Table of Contents

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, 2009

Commission file number: 1-33818

ENTEROMEDICS INC.
(Exact name of registrant as specified in its charter)

Delaware	**48-1293684**
(State or other jurisdiction of incorporation)	**(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, 2009, 37,374,404 shares of the registrant's Common Stock were outstanding.

Table of Contents

INDEX

PART I – FINANCIAL INFORMATION

PART II – OTHER INFORMATION

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 have received a Notice of Allowance and a third extension of time to file a Statement of Use on our application to register the mark EMPOWER. In addition, the marks VBLOC, MAESTRO and ENTEROMEDICS are the subject of either a trademark registration or application for registration in Australia, Brazil, China, Mexico, the European Community, Saudi Arabia, the United Arab Emirates and Switzerland. 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)

	September 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,051,733	$ 21,055,108
Short-term investments available for sale	—	5,239,892
Interest receivable	—	57,965
Other receivables	—	19,308
Prepaid expenses and other current assets	340,945	421,817
Total current assets	27,392,678	26,794,090
Property and equipment, net	1,054,205	1,263,903
Other assets	191,918	220,907
Total assets	$ 28,638,801	$ 28,278,900
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable	$ 7,549,445	$ 2,674,597
Accounts payable	210,296	163,377
Accrued expenses	2,873,836	2,862,102
Accrued interest payable	452,483	177,869
Total current liabilities	11,086,060	5,877,945
Notes payable, less current portion (net discounts of $1,245,096 and $1,329,592 at September 30, 2009 and December 31, 2008, respectively)	9,449,905	10,995,811
Common stock warrant liability	4,748,474	—
Total liabilities	25,284,439	16,873,756
Stockholders' equity:		
Common stock, $0.01 par value 85,000,000 and 50,000,000 shares authorized at September 30, 2009 and December 31, 2008, respectively; 30,805,338 and 16,899,935 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	308,053	168,999
Additional paid-in capital	133,530,454	112,552,256
Deferred compensation	(6,667)	(21,667)
Accumulated other comprehensive income	—	12,988
Deficit accumulated during development stage	(130,477,478)	(101,307,432)
Total stockholders' equity	3,354,362	11,405,144
Total liabilities and stockholders' equity	$ 28,638,801	$ 28,278,900

See accompanying notes to condensed consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Condensed Consolidated Statements of Operations
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,		Period from December 19, 2002 (inception) to September 30, 2009
	2009	2008	2009	2008	
Operating expenses:					
Research and development	$ 4,563,666	$ 8,192,624	$ 12,420,013	$ 23,286,790	$ 88,448,746
Selling, general and administrative	2,702,147	1,869,094	6,777,061	6,516,088	30,052,828
Total operating expenses	7,265,813	10,061,718	19,197,074	29,802,878	118,501,574
Other income (expense):					
Interest income	6,970	205,047	79,241	986,777	4,018,311
Interest expense	(918,032)	(347,291)	(2,469,564)	(1,182,837)	(7,946,769)
Change in value of warrant liability	(3,829,130)	—	(7,426,785)	—	(7,781,692)
Other, net	(1,918)	4,258	(24,896)	(53,360)	(134,786)
Net loss	$(12,007,923)	$(10,199,704)	$(29,039,078)	$(30,052,298)	$(130,346,510)
Net loss per share—basic and diluted	$ (0.40)	$ (0.61)	$ (1.06)	$ (1.79)	
Shares used to compute basic and diluted net loss per share	30,063,997	16,854,336	27,445,231	16,821,217	

See accompanying notes to condensed consolidated financial statements.

