30, 2014. The common stock warrant liability was recorded on July 8, 2015 as the common stock warrants issued with the July 8, 2015 public offering 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 a \$2.4 million decrease for the three months ended September 30, 2015 as our stock price decreased from \$0.37 on July 8, 2015 to \$0.26 on September 30, 2015.

Comparison of the Nine Months Ended September 30, 2015 and 2014

Sales. Sales were \$143,000 for the nine months ended September 30, 2015, compared to no sales for the nine months ended September 30, 2014. The increase of \$143,000 is the result of receiving FDA approval on January 14, 2015 and commencing a controlled commercial launch of the Maestro Rechargeable System at select bariatric centers of excellence in the United States.

Cost of Goods Sold. Cost of goods sold were \$54,000 for the nine months ended September 30, 2015, compared to no cost of goods sold for the nine months ended September 30, 2014. Gross margin was 62.2% for the nine months ended September 30, 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$14.0 million for the nine months ended September 30, 2015, compared to \$11.5 million for the nine months ended September 30, 2014. The increase of \$2.5 million, or 21.4%, was primarily due to increases of \$1.0 million, \$1.0 million and \$361,000 in professional services, payroll related expenses and travel, respectively. The increases in professional services, payroll-related expenses and travel are primarily the result of receiving FDA approval on January 14, 2015 and beginning a controlled commercial launch at select bariatric centers of excellence in the United States. The increase in payroll-related expenses is also the result of a special one-time bonus and an increase in the 2014 management incentive plan accrual in recognition of achieving FDA approval on January 14, 2015.

Research and Development Expenses. Research and development expenses were \$6.5 million for the nine months ended September 30, 2015, compared to \$8.0 million for the nine months ended September 30, 2014. The decrease of \$1.6 million, or 19.5%, was primarily due to a decrease of \$1.9 million in professional services. Professional services during the nine months ended September 30, 2014 were primarily related to preparation for the advisory panel meeting with the FDA, which was held June 17, 2014.

Interest Expense. Interest expense was \$840,000 for the nine months ended September 30, 2015, compared to \$436,000 for the nine months ended September 30, 2014. The increase of \$405,000, or 92.9%, is the result of \$532,000 of financing costs that were assigned to the common stock warrants issued with the July 8, 2015 financing being recognized immediately as interest expense as the warrants are exercisable upon issuance, together with a \$187,000 success fee paid to Silicon Valley Bank as a result of achieving FDA approval on January 14, 2015, offset by a reduction of interest expense due to the declining principal balance through monthly principal and interest loan payments that began on April 1, 2013.

Change in Value of Warrant Liability. The value of the common stock warrant liability decreased \$2.4 million for the nine months ended September 30, 2015, compared to no change for the nine months ended September 30, 2014. The common stock warrant liability was recorded on July 8, 2015 as the common stock warrants issued with the July 8, 2015 public offering 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 a \$2.4 million decrease for the nine months ended September 30, 2015 as our stock price decreased from \$0.37 on July 8, 2015 to \$0.26 on September 30, 2015.

Liquidity and Capital Resources

As of September 30, 2015, we had \$12.3 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

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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 September 30, 2015, we had \$12.3 million of cash and cash equivalents to fund our anticipated operations into 2016. We also announced on November 5, 2015 that we had entered into a securities 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 will be funded at the initial closing of around November 9, 2015, and the balance will be funded in two tranches of \$11.0 million and \$12.5 million which are subject to our shareholders approving a reverse stock split of our common stock and the terms of the issuance. 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 (further described below). 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.

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. As of September 30, 2015 we do not have any outstanding notes payable.

Equity Distribution Agreement – July 2013

On July 31, 2013, we entered into an equity distribution agreement with Canaccord Genuity Inc. (Canaccord) to sell shares of our common stock having aggregate gross sales proceeds of up to \$20.0 million, from time to time, through an ATM under which Canaccord acted as our sales agent (the Canaccord ATM). We determined, at our sole discretion, the timing and number of shares sold under the Canaccord ATM. We paid Canaccord a commission for its services in acting as agent in the sale of common stock equal to 2.0% of the gross sales price per share of all shares sold through it as agent under the equity distribution agreement. The equity distribution agreement with Canaccord was terminated effective June 10, 2014. As of the termination date, we had sold a total of 11,923,977 shares under the Canaccord ATM at a weighted-average selling price of \$1.67 per share for gross proceeds of \$19.9 million before deducting offering expenses.

