

**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, 2011

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, 2011, 36,749,566 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. In addition, the marks VBLOC, MAESTRO and ENTEROMEDICS are the subject of either a trademark registration or application for registration in Australia, Brazil, China, the European Community and Saudi Arabia and VBLOC is registered in Switzerland. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are registered in Mexico. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are the subject of pending trademark applications in the United Arab Emirates. This 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.
(A development stage company)**

**Condensed Consolidated Balance Sheets
(Unaudited)**

	<u>September 30, 2011</u>	<u>December 31, 2010</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,438,627	\$ 30,840,560
Restricted cash	200,000	6,527,031
Short-term investments available for sale	3,006,398	—
Prepaid expenses and other current assets	716,363	436,538
Total current assets	<u>36,361,388</u>	<u>37,804,129</u>
Property and equipment, net	568,267	741,564
Other assets	68,229	141,572
Total assets	<u>\$ 36,997,884</u>	<u>\$ 38,687,265</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable	\$ 2,271,092	\$ 921,998
Accounts payable	261,315	125,188
Accrued expenses	3,340,035	2,538,371
Accrued interest payable	434,930	411,492
Total current liabilities	<u>6,307,372</u>	<u>3,997,049</u>
Notes payable, less current portion (net discounts of \$263,721 and \$421,874 at September 30, 2011 and December 31, 2010, respectively)	3,425,030	4,983,159
Total liabilities	<u>9,732,402</u>	<u>8,980,208</u>
Stockholders' equity:		
Common stock, \$0.01 par value 85,000,000 shares authorized; 36,748,281 and 27,892,388 shares issued and outstanding at September 30, 2011 and December 31, 2010, respectively	367,483	278,924
Additional paid-in capital	195,554,395	180,143,120
Accumulated other comprehensive income	(174)	—
Deficit accumulated during development stage	<u>(168,656,222)</u>	<u>(150,714,987)</u>
Total stockholders' equity	<u>27,265,482</u>	<u>29,707,057</u>
Total liabilities and stockholders' equity	<u>\$ 36,997,884</u>	<u>\$ 38,687,265</u>

See accompanying notes to condensed consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Condensed Consolidated Statements of Operations
(Unaudited)

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>		<u>Period from</u>
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>	<u>December 19,</u>
					<u>2002</u>
					<u>(inception) to</u>
					<u>September 30,</u>
					<u>2011</u>
Operating expenses:					
Research and development	\$ 4,778,967	\$ 2,342,322	\$ 10,882,384	\$ 7,061,187	\$ 110,990,720
Selling, general and administrative	2,354,501	1,751,870	6,488,749	5,496,247	46,074,372
Total operating expenses	<u>7,133,468</u>	<u>4,094,192</u>	<u>17,371,133</u>	<u>12,557,434</u>	<u>157,065,092</u>
Other income (expense):					
Interest income	2,303	—	10,634	1,489	4,034,656
Interest expense	(167,794)	(286,490)	(563,656)	(975,370)	(11,403,567)
Change in value of warrant liability	—	—	—	158,834	(3,840,622)
Other, net	847	(4,689)	(17,080)	(19,950)	(250,629)
Net loss	<u>\$ (7,298,112)</u>	<u>\$ (4,385,371)</u>	<u>\$ (17,941,235)</u>	<u>\$ (13,392,431)</u>	<u>\$ (168,525,254)</u>
Net loss per share—basic and diluted	<u>\$ (0.26)</u>	<u>\$ (0.59)</u>	<u>\$ (0.64)</u>	<u>\$ (1.81)</u>	
Shares used to compute basic and diluted net loss per share	<u>28,209,522</u>	<u>7,478,075</u>	<u>27,999,412</u>	<u>7,390,857</u>	

