
**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, 2014

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 31, 2014, 69,103,909 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)**

	<u>September 30, 2014</u>	<u>December 31, 2013</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,269,578	\$ 23,297,479
Accounts receivable	—	17,742
Inventory	915,498	1,127,941
Prepaid expenses and other current assets	241,636	546,744
Total current assets	<u>17,426,712</u>	<u>24,989,906</u>
Property and equipment, net	462,271	577,095
Other assets	997,322	820,767
Total assets	<u>\$ 18,886,305</u>	<u>\$ 26,387,768</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable (net of discounts of \$43,167 at September 30, 2014)	\$ 3,956,833	\$ 4,000,000
Accounts payable	51,561	127,329
Accrued expenses	3,893,317	4,186,060
Accrued interest payable	517,741	526,672
Total current liabilities	<u>8,419,452</u>	<u>8,840,061</u>
Notes payable, less current portion (net of discounts of \$131,670 at December 31, 2013)	—	2,868,330
Total liabilities	<u>8,419,452</u>	<u>11,708,391</u>
Commitments and contingencies (note 4)		
Stockholders' equity:		
Common stock, \$0.01 par value; 200,000,000 and 125,000,000 shares authorized at September 30, 2014 and December 31, 2013, respectively; 68,885,842 and 63,551,350 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	688,858	635,514
Additional paid-in capital	255,678,852	239,996,934
Accumulated deficit	<u>(245,900,857)</u>	<u>(225,953,071)</u>
Total stockholders' equity	<u>10,466,853</u>	<u>14,679,377</u>
Total liabilities and stockholders' equity	<u>\$ 18,886,305</u>	<u>\$ 26,387,768</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>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Sales	\$ —	\$ —	\$ —	\$ —
Cost of goods sold	—	—	—	—
Gross profit	—	—	—	—
Operating expenses:				
Research and development	2,305,952	2,762,478	8,017,249	8,207,211
Selling, general and administrative	3,287,952	3,207,943	11,488,969	10,153,495
Total operating expenses	5,593,904	5,970,421	19,506,218	18,360,706
Operating loss	(5,593,904)	(5,970,421)	(19,506,218)	(18,360,706)
Other income (expense):				
Interest income	755	1,184	2,505	4,767
Interest expense	(120,917)	(224,771)	(435,739)	(733,424)
Other, net	(176)	(109,286)	(8,334)	(118,016)
Net loss	\$ (5,714,242)	\$ (6,303,294)	\$ (19,947,786)	\$ (19,207,379)
Net loss per share—basic and diluted	\$ (0.08)	\$ (0.11)	\$ (0.30)	\$ (0.36)
Shares used to compute basic and diluted net loss per share	68,885,435	55,978,107	67,414,867	52,864,039

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>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Net loss	\$ (5,714,242)	\$ (6,303,294)	\$ (19,947,786)	\$ (19,207,379)
Comprehensive loss	\$ (5,714,242)	\$ (6,303,294)	\$ (19,947,786)	\$ (19,207,379)

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>2014</u>	<u>2013</u>
Cash flows from operating activities:		
Net loss	\$(19,947,786)	\$(19,207,379)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	141,890	124,418
Stock-based compensation	4,781,299	4,376,955
Amortization of commitment fees, debt issuance costs and original issue discount	99,928	155,862
Other, net	—	8,030
Change in operating assets and liabilities:		
Accounts receivable	17,742	(8,906)
Inventory	212,443	98,932
Prepaid expenses and other current assets	305,108	1,365
Other assets	(187,980)	177,946
Accounts payable	(75,768)	102,936
Accrued expenses	(292,743)	54,331
Accrued interest payable	(8,931)	2,820
Net cash used in operating activities	<u>(14,954,798)</u>	<u>(14,112,690)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(27,066)	(410,462)
Net cash used in investing activities	<u>(27,066)</u>	<u>(410,462)</u>
Cash flows from financing activities:		
Proceeds from warrants exercised	2,242,265	9,500
Proceeds from sale of common stock and warrants for purchase of common stock	8,909,383	16,634,310
Common stock financing costs	(197,685)	(1,287,411)
Repayments on notes payable	(3,000,000)	(2,000,000)
Net cash provided by financing activities	<u>7,953,963</u>	<u>13,356,399</u>
Net decrease in cash and cash equivalents	<u>(7,027,901)</u>	<u>(1,166,753)</u>
Cash and cash equivalents:		
Beginning of period	<u>23,297,479</u>	<u>22,308,781</u>
End of period	<u>\$ 16,269,578</u>	<u>\$ 21,142,028</u>
Supplemental disclosure:		
Interest paid	\$ 344,741	\$ 574,741