Table of Contents

ENTEROMEDICS INC.
(A development stage company)

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	Nine months ended September 30,		Period from December 19, 2002 (inception) to September 30, 2009
	2009	2008	
Cash flows from operating activities:			
Net loss	$(29,039,078)	$(30,052,298)	$(130,346,510)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	319,983	402,675	1,475,939
Loss on sale of equipment	2,645	4,186	18,230
Employee stock-based compensation	2,302,875	2,037,073	5,882,074
Nonemployee stock-based compensation	368,299	(122,910)	3,356,053
Amortization of commitment fees, debt issuance costs and original issue discount	682,645	274,651	2,455,727
Amortization of short-term investment premium or discount	904	8,822	(308,051)
Change in value of warrant liability	7,426,785	—	7,781,692
Change in operating assets and liabilities:			
Interest receivable	57,965	6,623	—
Other receivables	19,308	3,899	—
Prepaid expenses and other current assets	80,872	163,100	(340,945)
Other assets	(27,015)	(70,000)	(27,015)
Accounts payable	101,019	166,602	218,327
Accrued expenses	11,734	3,018,669	2,873,836
Accrued interest payable	274,614	—	618,305
Net cash used in operating activities	(17,416,445)	(24,158,908)	(106,342,338)
Cash flows from investing activities:			
Purchases of short-term investments available for sale	—	(9,127,233)	(14,882,233)
Maturities of short-term investments available for sale	5,226,000	5,122,790	14,854,414
Purchases of short-term investments held-to-maturity	—	(1,185,838)	(22,414,130)
Maturities of short-term investments held-to-maturity	—	4,450,000	22,750,000
Purchases of property and equipment	(167,030)	(194,882)	(2,556,405)
Net cash provided by (used in) investing activities	5,058,970	(935,163)	(2,248,354)
Cash flows from financing activities:			
Proceeds from stock options exercised	19,801	48,248	159,441
Proceeds from warrants issued	819,400	—	835,057
Proceeds from warrants exercised	—	—	187,652
Proceeds from sale of common stock, net of underwriting fees of $3,074,315	—	—	40,874,977
Proceeds from sale of common stock in private placement financing	15,076,952	—	15,076,952
Common stock financing costs	(806,499)	—	(2,559,162)
Payment to shareholders for fractional shares upon reverse stock split	—	—	(355)
Proceeds from sale of Series A convertible preferred stock	—	—	1,803,348
Proceeds from sale of Series B convertible preferred stock	—	—	15,300,002
Series B convertible preferred stock financing costs	—	—	(111,079)
Proceeds from sale of Series C convertible preferred stock	—	—	40,825,003
Series C convertible preferred stock financing costs	—	—	(1,486,904)
Proceeds from convertible notes payable	—	—	6,814,846
Proceeds from notes payable	5,000,000	—	35,831,121
Repayments on notes payable	(1,755,554)	(4,085,117)	(17,586,675)
Debt issuance costs	—	—	(321,799)
Net cash provided by (used in) financing activities	18,354,100	(4,036,869)	135,642,425
Net increase (decrease) in cash and cash equivalents	5,996,625	(29,130,940)	27,051,733
Cash and cash equivalents:			
Beginning of period	21,055,108	48,732,309	—
End of period	$ 27,051,733	$ 19,601,369	$ 27,051,733
Supplemental disclosure:			
Interest paid	$ 1,512,307	$ 873,952	$ 4,872,738
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	542,144	—	2,907,676
Value of warrants issued for debt commitment	—	—	636,250
Value of warrants issued with Series C financing	—	—	735,438
Value of warrants issued with private placement financing	154,525	—	154,525
Cashless exercise of warrants	4,750,126	—	4,750,126
Conversion of notes payable to Series B convertible preferred shares	—	—	1,564,843
Conversion of interest payable to Series B convertible preferred shares	—	—	34,809
Conversion of notes payable to Series C convertible preferred shares	—	—	5,250,003

Conversion of interest payable to Series C convertible preferred shares	—	—	131,013
Options issued for deferred compensation	—	—	10,898
Common stock issued to Mayo Foundation and for deferred compensation	—	—	1,770,904
Reclassifications of stock warrant liability	1,529,670	—	2,620,015
Conversion of convertible preferred stock to common stock	—	—	103,138

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 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 Sárl, a wholly-owned subsidiary located in Switzerland.

Since inception, the Company has incurred losses through September 30, 2009 totaling approximately $130.3 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, 2008 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, 2008.

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.

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.

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, 2009 related entirely to the maturity of short-term investments and the realization of net unrealized gains on those short-term investments.

Fair Value of Financial Instruments

Carrying amounts of certain of the Company’s financial instruments, including cash and cash equivalents, 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 is approximately $18,201,000 as of September 30, 2009 based on the present value of estimated future cash flows using a discount rate commensurate with borrowing rates available to the Company.