Sales Agreement – June 2014

On June 13, 2014, we entered into a sales agreement with Cowen to sell shares of our common stock having aggregate gross sales proceeds of up to \$25.0 million, from time to time, through the Cowen ATM under which Cowen will act as our sales agent. 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 September 30, 2015, we have sold 5,518,536 shares under the Cowen ATM at a weighted-average selling price of \$1.37 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 September 30, 2015 through November 9, 2015. We may be restricted from issuing shares under the Cowen ATM per the terms of the Senior Amortizing Convertible Notes (further described below).

Sales Agreement – July 2015

On July 8, 2015, we closed a public offering, where we sold 32,000,000 units at an aggregate price of \$0.50 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 consists 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 \$0.50 per share (Series C Warrant); and (B) one Series A warrant to purchase one share of common stock at an exercise price equal to \$0.60 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 will 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.

Senior Amortizing Convertible Notes

We announced on November 5, 2015 that we had entered into a securities purchase agreement with institutional investors to issue \$25.0 million of Senior Amortizing Convertible Notes (the Notes) that are convertible into shares of our common stock at a price equal to \$0.29 per share. Each Note will be sold with a warrant (the Warrants) with an exercise price of \$0.31 per share that are initially exercisable for shares of our common stock equal to approximately 30% of the principal amount of the Notes, for a total of 29,381,039 warrants. The Notes and Warrants will be issued and sold for aggregate total proceeds of \$25.0 million in three separate closings, with the second and third closing subject to approval by our stockholders.

The first of the three closings will occur on or about November 9, 2015. At the first closing, we will issue and sell Notes with an aggregate principal amount of \$1.5 million, along with the accompanying Warrants initially exercisable for 1,762,862 shares, for aggregate proceeds of \$1.5 million. The second of the three closings will occur on the third trading day after the approval of the offering by our stockholders and the satisfaction of certain customary closing conditions, but in no case shall the second closing occur later than June 15, 2016. At the second closing, we will issue and sell Notes with an aggregate principal amount of \$11.0 million, along with the accompanying Warrants initially exercisable for 12,927,657 shares, for aggregate proceeds of \$11.0 million. The second closing is required to occur no later than June 15, 2016. The final of the three closings will occur forty-five days after the second closing upon satisfaction of customary closing conditions. At the third closing, we will issue and sell Notes with an aggregate principal amount of \$12.5 million, along with the accompanying Warrants initially exercisable for 14,690,520 shares, for aggregate proceeds of \$12.5 million. 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.

The Notes will be payable in monthly installments, will accrue interest at a rate of 7.0% per annum from the date of issuance and will mature 24 months after the initial closing, 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 \$0.29 per share. The holder of each Note will not have the right to convert any portion of such Note if the holder, together with its affiliates, beneficially own in excess of 4.99% of the number of shares of our common stock outstanding immediately after giving effect to the conversion, as such percentage ownership 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.

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The Warrants to be issued are 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, 29,381,039 shares of our common stock, subject to certain adjustments. The Warrants are initially exercisable at an exercise price equal to \$0.31, 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 shall be 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 will not have the right to exercise any portion of such Warrant if the holder, together with its affiliates, beneficially own in excess of 4.99% of the number of shares of our 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.