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 medical devices using neuroblocking technology to treat obesity, metabolic diseases and other gastrointestinal disorders. The Company was incorporated in the state of Minnesota on December 19, 2002 and was reincorporated in Delaware on July 22, 2004. The Company is headquartered in St. Paul, Minnesota. In January 2006, the Company established EnteroMedics Europe Srl, 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 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 submitted a premarket approval (PMA) application for the Maestro Rechargeable System to the U.S. Food and Drug Administration (FDA) in June 2013 using data from a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial, called the ReCharge trial, that was accepted for review and filing in July 2013. An Advisory Panel meeting was held on June 17, 2014 to review the Company's 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. The FDA is not bound by the Advisory Panel's recommendation, but will take it into consideration while reviewing the Company's PMA application. Assuming the FDA grants the Company approval in late 2014, the Company anticipates that it will be able to start commercializing the Maestro Rechargeable System in a controlled limited launch at select bariatric centers of excellence in the United States thereafter.

The Company's activities are subject to significant risk 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. See Note 2.

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, 2013 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, 2013.

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 long-term debt (including the current portion) is approximately \$4.4 million as of September 30, 2014, 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, long-term debt (including the current portion) 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 September 30, 2014 and December 31, 2013.

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 and nine months ended September 30, 2014 and 2013.

ENTEROMEDICS INC.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

Revenue Recognition

The Company recognizes revenue 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. The Company sells products internationally through distributors and recognizes revenue 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, 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 and nine months ended September 30, 2014 and 2013:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Numerator:				
Net loss	\$ (5,714,242)	\$ (6,303,294)	\$ (19,947,786)	\$ (19,207,379)
Denominator for basic and diluted net loss per share:				
Weighted-average common shares outstanding	68,885,435	55,978,107	67,414,867	52,864,039
Net loss per share—basic and diluted	\$ (0.08)	\$ (0.11)	\$ (0.30)	\$ (0.36)

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,	
	2014	2013
Stock options outstanding	12,336,783	11,622,700
Warrants to purchase common stock	24,199,705	25,565,950

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 will be effective for interim and annual reporting periods beginning after December 15, 2014; however, early application is permitted for any annual reporting period or interim period for which an entity’s financial statements have not yet been issued. The Company elected to adopt ASU 2014-10 effective with the quarter ending June 30, 2014. Therefore, the accompanying condensed consolidated financial statements no longer present or disclose any information previously required by Topic 915.

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 nine months ended September 30, 2014 as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2013.

(2) Liquidity and Management's Plans

The accompanying condensed consolidated financial statements have been prepared assuming the Company will continue as a going concern. As of September 30, 2014, the Company had \$16.3 million of cash and cash equivalents. Assuming the Company does not receive any additional funds, it estimates that it has sufficient funds to operate into 2015 (including scheduled or potentially accelerated debt obligations). In order to fund on-going operating cash requirements beyond that point or to further accelerate and execute its business plan, including commercialization of the Maestro Rechargeable System, the Company will need to raise additional funds.

The Company has financed its activities principally from the sale of equity securities, debt financing and interest earned on investments. While the Company has been successful in the past in obtaining the necessary capital to support its operations, and has similar future plans, there is no assurance that the Company will be able to obtain additional equity capital or other financing under commercially reasonable terms and conditions, or at all. Furthermore, if the Company issues equity or debt securities to raise additional funds, existing shareholders may experience dilution and the new equity or debt securities it issues may have rights, preferences and privileges senior to those of existing stockholders. In addition, if the Company raises 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. If the Company cannot execute its plan to raise funds on acceptable terms, the Company will not be able to continue as a going concern, develop or enhance products, obtain the required regulatory clearances or approvals, execute the Company's business plan, take advantage of future opportunities, or respond to competitive pressure or unanticipated customer requirements. If the Company is unable to obtain additional financing or the FDA does not approve the Maestro Rechargeable System for commercial use in the U.S., the Company may be required to reduce the scope of, delay, or eliminate some or all of, its planned research, development and commercialization activities, which could materially harm its business. Any of these events would adversely affect the Company's ability to achieve its development and commercialization goals, which could have a material adverse effect on the Company's business, results of operations and financial condition. The Company's financial statements do not include any adjustments relating to the recoverability or classification of assets or the amounts of liabilities that might result from the outcome of these uncertainties.