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, 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, 2009 and 2008:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Numerator:				
Net loss	$(12,007,923)	$(10,199,704)	$(29,039,078)	$(30,052,298)
Denominator for historical basic and diluted net loss per share:				
Weighted-average common shares outstanding	30,063,997	16,854,336	27,445,231	16,821,217
Weighted-average unvested common shares subject to repurchase	—	—	—	—
Denominator for net loss per common share—basic and diluted	30,063,997	16,854,336	27,445,231	16,821,217
Net loss per share—basic and diluted	$ (0.40)	$ (0.61)	$ (1.06)	$ (1.79)

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,	
	2009	2008
Stock options outstanding	5,516,177	3,052,607
Warrants to purchase common stock	8,279,524	683,235

Recently Issued Accounting Standards

In June 2009, the Financial Accounting Standards Board (FASB) approved the FASB Accounting Standards Codification (ASC or the Codification) as the single source of authoritative, nongovernmental accounting principles generally accepted in the United States of America (GAAP), excluding the guidance issued by the Securities and Exchange Commission (SEC). FASB approved an Exposure Draft that replaced SFAS 162 and modified GAAP by establishing only two levels of GAAP, authoritative and nonauthoritative. This was accomplished by authorizing the Codification to become the single source of authoritative U.S. accounting and reporting standards, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other nongrandfathered, non-SEC accounting literature not included in the Codification has become nonauthoritative. The Codification is effective for the Company during the quarter ended September 30, 2009. The adoption of the Codification did not have a material impact on the consolidated financial statements.

In June 2008, FASB issued ASC subtopic 815-40 (ASC 815-40), *Derivatives and Hedging: Contracts in Entity's Own Equity*, or Emerging Issues Task Force No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock.* ASC 815-40 requires entities to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock by assessing the instrument's contingent exercise provisions and settlement provisions. Instruments not indexed to their own stock fail to meet the scope exception of ASC 815, *Derivatives and Hedging*, or Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities*, paragraph 11(a), and should be classified as a liability and marked-to-market. The statement is effective for fiscal years beginning after December 15, 2008 and is to be applied to outstanding instruments upon adoption with the cumulative effect of the change in accounting principle recognized as an adjustment to the opening balance of retained earnings. The Company adopted ASC 815-40 on January 1, 2009 and assessed any outstanding equity-linked financial instruments. The Company concluded that effective January 1, 2009 warrants issued 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.

There have been no other significant changes in recent accounting pronouncements during the nine months ended September 30, 2009 as compared to the recent accounting pronouncements described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

(2) 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, 2009, future minimum payments under the lease are as follows:

Years ending December 31:	
Remaining three months in 2009	$ 59,884
2010	247,951
2011	274,564
2012	280,055
2013	285,656
2014	291,369
2015	221,788
	$1,661,267

(3) Notes Payable

On November 18, 2008 the Company entered into a Loan and Security Agreement (the Loan Agreement) with Silicon Valley Bank (SVB), Western Technology Investment (WTI) and Horizon Technology Management LLC (Horizon and, collectively with SVB and WTI, the Lenders), in an aggregate principal amount of up to $20.0 million with 11.0% warrant coverage. 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. The $5.0 million loan required monthly interest-only payments through June 30, 2009 at an annual percentage rate of 12.0% followed by 30 equal principal and interest installments beginning July 1, 2009 at an annual percentage rate of 11.0%. A final payment fee of $250,000 is due December 1, 2011, the maturity date. In conjunction with the funding, the Company issued 296,763 common stock warrants with an exercise price of $1.668 per share and a ten year life to Horizon. The warrants give Horizon the option to purchase either (i) shares of our common stock with a per share exercise price equal to $1.668, or (ii) shares of our stock (including common stock) issued in an equity financing that occurs after the warrant issue date and on or before May 18, 2010 at the per share price of the stock sold in the financing.