See accompanying notes to condensed consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	<u>Nine months ended September 30,</u>		<u>Period from</u>
	<u>2011</u>	<u>2010</u>	<u>December 19,</u>
			<u>2002</u>
			<u>(inception) to</u>
			<u>September 30,</u>
			<u>2011</u>
Cash flows from operating activities:			
Net loss	\$(17,941,235)	\$(13,392,431)	\$(168,525,254)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	223,590	286,364	2,179,656
Loss on sale of equipment	1,269	6,274	74,127
Stock-based compensation	2,092,058	2,178,259	13,662,528
Amortization of commitment fees, debt issuance costs and original issue discount	180,672	305,395	3,832,555
Amortization of short-term investment premium or discount	1,408	—	(306,643)
Change in value of warrant liability	—	(158,834)	3,840,622
Change in operating assets and liabilities:			
Prepaid expenses and other current assets	(279,825)	164,330	(716,363)
Other assets	50,824	(60,347)	(9,524)
Accounts payable	323,609	48,530	257,258
Accrued expenses	801,664	395,221	3,340,035
Accrued interest payable	23,438	98,542	600,752
Net cash used in operating activities	<u>(14,522,528)</u>	<u>(10,128,697)</u>	<u>(141,770,251)</u>
Cash flows from investing activities:			
Decrease (increase) in restricted cash	6,327,031	—	(200,000)
Purchases of short-term investments available for sale	(5,007,980)	—	(19,890,213)
Maturities of short-term investments available for sale	2,000,000	—	16,854,414
Purchases of short-term investments held-to-maturity	—	—	(22,414,130)
Maturities of short-term investments held-to-maturity	—	—	22,750,000
Purchases of property and equipment	(239,044)	(2,592)	(2,817,992)
Net cash provided by (used in) investing activities	<u>3,080,007</u>	<u>(2,592)</u>	<u>(5,717,921)</u>
Cash flows from financing activities:			
Proceeds from stock options exercised	2,164	23,697	203,018
Proceeds from warrants exercised	119,912	—	307,564
Proceeds from sale of common stock and warrants for purchase of common stock	14,520,000	5,259,183	114,354,439
Common stock financing costs	(1,234,300)	(339,547)	(9,498,659)
Payment to shareholders for fractional shares upon reverse stock split	—	—	(355)
Proceeds from sale of Series A, B and C convertible preferred stock	—	5,838,211	63,766,564
Series A non-voting convertible preferred stock proceeds receivable	—	(781,251)	—
Series A, B and C convertible preferred stock financing costs	—	(42,810)	(1,658,662)
Proceeds from notes payable and convertible notes payable	—	—	42,645,967
Repayments on notes payable	(367,188)	(1,889,904)	(29,871,278)
Debt issuance costs	—	—	(321,799)
Net cash provided by financing activities	<u>13,040,588</u>	<u>8,067,579</u>	<u>179,926,799</u>
Net increase (decrease) in cash and cash equivalents	<u>1,598,067</u>	<u>(2,063,710)</u>	<u>32,438,627</u>
Cash and cash equivalents:			
Beginning of period	<u>30,840,560</u>	<u>14,617,594</u>	<u>—</u>
End of period	<u>\$ 32,438,627</u>	<u>\$ 12,553,884</u>	<u>\$ 32,438,627</u>
Supplemental disclosure:			
Interest paid	\$ 359,505	\$ 562,867	\$ 6,961,654
Noncash investing and financing activities:			
Cancellation of Alpha Medical, Inc. Series A convertible preferred stock and common stock	\$ —	\$ —	\$ (661,674)
Issuance of Beta Medical, Inc. Series A convertible preferred stock in exchange for Alpha Medical, Inc. Series A convertible preferred stock and common stock	—	—	661,674
Value of warrants issued with debt and for debt commitment	—	289,257	3,833,183
Value of warrants issued with sale of common and preferred stock offerings	—	—	1,684,832
Cashless exercise of warrants	—	—	5,244,778
Conversion of notes and interest payable to Series B and C convertible preferred shares	—	—	6,980,668
Options issued for deferred compensation	—	—	10,898
Common stock issued to Mayo Foundation and for deferred compensation	—	—	1,770,904
Reclassifications of warrant liability	—	312,751	2,932,766
Conversion of convertible preferred stock to common stock	—	—	51,132

See accompanying notes to condensed consolidated financial statements.

EnteroMedics Inc.
(A development stage company)

Notes to Condensed Consolidated Financial Statements
(Unaudited)

(1) Summary of Significant Accounting Policies

Description of Business

EnteroMedics Inc. (formerly Beta Medical, 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 in the development stage and since inception has devoted substantially all of its resources to recruiting personnel, developing its product technology, obtaining patents to protect its intellectual property and raising capital, and has not derived revenues from its primary business activity. The Company is headquartered in St. Paul, Minnesota. In January 2006, the Company established EnteroMedics Europe Sàrl, a wholly-owned subsidiary located in Switzerland.

Since inception, the Company has incurred losses through September 30, 2011 totaling approximately \$168.5 million and has not generated positive cash flows from operations. The Company expects such losses to continue into the foreseeable future as it continues to develop and commercialize its technologies. The Company may need 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, 2010 was derived from audited 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, 2010.

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 significant intercompany balances and transactions have been eliminated in consolidation.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. The fair values of investments in debt and equity securities are disclosed in Note 2. The fair value of the Company's note payable is approximately \$5.7 million as of September 30, 2011 based on the present value of estimated future cash flows using a discount rate commensurate with borrowing rates available to the Company.

The Company recorded a financial liability in 2009 and through May 18, 2010 related to warrants outstanding, which was fair valued using Level 3 inputs (see "Derivative Instruments" below and Note 4).

Restricted Cash

The Company had \$200,000 and \$6.5 million in a cash collateral money market account as of September 30, 2011 and December 31, 2010, respectively. \$6.3 million of the December 31, 2010 balance was established per the terms of the Third Amendment to the Loan Agreement with Silicon Valley Bank dated November 12, 2010, which required the Company to have an amount equal to the principal balance outstanding in the restricted account. The restricted cash balance was eliminated per the terms of the Fourth Amendment to the Loan Agreement with Silicon Valley Bank dated March 3, 2011 (see Note 4).

Pursuant to the Lease Agreement the Company entered into with Roseville Properties Management Company in July 2008, the Company was required to deliver to Roseville Properties an irrevocable, unconditional, standby letter of credit in the amount of \$200,000 on the second anniversary of the commencement of lease payments. The standby letter of credit is to be maintained through October 1, 2013. The irrevocable standby letter of credit was issued by Silicon Valley Bank, who required the Company to set up a restricted cash collateral money market account to fully secure the standby letter of credit.

Inventory

Since inception, inventory related purchases have been used for research and development related activities and have accordingly been expensed as incurred. In the event inventory is determined to be recoverable in the future, the Company will account for it at the lower of cost or market.

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. The difference from reported net loss for the three and nine months ended September 30, 2011 related entirely to net unrealized losses on short-term investments. There was no difference from reported net loss for the three and nine months ended September 30, 2010.

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 and regulatory expenses, payroll and other personnel expenses, materials, supplies and consulting costs.