(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 \$843,000 and \$794,000 of long-term inventory, primarily consisting of raw materials, as of September 30, 2014 and December 31, 2013, respectively.

ENTEROMEDICS INC.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

Current inventory consists of the following as of:

	<u>September 30,</u> <u>2014</u>	<u>December 31,</u> <u>2013</u>
Raw materials	\$ 390,820	\$ 385,565
Work-in-process	481,777	624,530
Finished goods	42,901	117,846
Inventory	<u>\$ 915,498</u>	<u>\$ 1,127,941</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 month periods ended September 30, 2014 and 2013 was \$67,718, and for each of the nine month periods ended September 30, 2014 and 2013 was \$203,154. At September 30, 2014, future minimum payments under the lease are as follows:

<u>Years ending December 31:</u>	
Remaining three months in 2014	\$ 73,929
2015	<u>221,789</u>
	<u>\$295,718</u>

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 its product, 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. 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 System and to implant certain minimum numbers of Maestro 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.

ENTEROMEDICS INC.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

The First Amendment eliminated the financial covenants that required the Company to generate certain minimum amounts of revenue from the sale of its Maestro System and to implant certain minimum numbers of Maestro 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 through the use of the equity distribution agreement with Canaccord Genuity Inc. (see Note 7). The second financial covenant requires the Company to maintain a liquidity ratio (unrestricted cash divided by outstanding debt) of at least 1.25:1.00 until it receives FDA approval for the Maestro Rechargeable System at which point it will be reduced to 0.75:1.00. The First Amendment did not change the interest rate or the amortization structure. The Company will pay SVB a \$187,000 success fee in the event the Company receives FDA approval for the Maestro Rechargeable System.

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.

Scheduled debt principal payments are as follows as of September 30, 2014:

Years Ending December 31:	
Remaining three months in 2014	\$ 1,000,000
2015	3,000,000
	<u>4,000,000</u>
Less: Original issue discount	(43,167)
Notes payable, net	<u>\$3,956,833</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 and nine months ended September 30, 2014 and 2013 was allocated to operating expenses and employees and nonemployees as follows:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Research and development	\$ 329,772	\$ 373,187	\$ 1,125,985	\$ 1,041,777
Selling, general and administrative	1,176,465	1,157,186	3,655,314	3,335,178
Total	<u>\$1,506,237</u>	<u>\$ 1,530,373</u>	<u>\$ 4,781,299</u>	<u>\$ 4,376,955</u>

ENTEROMEDICS INC.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Employees	\$1,536,465	\$1,517,447	\$4,637,556	\$4,304,043
Nonemployees	(30,228)	12,926	143,743	72,912
Total	\$1,506,237	\$1,530,373	\$4,781,299	\$4,376,955

As of September 30, 2014, there was approximately \$10.3 million of total unrecognized compensation costs, net of estimated forfeitures, related to employee unvested stock option awards granted after January 1, 2006, which are expected to be recognized over a weighted-average period of 2.11 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, 2014 and 2013:

	Employees	
	Nine months ended September 30,	
	2014	2013
Risk-free interest rates	1.84%-1.96%	0.94%-1.33%
Expected life	6.00-6.25 years	6.00-6.25 years
Expected dividends	0%	0%
Expected volatility	119.94%-120.70%	148.00%-149.00%

There were no new employee grants for the three months ended September 30, 2014 and 2013.