On September 29, 2009, SVB completed a cashless exercise of the warrants issued to them as part of the Loan Agreement. SVB held a total of 956,522 common stock warrants with an exercise price of $1.15 per share. The cashless exercise of the warrants resulted in the Company issuing 752,818 shares of its common stock. The related warrant liability was marked-to-market to $4.8 million from $3.0 million on the date of exercise and reclassified to equity.

Scheduled debt principal payments are as follows as of September 30, 2009:

Years Ending December 31:	
Remaining three months in 2009	$ 1,810,576
2010	7,761,313
2011	8,672,557
	18,244,446
Less: Original issue discount	(1,245,096)
Notes payable, net	$16,999,350

(4) Stock-based Compensation

The provisions of Accounting Standards Codification 718, *Compensation – Stock Compensation*, or Statement of Financial Accounting Standards No. 123R, *Share-Based Payment*, are 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 follows Accounting Standards Codification subtopic 505-50, *Equity: Equity-based Payments to Non-Employees*, or Emerging Issues Task Force Abstract No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services*, which requires measuring the stock options at fair value and remeasuring 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 for the three and nine months ended September 30, 2009 and 2008 was allocated to operating expenses as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2009	2008	2009	2008
Research and development	$ 387,318	$ 154,826	$ 760,768	$ 665,155
Selling, general and administrative	928,809	419,105	1,910,406	1,249,008
Total	$ 1,316,127	$ 573,931	$ 2,671,174	$ 1,914,163

As of September 30, 2009 there was $9,084,917 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 3.09 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, 2009 and 2008:

	Employees Three months ended September 30,		Employees Nine months ended September 30,	
	2009	2008	2009	2008
Risk-free interest rates	2.73%	4.01%	1.90%-2.99%	3.49%-4.01%
Expected life	6.25 years	6.25 years	6.00 - 6.25 years	5.00 - 6.25 years
Expected dividends	0%	0%	0%	0%
Expected volatility	97.00%	67.75%	88.10%-99.00%	67.63%-69.38%

	Nonemployees Three months ended September 30,		Nonemployees Nine months ended September 30,	
	2009	2008	2009	2008
Risk-free interest rates	3.24%-3.64%	3.83%	2.68%-3.64%	3.43%-3.98%
Expected life	6.00 - 9.98 years	10 years	6.00 - 9.98 years	10 years
Expected dividends	0%	0%	0%	0%
Expected volatility	100.50%-108.10%	72.88%	99.70%-108.10%	72.88%-75.25%

Option activity under the Plan for the nine months ended September 30, 2009 was as follows:

	Shares Available For Grant	Outstanding Options Number of Shares	Outstanding Options Weighted-Average Exercise Price
Balance, December 31, 2008	851,236	2,797,178	$ 4.80
Shares reserved	3,000,000	—	—
Options granted	(2,886,200)	2,886,200	3.25
Options exercised	—	(42,192)	0.47
Options cancelled	125,009	(125,009)	5.26
Balance, September 30, 2009	1,090,045	5,516,177	$ 4.01

(5) Stock Purchase

On February 19, 2009, the Company entered into several securities purchase agreements for the sale of 13,110,393 shares of its common stock, together with warrants to purchase an aggregate of 6,555,197 shares of its common stock, in a private placement transaction with several accredited investors (the Private Placement). The purchase price per share was $1.15, which equaled the consolidated closing bid price of the Company's common stock as reported by the NASDAQ Stock Market on February 19, 2009. The warrants will be exercisable at any time and from time to time beginning on the date that is six months and one day after the closing of the Private Placement and ending four years after the closing of the Private Placement. The warrants have an exercise price of $1.38 per share, which equals 120% of the consolidated closing bid price of the Company's common stock as reported by the NASDAQ

Stock Market on February 19, 2009. On February 24, 2009, the Company completed the final closing of the Private Placement receiving gross proceeds of $15.9 million, less a placement agent fee of $617,443 and certain other expenses. In addition, the placement agent received a warrant to purchase 218,242 shares of common stock in the same form as that issued to participants in the Private Placement.