Net Cash Used in Operating Activities

Net cash used in operating activities was \$17.2 million and \$15.0 million for the nine months ended September 30, 2015 and 2014, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, less noncash expenses for stock-based compensation, depreciation and amortization, and partially offset by the change in value of warrant liability and changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$37,000 and \$27,000 for the nine months ended September 30, 2015 and 2014, respectively. Net cash used in investing activities for the nine months ended September 30, 2015 and 2014 is attributable to the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$17.9 million and \$8.0 million for the nine months ended September 30, 2015 and 2014, respectively. Net cash provided by financing activities for the nine months ended September 30, 2015 was due to gross proceeds of \$16.0 million from the July 8, 2015 public offering and ATM draws of \$6.7 million, offset by \$3.0 million in principal repayments on our long-term debt and \$1.7 million in financing costs. Net cash provided by financing activities for the nine months ended September 30, 2014 was due to gross proceeds from ATM draws of \$8.9 million and proceeds of \$2.2 million from the exercise of common stock warrants, offset by \$3.0 million in principal repayments on our long-term debt and \$198,000 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 bariatric centers of excellence in the United States. We had our first commercial sales within the United States in 2015 and for the nine months ended September 30, 2015 we recognized \$143,000 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 September 30, 2015, we had \$12.3 million of cash and cash equivalents to fund our anticipated operations into 2016. We also announced on November 5, 2015 that we had 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 will be funded at the initial closing of around November 9, 2015, and the balance will be funded in two tranches of \$11.0 million and \$12.5 million which are subject to our shareholders approving a reverse stock split of our common stock and the terms of the issuance. 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

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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, 2014. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Because of the numerous risks and uncertainties associated with the development of medical devices, such as our 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 nine months ended September 30, 2015, 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, 2014.

Contractual Obligations

On August 25, 2015, we entered into an amendment extending the term of our operating lease for three years until September 30, 2018, with monthly base rent ranging from \$18,925 to \$20,345. Other than the amendment to our operating lease and the repayment of our loan from SVB, during the nine months ended September 30, 2015, 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, 2014.

The following table summarizes our contractual obligations as of September 30, 2015 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	\$706,861	\$ 227,104	\$479,757	\$ —	\$ —
Total contractual cash obligations	\$706,861	\$ 227,104	\$479,757	\$ —	\$ —

The table above reflects only payment obligations that are fixed and determinable. Our operating lease commitments relate to our corporate headquarters in St. Paul, Minnesota.

Off-Balance Sheet Arrangements

As of September 30, 2015, we did not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (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 nine months ended September 30, 2015 as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the year ended December 31, 2014.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash and cash equivalents. As of September 30, 2015, we had \$12.3 million in cash and cash equivalents. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio, if any, are not leveraged, are classified as either available for sale or held-to-maturity and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any material negative impact on 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 September 30, 2015, our Chief Executive Officer and

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Chief Financial Officer/Chief Operating 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 September 30, 2015, 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 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, 2014.

Our inability to comply with the listing requirements of the NASDAQ Capital 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 to maintain the listing of our common stock on the NASDAQ Capital Market. We have received notice from the Listing Qualifications department of The Nasdaq Stock Market that we failed to comply with Nasdaq Listing Rule 5550(a)(2), which requires us to maintain a minimum closing bid price of \$1.00 per share for our common stock and Nasdaq Listing Rule 5550(b)(2), which requires us to maintain a minimum “Market Value of Listed Securities” of \$35 million. If we do not regain compliance with the continued listing requirements for the NASDAQ Capital Market within the specified periods, 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.

We may not have enough authorized shares available to allow the exercise of outstanding warrants and options, which may subject us to liability.

We have agreed to reserve 7,500,000 shares for the conversion of the Senior Amortizing Convertible Notes and the exercise of the accompanying warrants until the second trading day after we receive stockholder approval for the offering, at which point we will reserve the number of shares equal to 125% and 100%, respectively, of the number of shares issuable under the Senior Amortizing Convertible Notes and the exercise of the accompanying warrants, assuming no anti-dilution adjustments have occurred. Taking this reservation of shares into account, substantially all of our authorized shares are either outstanding or reserved for issuance under the Senior Convertible Amortizing Notes offering and other currently outstanding rights to acquire our common stock. As a result, in the near future we intend to seek stockholder approval of a reverse stock split in order to provide us with enough authorized shares to meet our obligations under the Senior Convertible Amortizing Notes offering, to continue to grant equity awards to incentivize our employees and to respond to strategic opportunities as they arise.