Derivative Instruments

The Company accounts for outstanding warrants that are not indexed to the Company's stock or warrants issued when the Company has insufficient authorized and unissued stock available to share settle the outstanding warrants as derivative instruments, which require that the warrants be classified as a liability and measured at fair value with changes in fair value recognized currently in earnings and recorded separately in the condensed consolidated statements of operations.

Effective January 1, 2009, as a result of a change in accounting guidance, the Company assessed any outstanding equity-linked financial instruments and concluded that warrants issued in November 2008 with a recorded value of \$1.4 million on December 31, 2008 were to be reclassified from equity to a liability. The cumulative effect of the change in accounting principle on January 1, 2009 was a \$130,968 increase to the deficit accumulated during development stage.

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 number of 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, unvested common shares subject to repurchase, convertible preferred stock 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, 2011 and 2010:

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Numerator:				
Net loss	\$ (7,298,112)	\$ (4,385,371)	\$ (17,941,235)	\$ (13,392,431)
Denominator for basic and diluted net loss per share:				
Weighted-average common shares outstanding	28,209,522	7,478,075	27,999,412	7,390,857
Weighted-average unvested common shares subject to repurchase	—	—	—	—
Denominator for net loss per common share—basic and diluted	28,209,522	7,478,075	27,999,412	7,390,857
Net loss per share—basic and diluted	\$ (0.26)	\$ (0.59)	\$ (0.64)	\$ (1.81)

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,	
	2011	2010
Stock options outstanding	2,799,908	911,220
Warrants to purchase common stock	23,927,766	4,903,728
Series A non-voting convertible preferred stock	—	3,394,309

Recently Issued Accounting Standards

In April 2011, the Financial Accounting Standards Board (FASB) issued amendments to achieve common fair value measurement and disclosure requirements between accounting principles generally accepted in the United States of America and International Financial Reporting Standards. This new guidance amends current fair value measurement and disclosure guidance to include increased transparency around valuation inputs and investment categorization. This new guidance is effective for fiscal years and interim periods beginning after December 15, 2011. The Company does not expect the adoption of these amendments to have a material impact on the preparation of the consolidated financial statements.

In June 2011, the FASB issued new guidance on the presentation of comprehensive income. Specifically, the new guidance allows an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. While the new guidance changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under current accounting guidance. The new guidance is effective for fiscal years beginning after December 15, 2011. The Company does not expect the adoption of this new guidance to have a material impact on the preparation of the consolidated financial statements.

There have been no other significant changes in recent accounting pronouncements during the nine months ended September 30, 2011 as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the year ended December 31, 2010.

(2) Short-term Investments and Fair Value Measurements

Effective January 1, 2008, the Company adopted fair value measurement and disclosure provisions for its financial assets and liabilities as described below.

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

- Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

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

The Company's assets that are measured at fair value on a recurring basis are classified within Level 1 or Level 2 of the fair value hierarchy. The Company does not hold any assets that are measured at fair value using Level 3 inputs. The types of instruments the Company invests in that are valued based on quoted market prices in active markets 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 the Company's U.S. agency securities, commercial paper, U.S. corporate bonds and municipal obligations. Such instruments are classified by the Company within Level 2 of the fair value hierarchy. The Company values these types of assets using consensus pricing or a weighted average price, which is based on multiple pricing sources received from a variety of industry standard data providers (e.g. Bloomberg), security master files from large financial institutions, and other third-party sources. The multiple prices obtained are then used as inputs into a distribution-curve-based algorithm to determine the daily market price.

The following table sets forth by level, within the fair value hierarchy, the Company's financial assets accounted for at fair value as of September 30, 2011. Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

All short-term investments at September 30, 2011 are classified as Level 2 and are as follows:

	Significant Other Observable Inputs Level 2
U.S. agency securities	\$ 3,006,398
Total	<u>\$ 3,006,398</u>

The short-term investments available for sale at September 30, 2011 had effective maturities of less than one year. The amortized cost and fair value of short-term investments available for sale, and the related gross unrealized gains and losses, were as follows at September 30, 2011:

	<u>Cost</u>	<u>Gross Unrealized</u>		<u>Fair value</u>
		<u>Gains</u>	<u>Losses</u>	
U.S. agency securities	\$3,006,571	\$ 270	\$ 443	\$3,006,398
Total	<u>\$3,006,571</u>	<u>\$ 270</u>	<u>\$ 443</u>	<u>\$3,006,398</u>

(3) Commitments

Operating Lease

The Company rents its office, warehouse and laboratory facilities under an operating lease, which expires on September 30, 2015. At September 30, 2011, future minimum payments under the lease were as follows:

<u>Years ending December 31:</u>	
Remaining three months in 2011	\$ 69,665
2012	280,055
2013	285,656
2014	291,369
2015	221,789
	<u>\$1,148,534</u>

(4) Notes Payable

On November 18, 2008 the Company entered into a new Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank (SVB), Venture Lending & Leasing V, Inc. (a private equity fund under the management of Western Technology Investment (WTI)) and Compass Horizon Funding Company LLC (Horizon and, collectively with SVB and WTI, the Lenders), in an aggregate principal amount of up to \$20.0 million. On November 21, 2008, SVB and WTI each funded a Term Loan in the aggregate principal amount of \$10.0 million and \$5.0 million, respectively. The additional \$5.0 million Term Loan was automatically funded by Horizon on April 28, 2009 when the trading price of the Company's common stock on the NASDAQ Global Market exceeded a target amount specified in the Loan Agreement. On December 1, 2009, the Company repaid the outstanding principal amount due to WTI and Horizon pursuant to the Loan Agreement.

