
**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 March 31, 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	<input type="checkbox"/>	Accelerated Filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting entity)	Smaller Reporting Company	<input type="checkbox"/>

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

As of April 30, 2015, 74,404,378 shares of the registrant's Common Stock were outstanding.

INDEX

PART I – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)	3
Condensed Consolidated Balance Sheets at March 31, 2015 and December 31, 2014	3
Condensed Consolidated Statements of Operations for the three months ended March 31, 2015 and 2014	4
Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2015 and 2014	4
Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2015 and 2014	5
Notes to Condensed Consolidated Financial Statements	6
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3. Quantitative and Qualitative Disclosures About Market Risk	19
Item 4. Controls and Procedures	19

PART II – OTHER INFORMATION

Item 1. Legal Proceedings	20
Item 1A. Risk Factors	20
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	20
Item 3. Defaults Upon Senior Securities	20
Item 4. Mine Safety Disclosures	20
Item 5. Other Information	20
Item 6. Exhibits	20
SIGNATURES	21

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

PART I – FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ENTEROMEDICS INC.
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,432,234	\$ 11,619,167
Accounts receivable	1,478	2,812
Inventory	1,126,297	980,519
Prepaid expenses and other current assets	462,986	421,673
Total current assets	13,022,995	13,024,171
Property and equipment, net	446,876	481,522
Other assets	866,554	879,905
Total assets	<u>\$ 14,336,425</u>	<u>\$ 14,385,598</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable (net of discounts of \$10,313 and \$23,836 at March 31, 2015 and December 31, 2014, respectively)	\$ 1,989,687	\$ 2,976,164
Accounts payable	47,522	399,336
Accrued expenses	4,473,759	3,830,766
Accrued interest payable	510,635	514,937
Total current liabilities	7,021,603	7,721,203
Total liabilities	7,021,603	7,721,203
Commitments and contingencies (note 4)		
Stockholders' equity:		
Common stock, \$0.01 par value; 200,000,000 shares authorized; 74,404,378 and 69,570,444 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	744,044	695,704
Additional paid-in capital	265,826,592	258,050,482
Accumulated deficit	(259,255,814)	(252,081,791)
Total stockholders' equity	7,314,822	6,664,395
Total liabilities and stockholders' equity	<u>\$ 14,336,425</u>	<u>\$ 14,385,598</u>

See accompanying notes to condensed consolidated financial statements.

[Table of Contents](#)

ENTEROMEDICS INC.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three months ended March 31,	
	2015	2014
Sales	\$ —	\$ —
Cost of goods sold	—	—
Gross profit	—	—
Operating expenses:		
Selling, general and administrative	4,727,519	3,934,977
Research and development	2,236,606	2,623,021
Total operating expenses	6,964,125	6,557,998
Operating loss	(6,964,125)	(6,557,998)
Other income (expense):		
Interest income	867	1,004
Interest expense	(214,546)	(169,373)
Other, net	3,781	(5,957)
Net loss	\$ (7,174,023)	\$ (6,732,324)
Net loss per share – basic and diluted	\$ (0.10)	\$ (0.10)
Shares used to compute basic and diluted net loss per share	72,735,912	65,656,591

See accompanying notes to condensed consolidated financial statements.

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

	Three months ended	
	March 31,	
	2015	2014
Net loss	\$ (7,174,023)	\$ (6,732,324)
Comprehensive loss	\$ (7,174,023)	\$ (6,732,324)

See accompanying notes to condensed consolidated financial statements.

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

	Three months ended March 31,	
	2015	2014
Cash flows from operating activities:		
Net loss	\$ (7,174,023)	\$ (6,732,324)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	48,651	47,495
Stock-based compensation	1,372,076	1,537,378
Amortization of commitment fees, debt issuance costs and original issue discount	165,291	38,031
Change in operating assets and liabilities:		
Accounts receivable	1,334	17,742
Inventory	(145,778)	36,773
Prepaid expenses and other current assets	(41,313)	(71,975)
Other assets	(138,417)	(52,383)
Accounts payable	(347,163)	146,708
Accrued expenses	642,993	(565,937)
Accrued interest payable	(4,302)	(2,214)
Net cash used in operating activities	<u>(5,620,651)</u>	<u>(5,600,706)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(18,656)	(7,281)
Net cash used in investing activities	<u>(18,656)</u>	<u>(7,281)</u>
Cash flows from financing activities:		
Proceeds from warrants exercised	—	2,026,765
Proceeds from sale of common stock and warrants for purchase of common stock	6,651,931	5,836,072
Common stock financing costs	(199,557)	(116,295)
Repayments on notes payable	(1,000,000)	(1,000,000)
Net cash provided by financing activities	<u>5,452,374</u>	<u>6,746,542</u>
Net (decrease) increase in cash and cash equivalents	<u>(186,933)</u>	<u>1,138,555</u>
Cash and cash equivalents:		
Beginning of period	11,619,167	23,297,479
End of period	<u>\$11,432,234</u>	<u>\$24,436,034</u>
Supplemental disclosure:		
Interest paid	\$ 53,556	\$ 133,556

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 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 thus far has only derived revenues from its primary business activity in 2012.