(6) Subsequent Events

On October 2, 2009, WTI completed a cashless exercise of the warrants issued to them as part of the Loan Agreement entered into on November 18, 2008. WTI held a total of 478,261 common stock warrants with an exercise price of $1.15 per share. The cashless exercise of the warrants resulted in the Company issuing 355,493 shares of its common stock. The related warrant liability was marked-to-market on the date of exercise and reclassified to equity. This resulted in a $2.0 million decrease in the fair value of the warrants. WTI also completed a cashless exercise of an additional 149,949 common stock warrants with an exercise price of $3.94 per share. The cashless exercise of the warrants resulted in the Company issuing 17,974 shares of its common stock.

On October 2, 2009, the Company announced preliminary results from its EMPOWER trial indicating that based on an initial analysis, the study did not meet its primary and secondary efficacy endpoints. The Company also announced that there were no therapy-related serious adverse events reported during the study. As announced on November 12, 2009, the ongoing detailed review suggests that vagal blocking therapy may promote safe and effective weight loss as an adjunct to behavioral support, diet and exercise in morbidly obese patients. The review further suggests that these effects were evident in both the treatment and control arms. The Company is continuing a comprehensive analysis of all clinical, statistical, and engineering data to understand this finding. Based on the analysis to date, the control arm of the trial, which was intended to be inactive, apparently provided a low-intensity blocking signal that introduced VBLOC therapy in human subjects.

On October 2, 2009, the Company entered into a securities purchase agreement with certain institutional investors for the sale of 6,161,068 shares of its common stock in a registered direct offering (the Offering), at a purchase price of $0.80 per share. On October 7, 2009, the Company completed the final closing of the Offering receiving gross proceeds of $4.9 million before deducting estimated offering expenses.

As a result of the Offering completed on October 7, 2009, the exercise price of 47,826 and 296,763 common stock warrants held by Horizon, was adjusted from $1.15 to $0.80 per share and from $1.668 to $0.80 per share, respectively, resulting in the issuance of 342,911 additional common stock warrants to Horizon.

On October 27, 2009, the Company implemented a plan to reduce its workforce and operating costs in order to preserve capital and streamline its operations following the announcement of top-line results from its pivotal EMPOWER study on October 2, 2009. The reduction in force will lower the number of employees by 40%, to a total of 33, by November 15, 2009. The reduction in force is expected to result in approximately $3.2 million in reduced operating expenses in 2010. The Company expects to incur a charge of approximately $0.5 million related to the workforce reduction in the fourth quarter of 2009.

The Company has evaluated subsequent events occurring through November 16, 2009, the date on which this Quarterly Report on Form 10-Q was issued.

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, 2008. 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 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 currently have no products approved for sale. Our initial product under development is the Maestro System, which uses VBLOC therapy to limit the expansion of the stomach, reduce the frequency and intensity of stomach contractions and produce 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 were 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.

We completed enrollment and implantation of patients in our first U.S. pivotal trial, the EMPOWER trial during 2008. On October 2, 2009, we announced that the study did not meet its primary and secondary efficacy endpoints, as results in the control and treatment arms were statistically indistinguishable, while achieving all of its safety endpoints. As announced on November 12, 2009, the ongoing detailed review suggests that vagal blocking therapy may promote safe and effective weight loss as an adjunct to behavioral support, diet and exercise in morbidly obese patients. The review further suggests that these effects were evident in both the treatment and control arms. We are continuing a comprehensive analysis of all clinical, statistical, and engineering data to understand this finding. Based on the analysis to date, the control arm of the trial, which was intended to be inactive, apparently provided a low-intensity blocking signal that introduced VBLOC therapy in human subjects.

On November 12, 2009 we also announced the following EMPOWER study findings:

- The EMPOWER study met all of its safety goals, including the finding that there were no therapy-related serious adverse events reported across the entire study population;
- Patients who met or exceeded the prescribed nine hours of daily device use (n=128, 51% of evaluated patients) averaged 10.9 hours of daily use and experienced an average excess weight loss (EWL) of 23.1% from implant by BMI method (18.3% from treatment initiation by Met Life method) in the treatment arm and 22.6% (BMI) from implant, (17.8% from initiation, Met Life) in the control arm at 12 months;
- Patients that did not meet the prescribed nine hours of daily device use (n=125) averaged 6.9 hours of daily use and experienced a mean EWL of 10.5% (BMI) from implant in the treatment arm (6.4% from initiation, Met Life) and 8.6% (BMI) in the control arm (4.6% from initiation, Met Life) at 12 months;
- For all patients (n=253), the average EWL at 12 months was 16.6% EWL (BMI) from implant (12.1% from initiation, MetLife) for the treatment arm and 16.4% EWL (BMI) from implant (12.0% from initiation, MetLife) for the control arm; and
- For those patients with a diagnosis of hypertension (n=110), a statistically significant reduction of systolic and diastolic blood pressure from baseline was observed, a result that will require follow-up study.