	Nonemployees		Nonemployees	
	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Risk-free interest rates	0.08%-2.37%	0.27%-0.92%	0.08%-2.63%	0.27%-1.03%
Expected life	0.76-9.01 years	1.76-3.67 years	0.76-9.51 years	1.76-3.92 years
Expected dividends	0%	0%	0%	0%
Expected volatility	56.54%-135.52%	90.00%-92.00%	56.54%-139.65%	82.00%-125.00%

Option activity under the Company's Amended and Restated 2003 Stock Incentive Plan for the nine months ended September 30, 2014 was as follows:

	Shares Available For Grant	Outstanding Options	
		Number of Shares	Weighted- Average Exercise Price
Balance, December 31, 2013	542,218	11,687,300	\$ 2.56
Shares reserved	7,500,000	—	—
Options granted	(727,500)	727,500	1.80
Options exercised	—	—	—
Options cancelled	78,017	(78,017)	3.65
Balance, September 30, 2014	7,392,735	12,336,783	\$ 2.51

(7) Stock Sales

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 "at-the-market" equity offering program (ATM) under which Canaccord acted as the Company's sales agent (the Canaccord ATM). The

ENTEROMEDICS INC.
Notes to Condensed Consolidated Financial Statements (Continued)
(Unaudited)

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. During 2014 the Company sold 4,006,222 shares under the Canaccord ATM at a weighted-average selling price of \$2.22 per share for gross proceeds of approximately \$8.9 million before deducting offering expenses. 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 approximately \$19.9 million before deducting offering expenses.

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, 2014, the Company had not sold any shares under the Cowen ATM. Subsequent to September 30, 2014 through November 12, 2014, the Company has sold 218,067 shares under the Cowen ATM at a weighted-average selling price of \$1.27 per share for gross proceeds of approximately \$276,000 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, 2013. 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 in 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 currently we only 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. Our initial product is the Maestro System, which uses VBLOC therapy to affect metabolic regulatory control, 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 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 System.

Based on our understanding of vagal nerve function and nerve blocking from our preclinical studies and the results of our clinical trials, we believe the Maestro System may offer obese patients a minimally-invasive treatment that has the potential to result in significant and sustained weight loss. We believe that our Maestro System will allow bariatric surgeons to help obese patients who are concerned about the risks and complications associated with currently available restrictive and malabsorptive surgical procedures. 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 continue to evaluate the Maestro System in human clinical trials in the United States, Australia, Mexico and Norway. To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in these clinical trials. We have also not observed any long-term problematic clinical side effects in any patients, including in those patients who have been using the Maestro System for more than one year.

In October 2010, we received an unconditional Investigational Device Exemption (IDE) Supplement approval from the U.S. Food and Drug Administration (FDA) to conduct a randomized, double-blind, sham-controlled, multicenter pivotal clinical trial, called the ReCharge trial, testing the effectiveness and safety of VBLOC therapy utilizing our second generation Maestro Rechargeable System. Enrollment and implantation in the ReCharge trial was completed in December 2011 in 239 randomized patients (233 implanted) at 10 centers. All patients in the trial received an implanted device and were randomized in a 2:1 allocation to treatment or 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 on February 7, 2013, the ReCharge trial met its primary safety endpoint, though it did not meet its predefined co-primary efficacy endpoints. The trial did however 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. On December 3, 2013, we announced 18 month efficacy and safety results from the ReCharge trial showing that VBLOC therapy-treated patients were maintaining their weight loss, while the sham control group gained back over 40% of the weight loss seen at 12 months. The trial's positive safety profile also continued with a device-related serious adverse event rate of 4.3% at 18 months for VBLOC therapy-treated patients.

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As a result of the positive safety and efficacy profile of VBLOC therapy, we used the data from the ReCharge trial to support a premarket approval (PMA) application for the Maestro Rechargeable System, which was submitted to the FDA in June 2013 and was accepted for review and filing in July 2013. An Advisory Panel meeting was held on June 17, 2014 to review our PMA application for approval of the 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. The FDA is not bound by the Advisory Panel’s recommendation, but will take it into consideration while reviewing our PMA application. Assuming the FDA grants us approval in late 2014, we anticipate we will be able to start commercializing the Maestro Rechargeable System in a controlled limited launch at select bariatric centers of excellence in the United States thereafter.

If we obtain FDA approval of our Maestro Rechargeable System, we intend to market our products in the United States through a direct sales force supported by field technical and marketing managers who provide training, technical and other support services to our customers. Outside the United States, we intend to use direct, dealer and distributor sales models as the targeted geography best dictates. To date, we have relied on third-party manufacturers and suppliers for the production of our Maestro System. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of the Maestro System.