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.

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.

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

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 debt is approximately \$2.5 million as of March 31, 2015 based on the present value of estimated future cash flows using a discount rate commensurate with borrowing rates available to the Company. If measured at fair value in the condensed consolidated financial statements, debt would be classified as Level 2 in the fair value hierarchy.

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 March 31, 2015 and December 31, 2014.

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. Under terms of the Company's note payable agreement (see Note 5), in the event of default, the lender has the right to enforce an account control agreement and restrict the Company's access to their cash and investment accounts.

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.

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.

Comprehensive Loss

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

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

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 internationally through distributors and revenue is recognized upon sale to the distributor as these sales are considered to be final and 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. The Company does not provide for rights of return to customers on product sales and therefore does not record a provision for returns.

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.

The following table sets forth the computation of basic and diluted net loss per share for the three months ended March 31, 2015 and 2014:

	Three months ended March 31,	
	2015	2014
Numerator:		
Net loss	\$ (7,174,023)	\$ (6,732,324)
Denominator for basic and diluted net loss per share:		
Weighted-average common shares outstanding	72,735,912	65,656,591
Net loss per share—basic and diluted	\$ (0.10)	\$ (0.10)

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

	March 31,	
	2015	2014
Stock options outstanding	14,232,792	11,666,051
Warrants to purchase common stock	24,199,705	24,411,389

Recently Issued Accounting Standards

In June 2014, the Financial Accounting Standards Board (FASB) issued *Development Stage Entities, Topic 915 (Accounting Standards Update No. 2014-10 (ASU 2014-10))*, which eliminates certain financial reporting requirements, with the objective of improving financial reporting by reducing the cost and complexity associated with the incremental reporting requirements for development stage entities. This guidance is effective for interim and annual reporting periods beginning after December 15, 2014; however, early application was permitted for any annual reporting period or interim period for which an entity’s financial statements had not yet been issued. The Company elected to adopt ASU 2014-10 effective with the quarter ending June 30, 2014.

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

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))*, which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2016. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

There have been no other significant changes in recent accounting pronouncements during the three months ended March 31, 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 March 31, 2015, the Company had \$11.4 million of cash and cash equivalents to fund its anticipated operations for 2015 and also has an "at-the-market" equity offering program (ATM) under which it can raise additional funds by instructing Cowen and Company, LLC (Cowen), the Company's sales agent, to sell shares of the Company's common stock having aggregate gross sales proceeds of up to \$25.0 million (the Cowen ATM), of which \$17.4 million remains available as of May 8, 2015 (further described in Note 7). These 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. In order to finance these anticipated operations, including the increase in internal expenditures resulting from the controlled commercial launch noted above, the Company has raised \$6.7 million in gross proceeds before deducting offering expenses from the Cowen ATM subsequent to December 31, 2014 through May 8, 2015. In addition, the Company believes that it has the ability to raise additional capital through (i) the sale of additional equity securities, including, but not limited to, the use of the Cowen ATM and the exercise of outstanding warrants; (ii) the sale of debt securities; or (iii) establishing a credit facility, and has the flexibility to manage the growth of its expenditures and expand 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 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 \$776,000 and \$825,000 of long-term inventory, primarily consisting of raw materials, as of March 31, 2015 and December 31, 2014, respectively.

Current inventory consists of the following as of:

	March 31, 2015	December 31, 2014
Raw materials	\$ 419,085	\$ 322,157
Work-in-process	679,036	632,615
Finished goods	28,176	25,747
Inventory	<u>\$1,126,297</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 expires on September 30, 2015. Total rent expense recognized for each of the three months ended March 31, 2015 and 2014 was \$67,718. At March 31, 2015, future minimum payments under the lease are as follows:

<u>Year ending December 31:</u>	
Remaining nine months in 2015	<u>\$ 147,859</u>

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

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.

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 is not available as the Company did not meet the predefined primary efficacy measures of the ReCharge trial and did not meet certain financial objectives for 2012), on the terms and conditions set forth in the Loan Agreement.