On October 27, 2009 we began taking steps to preserve capital and streamline operations while we analyze the EMPOWER trial results. This resulted in a reduction in force that lowered the number of employees by 40%, to a total of 33, by November 15, 2009. We expect to incur a charge of approximately $0.5 million related to the workforce reduction in the fourth quarter of 2009. We are continuing to evaluate the results of the EMPOWER trial and are taking steps to discuss the outcome of this study with the FDA to determine the appropriate regulatory path forward for the Maestro System as a treatment for morbid obesity.

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. We are continuing to evaluate the Maestro System in human clinical trials conducted internationally and to date the Maestro System has demonstrated a favorable safety profile. As of January 12, 2009, the most recent follow-up of nine RF2 patients, among the earliest patients implanted in the VBLOC-RF2 trial, showed an EWL of 37.6% at 18 months of VBLOC therapy. At that time, the most recent results for the prior follow-up periods demonstrated an EWL of 28.1% in 17 RF2 patients at 12 months and an EWL of 17.9% in 35 RF2 patients at six months of VBLOC therapy. In addition, data from sub-group analyses demonstrate that VBLOC therapy may hold promise in improving the co-morbidities of diabetes and hypertension, independent of, and prior to, substantial weight loss. We are conducting, or plan to conduct, feasibility studies in each of these co-morbidities to assess VBLOC therapy's potential in addressing multiple indications.

We obtained CE marking approval for sale of the Maestro RF System in the European Union on March 4, 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 used KEMA 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 or 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 following commercialization.

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, 2009, we had a deficit accumulated during the development stage of $130.3 million. We expect our losses to continue and to increase as we continue our development activities and eventually expand our commercialization activities. We have financed our operations primarily through public and private placement of our equity securities and issuance of debt.

Financial Overview

Revenue

To date, we have not commercialized any products and we have not generated any revenue. We do not expect to generate revenue in the United States unless we receive FDA approval of our Maestro System. Any revenue from initial sales of a new product is difficult to predict and in any event will only modestly reduce our continued and increasing 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, 2009, we have incurred a total of $88.4 million in research and development expenses.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of compensation for executive, finance, market development and administrative personnel, including stock-based compensation. Other significant expenses include costs associated with attending medical conferences, professional fees for legal services, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, and accounting services, cash management fees, consulting fees and travel expenses. From inception through September 30, 2009, we have incurred $30.1 million in selling, general and administrative expenses.

Results of Operations

Comparison of the Three Months Ended September 30, 2009 and 2008

Research and Development Expenses. Research and development expenses were $4.6 million for the three months ended September 30, 2009, compared to $8.2 million for the three months ended September 30, 2008. The decrease of $3.6 million, or 44.3%, is primarily due to decreases of $2.8 million, $525,000, and $304,000 in professional services, compensation expense, and travel, respectively. Professional services and travel is driven by the completion of enrollment and implants in our EMPOWER clinical study during 2008. We are currently incurring costs related to follow-up visits, which are less expensive than the cost of the implantation procedure, and do not require us to incur new device costs. The reduction in compensation expense is the result of a reduction-in-force completed December 1, 2008.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $2.7 million for the three months ended September 30, 2009, compared to $1.9 million for the three months ended September 30, 2008. The increase of $833,000, or 44.6%, is primarily due to increases of $510,000 and $356,000 in stock-based compensation and professional services, respectively. The increase in stock-based compensation is primarily due to options granted to employees on June 22, 2009 resulting in $152,600 in additional expense and stock options granted to consultants resulting in $255,000 in additional expense. The increase in professional services is the result of $208,000 for commercialization activity in anticipation of the unblinding of the EMPOWER trial and increases of $88,000 in legal fees and $57,000 in audit fees.