If we are unable to obtain stockholder approval for the issuance of all of the shares of common stock upon conversion of the Senior Amortizing Convertible Notes and the exercise of the accompanying warrants, we will be unable to complete the offering and will be limited in our ability to issue our equity securities.

Our common stock is listed on The NASDAQ Capital Market and, as such, we are subject to the NASDAQ Stock Market Rules. NASDAQ Stock Market Rule 5635(d) is referred to as the “NASDAQ 20% Rule.” In order to comply with the NASDAQ 20% Rule and to satisfy the closing conditions under the securities purchase agreement, we have agreed to seek stockholder approval for the potential issuance of more than 20% of our outstanding common stock upon conversion of the Senior Amortizing Convertible Notes and the exercise of the accompanying warrants. We have agreed to hold a special meeting of stockholders for the purpose of obtaining stockholder approval for this offering at the earliest practical date following the first closing of the offering, and in any event no later than January 15, 2016. If we are unable to obtain stockholder approval, we will be required to call an additional stockholder meeting no later than May 15, 2016, and semi-annually thereafter to continue seeking stockholder approval until obtained.

Additionally, if we do not obtain stockholder approval, we will be unable to issue and sell to the buyers the Senior Amortizing Convertible Notes and accompanying warrants to be issued and sold in the second and third closings (collectively, the Post-Approval Notes and Warrants) pursuant to the terms of the securities purchase agreement. Consequently we will not receive the additional \$23.5 million in gross proceeds to be paid at the second closing and the third closing in connection with the issuance of the Post-Approval Notes and Warrants. In addition, among other conditions, we will be required to comply with negative covenants that limit our ability to issue equity securities unless we pay-off the initial \$1.5 million Notes and find other means of raising capital, which may or may not be available or advantageous to current shareholders.

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.

SIGNATURES

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

ENTEROMEDICS INC.

BY: /s/ MARK B. KNUDSON, PH.D.
Mark B. Knudson, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

BY: /s/ GREG S. LEA
Greg S. Lea
Chief Financial
Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

Dated: November 9, 2015

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Document</u>
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company and all amendments thereto. (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	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†	Consulting Agreement, dated as of August 21, 2015, by and between Jon Tremmel & Associates, LLC and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on August 25, 2015 (File No. 1-33818)).
10.2	Amendment No. 1 to the Sales Agreement, dated as of August 25, 2015, by and between Cowen and Company, LLC and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on September 1, 2015 (File No. 1-33818)).
10.3	First Amendment to Lease Agreement, entered into August 25, 2015, by and between the Company and Roseville Properties Management Company. (Incorporated herein by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed on September 1, 2015 (File No. 1-33818)).
10.4†	Form of Tandem Stock Purchase Right and Bonus Share Agreement. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 13, 2015 (File No. 1-33818)).
10.5†	Executive Employment Agreement, dated October 28, 2015, by and between the Company and Dan W. Gladney. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 2, 2015 (File No. 1-33818)).
10.6	Form of Securities Purchase Agreement. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
10.7	Form of Senior Convertible Note. (Incorporated herein by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
10.8	Form of Warrant. (Incorporated herein by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on November 5, 2015 (File No. 1-33818)).
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 September 30, 2015, 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 arrangement.

CERTIFICATION

I, Mark B. Knudson, Ph.D., 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/ MARK B. KNUDSON, PH.D.

Mark B. Knudson, Ph.D.
President and Chief Executive Officer

Date: November 9, 2015

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

Greg S. Lea
Chief Financial Officer
and Chief Operating Officer

Date: November 9, 2015

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the Exchange Act), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Mark B. Knudson, Ph.D., in his capacity as Chief Executive Officer of EnteroMedics Inc., hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 to which this Certification is attached as Exhibit 32.1 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and the results of operations of EnteroMedics Inc. as of, and for, the periods covered by the Report.

By: /s/ MARK B. KNUDSON, PH.D.

Mark B. Knudson, Ph.D.
President and Chief Executive Officer

Date: November 9, 2015