Pursuant to the Loan Agreement, a term loan was funded in the aggregate principal amount of \$10.0 million on April 23, 2012, a portion of which was used to repay in full outstanding debt of approximately \$4.7 million. The term loan required interest only payments monthly through March 31, 2013 followed by 30 equal payments of principal in the amount of \$333,333 plus accrued interest beginning on April 1, 2013 and ending on September 1, 2015, payable monthly. Amounts borrowed under the Loan Agreement bear interest at a fixed annual rate equal to 8.0%. A 5.0% final payment fee will be due on September 1, 2015. The Company may voluntarily prepay the term loan in full, but not in part, and any voluntary or mandatory prepayment is subject to applicable prepayment premiums and will also include the final payment fee. The Company was required to comply with certain 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 ending June 30, 2015. The Company did not meet the financial covenants for the period ended March 31, 2013 and therefore 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 ending 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 have been 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. The Company is required to pay SVB a \$187,000 success fee as a result of receiving FDA approval for the Maestro Rechargeable System on January 14, 2015.

The Company has 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 has entered into a negative pledge arrangement with SVB pursuant to which it has 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.

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

Scheduled debt principal payments are as follows as of March 31, 2015:

Year Ending December 31:	
Remaining nine months in 2015	\$2,000,000
Less: Original issue discount	(10,313)
Notes payable, net	<u>\$1,989,687</u>

(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 months ended March 31, 2015 and 2014 was allocated to operating expenses and employees and nonemployees as follows:

	Three months ended	
	March 31,	
	2015	2014
Selling, general and administrative	\$1,036,446	\$1,155,555
Research and development	335,630	381,823
Total	<u>\$1,372,076</u>	<u>\$1,537,378</u>
Employees	\$1,387,924	\$1,490,341
Nonemployees	(15,848)	47,037
Total	<u>\$1,372,076</u>	<u>\$1,537,378</u>

As of March 31, 2015 there was approximately \$9.3 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 2.13 years.

The estimated grant-date fair values of the stock options were calculated using the Black-Scholes valuation model, based on the following assumptions for the three months ended March 31, 2015 and 2014:

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

There were no new employee grants for the three months ended March 31, 2014.

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

	Nonemployees	
	Three months ended March 31,	
	2015	2014
Risk-free interest rates	0.03%-1.77%	0.21%-2.63%
Expected life	0.25-8.51 years	1.25-9.51 years
Expected dividends	0%	0%
Expected volatility	37.36%-131.49%	79.90%-139.65%

Option activity under the Company's Amended and Restated 2003 Stock Incentive Plan for the three months ended March 31, 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	(1,577,000)	1,577,000	1.12
Options exercised	—	—	—
Options cancelled	—	—	—
Balance, March 31, 2015	<u>5,496,726</u>	<u>14,232,792</u>	\$ 2.32

(7) Stock Sales

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 March 31, 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 subsequent to March 31, 2015 through May 8, 2015.

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.

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 anticipate having the first commercial sale within the United States in 2015. We hired a Chief Commercial Officer in November 2014 to oversee the commercialization process and 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 will be supported by field technical managers who provide training, technical and other support services to our customers. As announced on April 30, 2015, 30 centers have been certified and 40 surgeons were 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.

[Table of Contents](#)

Although the trial did not meet its predefined co-primary efficacy endpoints, it did demonstrate in the intent to treat (ITT) population (n=239) a clinically meaningful and statistically significant excess weight loss (EWL) of 24.4% (approximately 10% total body weight loss (TBL)) for vBloc Therapy-treated patients, with 52.5% of patients achieving at least 20% EWL. In the per protocol population, the trial demonstrated an EWL of 26.3% for vBloc Therapy-treated patients, with 56.8% of patients achieving at least 20% EWL.

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

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

We subsequently announced that vBloc Therapy-treated patients were maintaining their weight loss at 18 months and 24 months with an EWL of 23.5% and 21.1%, respectively. The trial's positive safety profile also continued throughout this reported time period.

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.

Thus far, we have only generated revenue from the sale of products in 2012 because we focused our resources on the United States regulatory approval process, and expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. Having recently received FDA approval, 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 significant and increasing 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.

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 and anticipate having the first commercial sale within the United States in 2015. As announced on April 30, 2015, 30 centers have been certified and 40 surgeons were trained in implanting and administering vBloc Therapy, exceeding our goal of training 20-25 vBloc Therapy centers and surgeons by the end of 2015.

[Table of Contents](#)

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 for the years ended December 31, 2013 and 2014, 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 research and development and other activities.

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.