Interest Income. Interest income was $7,000 for the three months ended September 30, 2009, compared to $205,000 for the three months ended September 30, 2008. The decrease of $198,000, or 96.6%, is primarily due to a decrease in the short-term interest rate environment and a decrease in the average cash, cash equivalents and short-term investment balance from $31.9 million during the third quarter of 2008 to $31.0 million during the third quarter of 2009. The decreased average cash, cash equivalents and short-term investments balance is the result of $43.2 million in net cash used in operating and investing activities from January 1, 2008 through September 30, 2009, offset by $15.0 million of debt funding received in November 2008, of which we received net proceeds of $7.1 million after transaction expenses, facility charges and existing debt pay off, $15.1 million of net private placement proceeds received February 24, 2009, and $5.0 million of additional debt funding received in April 2009.

Interest Expense. Interest expense was $918,000 for the three months ended September 30, 2009, compared to $347,000 for the three months ended September 30, 2008. The increase of $571,000, or 164.3%, was primarily the result of entering into a $20.0 million debt facility, of which $15.0 million was funded in November 2008 that resulted in net proceeds of $7.1 million after transaction expenses, facility charges and existing debt pay off and the funding of the remaining $5.0 million in April 2009. The effective rates on the $15.0 million and $5.0 million debt fundings are approximately 19% and 22%, respectively, compared to the old debt facility containing several outstanding loans with effective interest rates primarily ranging from approximately 15% to 17%.

Change in Value of Warrant Liability. The change in value of warrant liability was $3.8 million for the three months ended September 30, 2009, compared to zero for the three months ended September 30, 2008. This is the result of adopting the provisions of ASC 815-40 on January 1, 2009, which resulted in warrants issued November 2008 with a recorded value of $1.4 million on December 31, 2008 being reclassified from equity to a liability. On September 29, 2009, Silicon Valley Bank completed a cashless exercise of 956,522 common stock warrants with an exercise price of $1.15 per share. The related warrant liability was marked-to-market to $4.8 million from $3.0 million on the date of exercise and reclassified to equity. The fair market value of the remaining 822,850 warrants, with a weighted-average exercise price of $1.34, was $4.7 million as of September 30, 2009. The fair market value was calculated using the Black-Scholes valuation model, which resulted in a $2.1 million increase for the three months ended September 30, 2009. The increase was primarily the result of an increase of our stock price from a closing price of $3.33 on June 30, 2009 to $4.79 on September 30, 2009.

Comparison of the Nine Months Ended September 30, 2009 and 2008

Research and Development Expenses. Research and development expenses were $12.4 million for the nine months ended September 30, 2009, compared to $23.3 million for the nine months ended September 30, 2008. The decrease of $10.9 million, or 46.7%, is primarily due to decreases of $7.4 million, $1.9 million and $1.0 million in professional services, device costs and compensation expense, respectively. Professional services and device cost decreases are driven by the completion of enrollment and implants in our EMPOWER clinical study during 2008. We are currently incurring costs related to follow-up visits, which are less expensive than the cost of the implantation procedure, and do not require us to incur new device costs. The reduction in compensation expense is the result of a reduction-in-force completed December 1, 2008.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $6.8 million for the nine months ended September 30, 2009, compared to $6.5 million for the nine months ended September 30, 2008. The increase of $261,000, or 4.0%, is primarily made up of an increase of $661,000 in stock based compensation due to options granted to employees on June 22, 2009 and stock option grants associated with consulting agreements. This increase is offset by decreases of $309,000 and $52,000 in professional services and reduced marketing and public relations activity, respectively. The decrease in professional services is made up of decreases of $98,000 in legal fees for efficiencies gained after being a public company for over a year and $211,000 in other general consulting services, including the conversion of certain consultants to employees.