Warrants were issued with the November 18, 2008 Loan Agreement that contained down round protection provisions through May 18, 2010. As of September 30, 2011, Horizon had outstanding 141,025 common stock warrants with an exercise price of \$3.90 per share. The fair value of the warrant liability associated with these warrants was \$312,751 as of May 18, 2010, the date on which the warrants' down round protection expired. This Level 3 fair value was calculated using a weighted-average Black-Scholes valuation model and the following assumptions: volatility between 113.25% and 113.33%, dividend rate of 0%, risk-free interest rate of 3.38% and a remaining life between 8.51 and 8.95 years. As a result of the down round protection expiring, on May 18, 2010 the Company recorded a net decrease of \$158,834 for the nine months ended September 30, 2010, and reclassified the warrant liability to equity.

During 2010, the Company and SVB entered into three amendments to the Loan Agreement, which modified the payment terms, annual interest rate and financial covenants. A brief summary of the three amendments is provided below.

On February 8, 2010, the Company and SVB entered into the First Amendment to the Loan Agreement, which reduced the annual interest rate from 11.0% to a fixed annual rate of 10.0%, payable monthly, revised the liquidity financial covenant and added a New Capital Transaction covenant.

On July 8, 2010, the Company and SVB entered into a Second Amendment to the Loan Agreement, which modified the repayment terms of the loan such that interest only payments were required through December 31, 2010 followed by 30 equal payments of principal and interest, increased the annual interest rate from 10.0% to a fixed annual rate of 11.0%, payable monthly, revised the liquidity financial covenant and added additional New Capital Transaction requirements. On July 8, 2010, per the terms of the Second Amendment to the Loan Agreement, SVB was issued a warrant to purchase 150,642 shares of the Company's common stock with an exercise price of \$2.10 per share.

On November 4, 2010, the Company and SVB entered into a Third Amendment (the Third Amendment) to the Loan Agreement, which modified the New Capital Transaction covenant, suspended the liquidity financial covenant and required the Company to maintain a blocked cash collateral account with funds equal to the principal balance outstanding.

On March 3, 2011 the Company entered into a Fourth Amendment (the Fourth Amendment) to the Loan Agreement with SVB. The Fourth Amendment modified the repayment terms of the Term Loan such that beginning April 1, 2011 through September 30, 2011, the Company was only required to make interest only monthly payments on the Term Loan. Then, beginning on October 1, 2011, the remaining balance due on the Term Loan amortizes over 30 equal payments of principal and interest, which is payable monthly. In addition, the Fourth Amendment amended the interest rate due effective March 1, 2011 on the remaining principal amount of the Term Loan from 11.0% to a fixed annual rate of 6.25% if the liquidity ratio is greater than 1.50:1.00 and no Event of Default (as defined in the Loan Agreement) has occurred or is continuing or 9.00% if the liquidity ratio is less than 1.50:1.00 or an Event of Default has occurred or is continuing, payable

monthly. The Fourth Amendment also reinstated the financial covenant related to the liquidity ratio, which is not permitted to be less than 1.00:1.00, and added an EBITDA test should the liquidity ratio fall below 1.50:1.00. The EBITDA test requires that the trailing 90 day actual EBITDA be more favorable than 110% of the projected EBITDA for the same period if the projected EBITDA for such period was less than zero or at least 90% of the projected EBITDA for the same period if the projected EBITDA for such period was greater than or equal to zero. In addition, the Fourth Amendment amended the prepayment terms of the Loan Agreement such that a Make-Whole Premium equal to 1% of the amount of the Term Loan being prepaid will be due for any voluntary or required prepayment of the Term Loan occurring before the first anniversary of the Fourth Amendment, unless the Term Loan is being voluntarily prepaid and replaced with a new SVB facility. Lastly, the Fourth Amendment eliminated SVB's springing lien on the Company's intellectual property, the New Capital Transactions requirement and the requirement of the Third Amendment to maintain a blocked cash collateral account with funds equal to the principal balance outstanding.

Scheduled debt principal payments are as follows as of September 30, 2011:

<u>Years Ending December 31:</u>	
Remaining three months in 2011	\$ 554,810
2012	2,307,161
2013	2,458,599
2014	639,273
	<u>5,959,843</u>
Less: Original issue discount	(263,721)
Notes payable, net	<u>\$5,696,122</u>

(5) 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 2003 Stock Incentive Plan (the Plan) for the three and nine months ended September 30, 2011 and 2010 was allocated to operating expenses and to employees and nonemployees as follows:

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Research and development	\$208,942	\$232,622	\$ 680,431	\$ 767,022
Selling, general and administrative	488,821	452,006	1,411,627	1,411,237
Total	<u>\$697,763</u>	<u>\$684,628</u>	<u>\$2,092,058</u>	<u>\$2,178,259</u>

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2011</u>	<u>2010</u>	<u>2011</u>	<u>2010</u>
Employees	\$682,733	\$681,117	\$2,060,581	\$2,143,388
Nonemployees	15,030	3,511	31,477	34,871
Total	<u>\$697,763</u>	<u>\$684,628</u>	<u>\$2,092,058</u>	<u>\$2,178,259</u>

As of September 30, 2011 there was approximately \$5.7 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 2.85 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, 2011 and 2010:

	Employees		Employees	
	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Risk-free interest rates	1.20%-2.16%	1.87%	1.20%-2.68%	1.87%-2.62%
Expected life	6.25 years	6.25 years	5.42-6.25 years	6.00-6.25 years
Expected dividends	0%	0%	0%	0%
Expected volatility	116.75%-119.35%	124.78%	116.75%-124.40%	113.20%-124.78%
	Nonemployees		Nonemployees	
	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Risk-free interest rates	0.66%-1.91%	2.82%	0.66%-3.45%	2.82%-3.81%
Expected life	3.75-9.95 years	9.54 years	3.75-9.95 years	9.01-9.87 years
Expected dividends	0%	0%	0%	0%
Expected volatility	116.40%-120.50%	127.93%	116.40%-123.80%	113.25%-127.93%

Option activity under the Plan for the nine months ended September 30, 2011 was as follows:

	Shares Available For Grant	Outstanding Options	
		Number of Shares	Weighted-Average Exercise Price
Balance, December 31, 2010	1,423,361	812,515	\$ 5.60
Shares reserved	2,000,000	—	—
Options granted	(2,033,964)	2,033,964	2.62
Options exercised	—	(1,139)	1.90
Options cancelled	45,432	(45,432)	3.45
Balance, September 30, 2011	<u>1,434,829</u>	<u>2,799,908</u>	\$ 3.47

(6) Stock Sale

On September 28, 2011, the Company closed a public offering, selling 8,800,000 shares of common stock together with warrants to purchase an additional 1,760,000 shares of common stock at an aggregate price of \$1.65 per share and corresponding warrant, for gross proceeds of approximately \$14.5 million before deducting offering expenses.

The warrants have an exercise price of \$1.90 per share of common stock and are exercisable for a period of five years from September 28, 2011. Holders of the warrants are not permitted to exercise those warrants for an amount of common stock that would result in the holder owning more than 19.99% of the Company's common stock. The warrants may be redeemed in whole or in part at the option of the Company, at a redemption price of \$0.01 per warrant at any time after any date on which the closing sale price of the common stock, as reported on the principal exchange or trading facility on which it is then traded, has equaled or exceeded \$1.00 more than the exercise price of the warrants for 10 consecutive trading days. The Company is required to provide 30 days' prior written notice to the warrant holder of the Company's intention to redeem the warrant; provided, that the Company may not provide this notice until the earlier of (i) 30 days following the date the Company initially releases the results of the blinded portion of the ReCharge trial or (ii) June 30, 2013. The Company may not redeem any portion of a warrant if, had the holder exercised that portion of the warrant in lieu of redemption, it would have resulted in such holder owning more than 19.99% of the common stock outstanding after such exercise.

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 Exhibit 99.2 of our Current Report on Form 8-K filed September 28, 2011. 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 development stage medical device company 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 we currently have no products approved for sale in the United States. We have received CE Mark certification in the European Union. Our initial product under development is the Maestro System, which delivers VBLOC therapy. We believe VBLOC therapy limits the expansion of the stomach, helps control hunger sensations between meals, reduces the frequency and intensity of stomach contractions and produces a feeling of early and prolonged fullness. We were formerly known as Beta Medical, Inc. and were incorporated in Minnesota on December 19, 2002. We later reincorporated in Delaware on July 22, 2004. Since inception, 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 initial clinical trials, we believe the Maestro System may offer obese patients a minimally-invasive treatment alternative 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 gastric banding and gastric bypass surgery. In addition, data from our VBLOC-DM2 ENABLE trial outside the United States demonstrate that VBLOC therapy may hold promise in improving the obesity-related co-morbidities of diabetes and hypertension. We are conducting, or plan to conduct, further studies in each of these co-morbidities to assess VBLOC therapy's potential in addressing multiple indications.

We are currently evaluating the Maestro System in human clinical trials conducted in the United States, Australia, Mexico, Norway and Switzerland. 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.

On October 2, 2009, we announced preliminary results from our first pivotal clinical study, the EMPOWER trial, a multi-center, randomized, double-blind, prospective, placebo-controlled pivotal study being conducted in the United States and selected international centers. Initial results from the trial indicated that the study did not meet its primary and secondary comparative efficacy endpoints in that the weight loss for the treatment arm was not statistically different from the control arm in which therapy was turned off. The study did meet its safety endpoint. Our further review of the data suggests that: (i) patients that used the device for the prescribed amount of time (39 hours) had clinically meaningful weight-loss; (ii) both the treatment and control arm subjects experienced comparable, significant, dose-dependent excess weight loss (EWL) at 12 months; and (iii) there was an unanticipated therapeutic effect in the control group.

In October 2010, we received an unconditional approval from the U.S. Food and Drug Administration (FDA) for a pivotal trial using our second generation fully implantable Maestro Rechargeable (RC) System, the ReCharge trial, a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in approximately 234 patients at up to 12 U.S. centers. All patients in the study will receive an implanted device and will be randomized in a 2:1 allocation to treatment or control groups. The control group will receive a non-functional device during the study period. All patients are expected to participate in a weight management counseling program.

We have begun the enrollment process for the ReCharge trial and in May 2011 announced that the first patient had been implanted. We expect completion of implants by the end of 2011. Assuming that we successfully enroll and implant the trial, conclude the 12-month blinding period at the end of 2012 and achieve favorable results, we plan to use data from that trial to support a premarket approval (PMA) application for the Maestro System, which we expect to submit after analyzing and compiling the clinical data. We anticipate that we will be able to commercialize the Maestro System in the United States in late 2013 at the earliest.