Selling, General and Administrative Expenses

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

Results of Operations

Comparison of the Three Months Ended March 31, 2015 and 2014

Sales. There were no sales for the three months ended March 31, 2015 and 2014, which was primarily the result of focusing our resources on the United States regulatory approval process.

Cost of Goods Sold. There were no cost of goods sold for the three months ended March 31, 2015 and 2014.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$4.7 million for the three months ended March 31, 2015, compared to \$3.9 million for the three months ended March 31, 2014. The increase of \$793,000, or 20.1%, was primarily due to increases of \$655,000 and \$175,000 in payroll-related expenses and professional services, respectively. The increase in both payroll-related expenses and professional services is 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 \$2.2 million for the three months ended March 31, 2015, compared to \$2.6 million for the three months ended March 31, 2014. The decrease of \$386,000, or 14.7%, was primarily due to a decrease of \$759,000 in professional services offset by an increase of \$349,000 in payroll-related expenses. Professional services during the first quarter of 2014 were primarily related to preparation for the advisory panel meeting with the FDA, which was held June 17, 2014. The increase in payroll-related expenses is primarily 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.

Interest Expense. Interest expense was \$215,000 for the three months ended March 31, 2015, compared to \$169,000 for the three months ended March 31, 2014. The increase of \$45,000, or 26.7%, is the result of being required to pay SVB a \$187,000 success fee 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.

Liquidity and Capital Resources

As of March 31, 2015, we had \$11.4 million in cash and cash equivalents. Of this amount \$8.2 million was invested in short-term money market funds that are not considered to be bank deposits and are not insured or guaranteed by the Federal Deposit Insurance Company or other government agency. These money market funds seek to preserve the value of the investment at \$1.00 per share; however, it is possible to lose money investing in these funds. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. At times, such deposits may be in excess of insured limits. We have not experienced any losses on our deposits of cash and cash equivalents.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of March 31, 2015, we had \$11.4 million of cash and cash equivalents to fund our anticipated operations for 2015 and also have an “at-the-market” equity offering program (ATM) under which we can raise additional funds by instructing Cowen and Company, LLC (Cowen), our sales agent, to sell shares of our common stock having aggregate gross sales proceeds of up to \$25.0 million (the Cowen ATM), of which \$17.4 million remains available as of May 8, 2015 (further described below). These 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. In order to finance these anticipated operations, including the increase in internal expenditures resulting from the controlled commercial launch noted above, we have raised \$6.7 million in gross proceeds before deducting offering expenses from the Cowen ATM subsequent to December 31, 2014 through May 8, 2015. In addition, we believe that we have the ability to raise additional capital through (i) the sale of additional equity securities, including, but not limited to, the use of the Cowen ATM and the exercise of outstanding warrants; (ii) the sale of debt securities; or (iii) establishing a credit facility, and we have the flexibility to manage the growth of our expenditures and expand operations. In order to fund on-going operating cash requirements or to further accelerate and execute our business plan, including commercialization of the Maestro Rechargeable System, we will need to raise additional funds.

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 is 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%. A 5.0% final payment fee will be due on September 1, 2015. We may voluntarily prepay the term loan in full, but not in part, and any voluntary or mandatory prepayment is subject to applicable prepayment premiums and will also include the final payment fee. We were required to comply with certain 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 ending June 30, 2015. We did not meet the financial covenants for the period ended March 31, 2013 and therefore 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 ending 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 have been 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. We are required to pay SVB a \$187,000 success fee as a result of receiving FDA approval for the Maestro Rechargeable System on January 14, 2015.

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.

[Table of Contents](#)

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 March 31, 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 March 31, 2015 through May 8, 2015.

Net Cash Used in Operating Activities

Net cash used in operating activities was \$5.6 million for each of the three months ended March 31, 2015 and 2014. 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 changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$19,000 and \$7,000 for the three months ended March 31, 2015 and 2014, respectively. Net cash used in investing activities for the three months ended March 31, 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 \$5.5 million and \$6.7 million for the three months ended March 31, 2015 and 2014, respectively. Net cash provided by financing activities for the three months ended March 31, 2015 was due to gross proceeds from ATM draws of \$6.7 million, offset by \$1.0 million in principal repayments on our long-term debt and \$200,000 in financing costs. Net cash provided by financing activities for the three months ended March 31, 2014 was due to gross proceeds from ATM draws of \$5.8 million and proceeds of \$2.0 million from the exercise of common stock warrants, offset by \$1.0 million in principal repayments on our long-term debt and \$116,000 in financing costs.