We obtained European CE Mark approval for our Maestro Rechargeable System in 2011. 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 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, including Saudi Arabia, Kuwait, Bahrain, Qatar and the United Arab Emirates, respectively. We continue to explore additional select international markets to commercialize the Maestro Rechargeable System, including Europe.

The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which is considered an Active Implantable Medical Device (AIMD) in Australia and the European Economic Area, and falls into Class III within the United States), the method involved a combination of self-assessment and issuance of declaration and conformity by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body of the design of the device and of our quality system. We use DEKRA Certification B.V. (formerly known as KEMA Quality) in the Netherlands as the Notified Body for our CE marking approval process.

Thus far, we have only generated revenue from the sale of products in 2012 because we continue to focus our resources on the U.S. regulatory approval process. Although we have received ARTG listings to sell our Maestro Rechargeable System in Australia and European CE Mark to sell our Maestro Rechargeable System in the European Economic Area and other countries that recognize the European CE Mark, resulting in our first commercial sales in 2012, we expect to incur significant sales and marketing expenses prior to recording sufficient revenue to offset these expenses. We expect our general and administrative expenses to increase as we continue to add the infrastructure necessary to support our initial commercial sales, operate as a public company and develop our intellectual property portfolio. For these reasons, we expect to continue to incur significant 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 obtained European CE Mark approval for our Maestro Rechargeable System in 2011, which enables commercialization in the European Economic Area and other countries that recognize the European CE Mark. 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, 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 have not recognized any revenue subsequent to December 31, 2012, primarily due to focusing our resources on the U.S. 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 and clinical and regulatory expenses, incurred in the development of our Maestro 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, 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 September 30, 2014 and 2013

Sales. There were no sales for the three months ended September 30, 2014 and 2013, which was primarily the result of focusing our resources on the U.S. regulatory approval process.

Cost of Goods Sold. There were no cost of goods sold for the three months ended September 30, 2014 and 2013.

Research and Development Expenses. Research and development expenses were \$2.3 million for the three months ended September 30, 2014, compared to \$2.8 million for the three months ended September 30, 2013. The decrease of \$457,000, or 16.5%, was primarily due to decreases of \$376,000 and \$122,000 in professional services and device costs, respectively. The decrease in professional services was primarily related to the use of engineering consultants in 2013 during the PMA submission process that were not required in 2014. The decrease in device costs is primarily related to a higher number of conversions to active devices for the three months ended September 30, 2013 compared to the three months ended September 30, 2014.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were relatively flat at \$3.3 million for the three months ended September 30, 2014, compared to \$3.2 million for the three months ended September 30, 2013. The increase of \$80,000, or 2.5%, was primarily due to an increase of \$257,000 in personnel-related expenses, including payroll, benefits and employee stock-based compensation, offset by a decrease of \$231,000 in professional services. The increase in personnel-related expenses was related to new hires in 2014 and annual compensation adjustments. The decrease in professional services was primarily related to preparation for the Advisory Panel meeting that began in 2013 and concluded June 17, 2014.

Interest Expense. Interest expense was \$121,000 for the three months ended September 30, 2014, compared to \$225,000 for the three months ended September 30, 2013. The decrease of \$104,000, or 46.2%, was the result of a reduction in the loan principal balance through monthly principal and interest loan payments beginning April 1, 2013.

Comparison of the Nine Months Ended September 30, 2014 and 2013

Sales. There were no sales for the nine months ended September 30, 2014 and 2013, which was primarily the result of focusing our resources on the U.S. regulatory approval process.

Cost of Goods Sold. There were no cost of goods sold for the nine months ended September 30, 2014 and 2013.