We have begun to take the initial steps necessary to commercialize the Maestro RC System in Australia and other countries, which includes applying for European CE Mark certification and Australian Therapeutic Goods Administration (TGA) approval. During the first quarter of 2011 we received European CE Mark certification of the Maestro RC System and are currently in the application process with the TGA for supply in Australia of the Maestro RC System and intend to commercialize the device following receipt of that approval, which we anticipate to occur during the fourth quarter of 2011. We also continue to explore select European and other international markets to commercialize the Maestro RC System.

On March 28, 2011, we entered into a multi-year distribution agreement with Device Technologies Australia Pty Limited (Device Technologies) appointing Device Technologies as our exclusive distributor of the Maestro RC System in Australia and New Zealand during the term of the agreement.

We are working with a network (Australian Institute of Weight Control (AIWC)) of bariatric surgeons and clinics specializing in laparoscopic weight loss surgery and clinical research for the morbidly obese. With this relationship, we have designated these and associated surgeons and clinics as authorized training and implantation centers for our products. These surgeons will be the first in Australia to implant the Maestro System when it has received approval by the TGA. These surgeons will work with us to provide research, communications, training and accreditation support related to the Maestro RC System in Australia and other international territories. In addition, the surgeons are working with us toward TGA approval of the Maestro RC System, will collaborate on subsequent marketing and distribution efforts in Australia and will support our efforts in gaining reimbursement for the private sector through the Medical Services Advisory Committee (MSAC) in Australia.

We received European CE Mark approval for our Maestro RC System in March 2011 and for our Maestro RF System in March 2009. The method of assessing conformity with applicable regulatory requirements varies depending on the class of the device, but for our Maestro System (which falls into Class III), the method involved a combination of self-assessment by the manufacturer of the safety and performance of the device, and a third-party assessment by a Notified Body, usually of the design of the device and of the manufacturer's quality system. We use DEKRA Certification Inc. (formerly known as KEMA Quality) in the Netherlands as the Notified Body for our CE marking approval process.

If and when we obtain FDA approval of our Maestro 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.

To date, we have generated no revenue from the sale of products, and we have incurred net losses in each year since our inception. As of September 30, 2011, we had experienced net losses during the development stage of \$168.5 million. We expect our losses to continue as we continue our development activities. We have financed our operations to date principally through the sale of capital stock, debt financing and interest earned on investments.

Financial Overview

Revenue

To date, we have not commercialized any products and we have not generated any revenue. We received European CE Mark certification for our Maestro RC System in March 2011 and are continuing to take the necessary steps to commercialize the Maestro RC System in Australia, which includes the filing of an application with the TGA for supply in Australia, and select European markets. In the United States, we have begun the enrollment process for the ReCharge trial, a pivotal trial using the Maestro RC System, and expect completion of implants by the end of 2011. Assuming that we successfully enroll and implant the trial, conclude the 12-month blinding period at the end of 2012 and achieve favorable results, we plan to use data from that trial to support a PMA application, which we expect to submit after analyzing and compiling the clinical data. As such, we do not expect to generate revenue in the United States until late 2013 at the earliest. 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, supplies, depreciation and travel. We expense research and development costs as they are incurred. From inception through September 30, 2011, we have incurred a total of \$111.0 million in research and development expenses. We expect research and development expense to increase during 2011 in support of the ReCharge clinical trial, in addition to continued follow-up on existing trials, including VBLOC-DM2 ENABLE and EMPOWER.

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. From inception through September 30, 2011, we have incurred \$46.1 million in selling, general and administrative expenses.

Results of Operations

Comparison of the Three Months Ended September 30, 2011 and 2010

Research and Development Expenses. Research and development expenses were \$4.8 million for the three months ended September 30, 2011, compared to \$2.3 million for the three months ended September 30, 2010. The increase of \$2.4 million, or 104.0%, is primarily due to increases of \$1.9 million, \$394,000 and \$79,000 in professional services, device costs, and compensation and benefits expense, respectively, which are all the result of increased efforts in support of the ReCharge trial.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$2.4 million for the three months ended September 30, 2011, compared to \$1.8 million for the three months ended September 30, 2010. The increase of \$603,000, or 34.4%, is primarily due to an increase of \$339,000, \$106,000, and \$86,000 in professional services, compensation and benefits expense and travel, respectively, which are all the result of our international commercialization efforts.

Interest Expense. Interest expense was \$168,000 for the three months ended September 30, 2011, compared to \$286,000 for the three months ended September 30, 2010. The decrease of \$119,000, or 41.4%, was the result of a decrease in the gross principal balance outstanding from approximately \$6.3 million on September 30, 2010 to approximately \$5.9 million on September 30, 2011 and a modification to the Loan Agreement that reduced our annual interest rate from 11.0% to 6.25% effective March 1, 2011.

Comparison of the Nine Months Ended September 30, 2011 and 2010

Research and Development Expenses. Research and development expenses were \$10.9 million for the nine months ended September 30, 2011, compared to \$7.1 million for the nine months ended September 30, 2010. The increase of \$3.8 million, or 54.1%, is primarily due to increases of \$2.4 million and \$1.5 million in professional services and device costs, respectively, primarily as a result of increased efforts in support of the ReCharge trial. These increases were offset by a Minnesota Research and Development tax credit of \$169,000 recorded during 2011.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$6.5 million for the nine months ended September 30, 2011, compared to \$5.5 million for the nine months ended September 30, 2010. The increase of \$993,000, or 18.1%, is primarily due to increases of \$641,000, \$198,000, and \$112,000 in professional services, compensation and benefits expense and travel, respectively, which are all the result of our international commercialization efforts.