Operating Capital and Capital Expenditure Requirements

We have only generated revenue from the sale of products in 2012 because we continued to focus our resources on the United States regulatory approval process. In January 2015 the FDA granted us approval and we have begun to commercialize the Maestro Rechargeable System in a controlled commercial launch at select bariatric centers of excellence in the United States. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our products, commercialize our Maestro Rechargeable System, develop the corporate infrastructure required to sell our products, operate as a publicly-traded company and pursue additional applications for our technology platform.

We have financed our operations to date principally through the sale of equity securities, debt financing and interest earned on investments. As of March 31, 2015, we had \$11.4 million of cash and cash equivalents to fund our anticipated operations for 2015 and also have the Cowen ATM under which we can raise additional funds by selling shares of our common stock. These 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. In order to finance these anticipated operations, including the increase in internal expenditures resulting from the controlled commercial launch noted above, we have raised \$6.7 million in gross proceeds before deducting offering expenses from the Cowen ATM subsequent to December 31, 2014 through May 8, 2015. In addition, we believe that we have the ability to raise additional capital through (i) the sale of additional equity securities, including, but not limited to, the use of the Cowen ATM and the exercise of outstanding warrants; (ii) the sale of debt securities; or (iii) establishing a credit facility, and we have the flexibility to manage the growth of our expenditures and expand operations. In order to fund on-going operating cash requirements or to further accelerate and execute our business plan, including commercialization of the Maestro Rechargeable System, we will need to raise additional funds. Obtaining funds through the Cowen ATM or 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. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities, which could materially harm our business. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to products or proprietary technologies, or grant licenses on terms that are not favorable.

[Table of Contents](#)

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 of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the effect of competing products and market developments;
- the cost of explanting clinical devices;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish;
- any revenue generated by sales of our Maestro Rechargeable System or our future products;
- the scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of obtaining any further required regulatory approvals;
- the cost of any recalls or other field actions required either by us or by regulatory bodies in those countries in which we market our products; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Critical Accounting Policies and Estimates

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

During the three months ended March 31, 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

During the three months ended March 31, 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.

[Table of Contents](#)

The following table summarizes our contractual obligations as of March 31, 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	\$ 147,859	\$ 147,859	\$ —	\$ —	\$ —
Long-term debt, including interest and final payment fee	2,547,630	2,547,630	—	—	—
Total contractual cash obligations	<u>\$2,695,489</u>	<u>\$2,695,489</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

The table above reflects only payment obligations that are fixed and determinable and does not reflect potential accelerated debt payments in the event of a default. The table above also does not reflect the \$187,000 success fee owed to SVB as a result of receiving FDA approval for our Maestro Rechargeable System on January 14, 2015. Our operating lease commitments relate to our corporate headquarters in St. Paul, Minnesota.

Off-Balance Sheet Arrangements

As of March 31, 2015, we did not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board (FASB) issued *Development Stage Entities, Topic 915 (Accounting Standards Update No. 2014-10 (ASU 2014-10))*, which eliminates certain financial reporting requirements, with the objective of improving financial reporting by reducing the cost and complexity associated with the incremental reporting requirements for development stage entities. This guidance is effective for interim and annual reporting periods beginning after December 15, 2014; however, early application was permitted for any annual reporting period or interim period for which an entity's financial statements had not yet been issued. We elected to adopt ASU 2014-10 effective with the quarter ending June 30, 2014.

In May 2014, FASB issued *Revenue from Contracts with Customers, Topic 606 (Accounting Standards Update No. 2014-09 (ASU 2014-09))*, which provides a framework for the recognition of revenue, with the objective that recognized revenues properly reflect amounts an entity is entitled to receive in exchange for goods and services. This guidance will be effective for interim and annual reporting periods beginning after December 15, 2016. We are currently evaluating the impact of adopting ASU 2014-09 on our consolidated financial statements.

There have been no other significant changes in recent accounting pronouncements during the three months ended March 31, 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 March 31, 2015, we had \$11.4 million in cash and cash equivalents. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio, if any, are not leveraged, are classified as either available for sale or held-to-maturity and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), defines the term "disclosure controls and procedures" as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation as of March 31, 2015, our Chief Executive Officer and Chief Financial Officer/Chief Operating Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e))

[Table of Contents](#)

and 15d-15(e) under the Exchange Act) were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 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

There have been no material changes during the three months ended March 31, 2015 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.

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: May 8, 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)).
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 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.

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: May 8, 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: May 8, 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 March 31, 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: May 8, 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), Greg S. Lea, in his capacity as Chief Financial 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 March 31, 2015 to which this Certification is attached as Exhibit 32.2 (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/ GREG S. LEA
Greg S. Lea
Chief Financial Officer
and Chief Operating Officer

Date: May 8, 2015