Research and Development Expenses. Research and development expenses were \$8.0 million for the nine months ended September 30, 2014, compared to \$8.2 million for the nine months ended September 30, 2013. The decrease of \$190,000, or 2.3%, was primarily due to decreases of \$648,000 for professional services, offset by increases of \$162,000, \$145,000, \$65,000 and \$64,000 in device costs, travel, nonemployee stock-based compensation and payroll-related expenses, respectively. The decrease in professional services was primarily related to the use of engineering consultants in 2013 during the PMA submission process that were not required in 2014. The increase in device costs was primarily related to conversions to active devices, on-going clinical trial support, inventory valuation adjustments and commercialization process development and validation efforts. The increases in travel and nonemployee stock-based compensation were primarily related to preparation for the Advisory Panel meeting. The increase in payroll-related expenses was primarily the result of a special one-time bonus in recognition of the Advisory Panel vote regarding the safety efficacy and benefit/risk profile of our Maestro Rechargeable System that occurred on June 17, 2014 (the Special Bonus).

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Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$11.5 million for the nine months ended September 30, 2014, compared to \$10.2 million for the nine months ended September 30, 2013. The increase of \$1.3 million, or 13.2%, was primarily due to increases of \$693,000, \$315,000 and \$95,000 in payroll-related expenses, employee stock-based compensation and professional services. The increase in payroll-related expenses was primarily the result of the Special Bonus. The increase in employee stock-based compensation was primarily the result of stock option grants made to management on May 31, 2013 and new hires in 2014. The increase in professional services was primarily the result of ongoing commercialization efforts and preparation for the Advisory Panel meeting.

Interest Expense. Interest expense was \$436,000 for the nine months ended September 30, 2014, compared to \$733,000 for the nine months ended September 30, 2013. The decrease of \$298,000, or 40.6%, was the result of a reduction in the loan principal balance through monthly principal and interest loan payments beginning April 1, 2013.

Liquidity and Capital Resources

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, 2014, we had \$16.3 million in cash and cash equivalents. Of this amount \$14.8 million was invested in short-term money market funds that are not considered to be bank deposits and are not insured or guaranteed by the Federal Deposit Insurance Company or other government agency. These money market funds seek to preserve the value of the investment at \$1.00 per share; however, it is possible to lose money investing in these funds. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. At times, such deposits may be in excess of insured limits. We have not experienced any losses on our deposits of cash and cash equivalents. We believe that our cash and cash equivalents balance of \$16.3 million as of September 30, 2014, together with any interest income we earn on these balances, will be sufficient to meet our anticipated cash requirements (including scheduled or potentially accelerated debt obligations) into 2015, assuming we do not receive any additional funds. In order to fund on-going operating cash requirements beyond that point or to further accelerate and execute our business plan, including commercialization of the Maestro Rechargeable System, we will need to raise additional funds. See further discussion in the below section titled "Operating Capital and Capital Expenditure Requirements."

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. 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 System and to implant certain minimum numbers of Maestro 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 System and to implant certain minimum numbers of Maestro 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 through the use of the equity distribution agreement with Canaccord Genuity Inc. (see discussion below). The second financial covenant requires us to maintain a liquidity ratio (unrestricted cash divided by outstanding debt) of at least 1.25:1.00 until we receive FDA approval for the Maestro Rechargeable System at which point it will be reduced to 0.75:1.00. The First Amendment did not change the interest rate or the amortization structure. We will pay SVB a \$187,000 success fee in the event we receive FDA approval for the Maestro Rechargeable System.

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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 “at-the-market” equity offering program (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. During 2014 we sold 4,006,222 shares under the Canaccord ATM at a weighted-average selling price of \$2.22 per share for gross proceeds of approximately \$8.9 million before deducting offering expenses. 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 approximately \$19.9 million before deducting offering expenses.

On June 13, 2014, we entered into a sales agreement with Cowen and Company, LLC (Cowen) to sell shares of our common stock having aggregate gross sales proceeds of up to \$25.0 million, from time to time, through an ATM under which Cowen will act as our sales agent (the Cowen ATM). We will determine, at our sole discretion, the timing and number of shares to be sold under the Cowen ATM. We will pay Cowen a commission for its services in acting as agent in the sale of common stock equal to 3.0% of the gross sales price per share of all shares sold through it as agent under the sales agreement. As of September 30, 2014, we had not sold any shares under the Cowen ATM. Subsequent to September 30, 2014 through November 12, 2014, we have sold 218,067 shares under the Cowen ATM at a weighted-average selling price of \$1.27 per share for gross proceeds of approximately \$276,000 before deducting offering expenses.