Interest Expense. Interest expense was \$564,000 for the nine months ended September 30, 2011, compared to \$975,000 for the nine months ended September 30, 2010. The decrease of \$412,000, or 42.2%, was the result of a decrease in the gross principal balance outstanding from approximately \$6.3 million on September 30, 2010 to approximately \$5.9 million on September 30, 2011 and a modification to the Loan Agreement that reduced our annual interest rate from 11.0% to 6.25% effective March 1, 2011.

Change in Value of Warrant Liability. There was no warrant liability during the nine months ended September 30, 2011. The value of the warrant liability decreased \$159,000 for the nine months ended September 30, 2010. For the nine months ended September 30, 2010 the warrant liability consisted of warrants issued to Horizon. The fair market value of the remaining 141,025 warrants, with a weighted-average exercise price of \$3.90, was \$313,000 as of May 18, 2010, the date on

which the warrants' down round protection expired. The fair market value for these remaining warrants was calculated using the Black-Scholes valuation model, which resulted in a decrease of \$159,000 for the nine months ended September 30, 2010 as our stock price decreased from \$3.36 on December 31, 2009 to \$2.46 on May 18, 2010.

Liquidity and Capital Resources

We have incurred losses since our inception in December 2002 and, as of September 30, 2011 we had experienced net losses during the development stage of \$168.5 million. We have financed our operations to date principally through the sale of capital stock, debt financing and interest earned on investments. Through December 31, 2010, we had received net proceeds of \$160.5 million from the sale of common stock and preferred stock, including \$39.1 million from our initial public offering in November 2007 and \$58.2 million from a public offering, private placements and registered direct offerings in 2010 and 2009. In addition, through December 31, 2010, we had received \$35.8 million in debt financing, \$746,000 to finance equipment purchases and \$35.0 million to finance working capital. On September 28, 2011, we completed the sale of 8,800,000 shares of common stock, together with warrants to purchase an additional 1,760,000 shares of common stock with an exercise price of \$1.90 per share, in a public offering at an aggregate price of \$1.65 per share and corresponding warrant. We received gross proceeds of \$14.5 million before deducting offering expenses.

As of September 30, 2011, we had \$35.6 million in cash, cash equivalents, restricted cash and short-term investments. Of this amount \$30.4 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 the cash, cash equivalents, restricted cash and short-term investments balance as of September 30, 2011, together with any interest income we earn on these balances, will be sufficient to fund operations into 2013, assuming our planned commercialization and we do not receive any other additional funds.

On March 3, 2011 we entered into a Fourth Amendment (the Fourth Amendment) to the Loan Agreement with SVB. The Fourth Amendment modified the repayment terms of the Term Loan such that beginning April 1, 2011 through September 30, 2011, we were only required to make monthly payments of interest only on the Term Loan. Then, beginning on October 1, 2011, the remaining balance due on the Term Loan amortizes over 30 equal payments of principal and interest, which is payable monthly. In addition, the Fourth Amendment amended the interest rate due effective March 1, 2011 on the remaining principal amount of the Term Loan from 11.0% to a fixed annual rate of 6.25% if the liquidity ratio is greater than 1.50:1.00 and no Event of Default (as defined in the Loan Agreement) has occurred or is continuing or 9.00% if the liquidity ratio is less than 1.50:1.00 or an Event of Default has occurred or is continuing, payable monthly. The Fourth Amendment also reinstated the financial covenant related to the liquidity ratio, which is not permitted to be less than 1.00:1.00, and adds an EBITDA test should the liquidity ratio fall below 1.50:1.00. The EBITDA test requires that the trailing 90 day actual EBITDA be more favorable than 110% of the projected EBITDA for the same period if the projected EBITDA for such period was less than zero or at least 90% of the projected EBITDA for the same period if the projected EBITDA for such period was greater than or equal to zero. In addition, the Fourth Amendment amended the prepayment terms of the Loan Agreement such that a Make-Whole Premium equal to 1% of the amount of the Term Loan being prepaid will be due for any voluntary or required prepayment of the Term Loan occurring before the first anniversary of the Fourth Amendment, unless the Term Loan is being voluntarily prepaid and replaced with a new SVB facility. Lastly, the Fourth Amendment eliminated SVB's springing lien on our intellectual property, the New Capital Transactions requirement and the requirement of the Third Amendment to maintain a blocked cash collateral account with funds equal to the principal balance outstanding.

Net Cash Used in Operating Activities

Net cash used in operating activities was \$14.5 million and \$10.1 million for the nine months ended September 30, 2011 and 2010, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, which was partially offset by depreciation and amortization, change in the carrying value of warrant liability, stock-based compensation and changes in operating assets and liabilities.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$3.1 million for the nine months ended September 30, 2011 compared to net cash used in investing activities of \$2,600 for the nine months ended September 30, 2010. Net cash provided by investing activities for the nine months ended September 30, 2011 is primarily attributable to a \$6.3 million decrease in the restricted cash balance as a result of the Fourth Amendment and \$2.0 million in maturities of short-term investments available for sale offset by \$5.0 million in purchases of short-term investments available for sale and \$239,000 of property and equipment. Net cash used in investing activities during the nine months ended September 30, 2010 is attributable to the purchase of property and equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$13.0 million and \$8.1 million for the nine months ended September 30, 2011 and 2010, respectively. Net cash provided by financing activities for the nine months ended September 30, 2011 is primarily attributable to the completion of a public offering that resulted in gross proceeds of \$14.5 million for the issuance of common stock and common stock warrants, offset by \$1.2 million in financing costs incurred through September 30, 2011, partially offset by repayments on our note payable of \$367,000. Net cash provided by financing activities for the nine months ended September 30, 2010 is primarily attributable to the completion of a private placement transaction that resulted in gross proceeds of \$6.3 million for the issuance of preferred stock and common stock warrants, of which \$781,000 was received in early October 2010, offset by \$43,000 in financing costs incurred through September 30, 2010 and a registered direct offering that resulted in gross proceeds of \$4.8 million for the issuance of common stock, offset by \$340,000 in financing costs, partially offset by repayments on our note payable.