Net Cash Used in Operating Activities

Net cash used in operating activities was \$15.0 million and \$14.1 million for the nine months ended September 30, 2014 and 2013, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, which was partially offset by stock-based compensation, depreciation and amortization, and changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities was \$27,000 and \$410,000 for the nine months ended September 30, 2014 and 2013, respectively. Net cash used in investing activities for the nine months ended September 30, 2014 and 2013 is attributable to the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$8.0 million and \$13.4 million for the nine months ended September 30, 2014 and 2013, respectively. 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. Net cash provided by financing activities for the nine months ended September 30, 2013 was primarily due to a public offering that resulted in gross proceeds of \$13.1 million for the issuance of common stock and common stock warrants and gross proceeds from ATM draws of \$3.6 million, offset by \$1.3 million in financing costs and \$2.0 million in principal repayments on our long-term debt.

Operating Capital and Capital Expenditure Requirements

We have only generated revenue from the sale of products in 2012 because we continue to focus our resources on the U.S. regulatory approval process. Assuming the FDA grants us approval in late 2014, we anticipate we will be able to start commercializing the Maestro Rechargeable System in a controlled limited launch at select bariatric centers of excellence in the United States thereafter. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our products, prepare for the potential commercial launch of 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 believe that the cash and cash equivalents balance of approximately \$16.3 million as of September 30, 2014, together with any interest income we earn on these balances, will be sufficient to meet our anticipated cash requirements (including scheduled or potentially accelerated debt obligations) into 2015, assuming we do not receive any additional funds. In order to fund on-going operating cash requirements beyond that point or to further accelerate and execute our business plan, including commercialization of the Maestro Rechargeable System, we will need to raise additional funds. If our available cash and cash equivalents balances are insufficient to satisfy our liquidity requirements, we may seek additional funding through the Cowen ATM, sell additional equity or debt securities or enter into a credit facility. 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

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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, or the FDA does not approve the Maestro Rechargeable System for commercial use in the U.S., 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, 2013. 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 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 scope, rate of progress, results and cost of our clinical trials and other research and development activities;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- 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;
- the cost of establishing clinical and commercial supplies of our Maestro System and any products that we may develop;
- the rate of market acceptance of our Maestro 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 System or our future 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, 2014, 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, 2013.

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Contractual Obligations

During the nine months ended September 30, 2014, 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, 2013.

The following table summarizes our contractual obligations as of September 30, 2014 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	\$ 295,718	\$ 295,718	\$ —	\$ —	\$ —
Long-term debt, including interest and final payment fee	4,675,333	4,675,333	—	—	—
Total contractual cash obligations	<u>\$4,971,051</u>	<u>\$4,971,051</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. Our operating lease commitments relate to our corporate headquarters in St. Paul, Minnesota.

Off-Balance Sheet Arrangements

As of September 30, 2014, 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 will be effective for interim and annual reporting periods beginning after December 15, 2014; however, early application is permitted for any annual reporting period or interim period for which an entity’s financial statements have not yet been issued. We elected to adopt ASU 2014-10 effective with the quarter ending June 30, 2014. Therefore, the accompanying condensed consolidated financial statements no longer present or disclose any information previously required by Topic 915.

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 nine months ended September 30, 2014 as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the year ended December 31, 2013.

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, 2014, we had \$16.3 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, 2014, 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) 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, 2014 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 nine months ended September 30, 2014 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, 2013.

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
Senior Vice President, Chief Financial
Officer and Chief Operating Officer
(Principal Financial and Accounting Officer)

Dated: November 12, 2014

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)).
4.1	Amended and Restated Investors' Rights Agreement, dated as of July 6, 2006, by and between the Company and the parties named therein. (Incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)).
10.1†	Amendment No. 2 to Consulting Agreement, effective September 1, 2014, by and between Anthony Jansz and the Company. (Incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 1, 2014 (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, 2014, formatted in Extensible Business Reporting Language: (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Comprehensive Loss, (iv) the Condensed Consolidated Statements of Cash flows and (v) the Notes to Condensed Consolidated Financial Statements.

* Filed herewith.

† Indicates management contract or compensation plan or agreement.

CERTIFICATION

I, 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 12, 2014

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

**Senior Vice President, Chief Financial Officer
and Chief Operating Officer**

Date: November 12, 2014