Operating Capital and Capital Expenditure Requirements

To date, we have not commercialized any products and we have not generated any operating revenues. We received European CE Mark certification for our Maestro RC System in March 2011 and are continuing to take the necessary steps to commercialize the Maestro RC System in Australia, which includes the filing of an application with the TGA for supply in Australia, and select European markets. In the United States, we have begun the enrollment process for the ReCharge trial, a pivotal trial using the Maestro RC System, and expect completion of implants by the end of 2011. Assuming that we successfully enroll and implant the trial, conclude the 12-month blinding period at the end of 2012 and achieve favorable results, we plan to use data from that trial to support a PMA application, which we expect to submit after analyzing and compiling the clinical data. As such, we do not expect to generate revenue in the United States until late 2013 at the earliest. 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 RC 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 our cash, cash equivalents, restricted cash and short-term investments balance of \$35.6 million as of September 30, 2011, and any interest income we earn on these balances will be sufficient to fund operations into 2013, assuming our planned commercialization and we do not receive any other additional funds. If our available cash, cash equivalents, restricted cash and short-term investments balances are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or enter into a credit facility. 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.

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 Exhibit 99.2 of our Current Report on Form 8-K filed September 28, 2011. 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 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.

Our significant accounting policies 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, 2010 filed with the U.S. Securities and Exchange Commission (SEC).

Contractual Obligations

During the nine months ended September 30, 2011, 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, 2010.

The following table summarizes our contractual obligations as of September 30, 2011 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	\$1,148,534	\$ 278,662	\$ 574,154	\$295,718	\$ —
Long-term debt, including interest	6,960,551	2,584,220	4,376,331	—	—
Total contractual cash obligations	<u>\$8,109,085</u>	<u>\$2,862,882</u>	<u>\$4,950,485</u>	<u>\$295,718</u>	<u>\$ —</u>

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

Off-Balance Sheet Arrangements

As of September 30, 2011, we did not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

In April 2011, the Financial Accounting Standards Board (FASB) issued amendments to achieve common fair value measurement and disclosure requirements between accounting principles generally accepted in the United States of America and International Financial Reporting Standards. This new guidance amends current fair value measurement and disclosure guidance to include increased transparency around valuation inputs and investment categorization. This new guidance is effective for fiscal years and interim periods beginning after December 15, 2011. We do not expect the adoption of these amendments to have a material impact on the preparation of the consolidated financial statements.

In June 2011, the FASB issued new guidance on the presentation of comprehensive income. Specifically, the new guidance allows an entity to present components of net income and other comprehensive income in one continuous statement, referred to as the statement of comprehensive income, or in two separate, but consecutive statements. The new guidance eliminates the current option to report other comprehensive income and its components in the statement of changes in equity. While the new guidance changes the presentation of comprehensive income, there are no changes to the components that are recognized in net income or other comprehensive income under current accounting guidance. The new guidance is effective for fiscal years beginning after December 15, 2011. We do not expect the adoption of this new guidance to have a material impact on the preparation of the consolidated financial statements.

There were no other significant changes in recent accounting pronouncements during the nine months ended September 30, 2011 as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the year ended December 31, 2010.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents, restricted cash and short-term investments. As of September 30, 2011, we had \$35.6 million in cash, cash equivalents, restricted cash and short-term investments. 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 and investments, 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, 2011, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2011 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, 2011 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, 2010, except for the updated risk factors set forth in Exhibit 99.2 of our Current Report on Form 8-K filed September 28, 2011.

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. RESERVED

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 and Chief Financial Officer
(Principal Financial and Accounting Officer)

Dated: November 4, 2011

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description of Document</u>
3.1	Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.2 to Amendment No. 6 to the Company's Registration Statement on Form S-1 filed on November 9, 2007 (File No. 333-143265)).
3.2	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2009 (File No. 1-33818)).
3.3	Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 13, 2010 (File No. 1-33818)).
3.4	Amended and Restated Bylaws of the Company, as currently in effect. (Incorporated herein by reference to Exhibit 3.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)).
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	Fourth Amendment to Loan and Security Agreement, dated as of March 3, 2011, by and between Silicon Valley Bank and the Company. (Incorporated herein by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K filed on March 7, 2011 (File No. 1-33818)).
10.2	Distribution Agreement, dated as of March 28, 2011, by and between Device Technologies Australia Pty Limited and the Company. (Incorporated herein by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 6, 2011 (File No. 1-33818)).
10.3	Consulting Agreement, effective June 1, 2011, 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 July 8, 2011 (File No. 1-33818)).
10.4	Securities Purchase Agreement, dated as of September 23, 2011, by and between Craig-Hallum Capital Group LLC and the Company. (Incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed on September 23, 2011 (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, 2011, 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 Cash Flows and (iv) 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: November 4, 2011

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 and Chief Financial Officer

Date: November 4, 2011