Interest Income. Interest income was $79,000 for the nine months ended September 30, 2009, compared to $987,000 for the nine months ended September 30, 2008. The decrease of $908,000, or 92.0%, is primarily due to a decrease in short-term interest rates and a reduction in total cash available to invest. The average cash, cash equivalents and short-term investment balance was $32.2 million and $41.5 million for the nine months ended September 30, 2009 and 2008, respectively. The decreased average cash, cash equivalents and short-term investments balance is the result of $43.2 million in net cash used in operating and investing activities from January 1, 2008 through September 30, 2009, offset by $15.0 million of debt funding received in November 2008, of which we received net proceeds of $7.1 million after transaction expenses, facility charges and existing debt pay off, $15.1 million of net private placement proceeds received February 24, 2009, and $5.0 million of additional debt funding received in April 2009.

Interest Expense. Interest expense was $2.5 million for the nine months ended September 30, 2009, compared to $1.2 million for the nine months ended September 30, 2008. The increase of $1.3 million, or 108.8%, was primarily the result of entering into a $20.0 million debt facility, of which $15.0 million was funded in November 2008 that resulted in net proceeds of $7.1 million after transaction expenses, facility charges and existing debt pay off and the funding of the remaining $5.0 million in April 2009. The effective rates on the $15.0 million and $5.0 million debt fundings are approximately 19% and 22%, respectively, compared to the old debt facility containing several outstanding loans with effective interest rates primarily ranging from approximately 15% to 17%.

Change in Value of Warrant Liability. The change in value of warrant liability was $7.4 million for the nine months ended September 30, 2009, compared to zero for the nine months ended September 30, 2008. This is the result of adopting the provisions of ASC 815-40 on January 1, 2009, which resulted in warrants issued November 2008 with a recorded value of $1.4 million on December 31, 2008 being reclassified from equity to a liability. On September 29, 2009, Silicon Valley Bank completed a cashless exercise of 956,522 common stock warrants with an exercise price of $1.15 per share. The related warrant liability was marked-to-market on the date of exercise and reclassified to equity. The change in fair value of these warrants from January 1, 2009 to the date of

exercise was $3.8 million. The fair market value of the remaining 822,850 warrants, with a weighted-average exercise price of $1.34, was $4.7 million as of September 30, 2009. The fair market value was calculated using the Black-Scholes valuation model, which resulted in a $3.6 million increase for the nine months ended September 30, 2009. The increase was primarily the result of our stock price increasing from a closing price of $1.46 on January 1, 2009 to $4.79 on September 30, 2009.

Liquidity and Capital Resources

We have incurred losses since our inception in December 2002 and, as of September 30, 2009 we had a deficit accumulated during the development stage of $130.3 million. We have financed our operations to date principally through the sale of capital stock, debt financing and interest earned on investments. Prior to our initial public offering (IPO) in November 2007, we had received net proceeds of $63.2 million from the sale of common stock and preferred stock and $30.8 million in debt financing, $746,000 to finance equipment purchases and $30.0 million to finance working capital. Through our IPO we received net proceeds of $39.1 million after expenses and underwriters' discounts and commissions and including the partial exercise of the underwriters' over-allotment option. In November 2008, we entered into a $20.0 million working capital debt facility, replacing the existing debt financing. We received net proceeds of $7.1 million from the first draw of $15.0 million after transaction expenses, facility charges and existing debt pay off. The debt facility provided that the additional $5.0 million draw was to be available and automatically fund under the terms of the loan agreement if and when the trading price of our common stock on the NASDAQ Global Market met or exceeded a target amount on or before June 30, 2009. The Company's trading price achieved this target and therefore, on April 28, 2009, the automatic funding of the additional $5.0 million was made to the Company under the debt facility. On February 24, 2009, we completed the sale of 13,110,393 shares of our common stock, together with warrants to purchase an aggregate of 6,555,197 shares of our common stock, in a private placement transaction with several accredited investors. We received gross proceeds of $15.9 million less a placement agent fee of $617,000 and certain other expenses. On October 7, 2009, we completed the sale of 6,161,068 shares of our common stock in a registered direct offering, at a purchase price of $0.80 per share. We received gross proceeds of $4.9 million before deducting estimated offering expenses.

As of September 30, 2009, we had $27.1 million in cash and cash equivalents. Of this amount $25.1 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.

The remaining unpaid balance of $18.2 million in debt financing as of September 30, 2009 is collateralized by a first security priority lien on all of our assets, excluding intellectual property. We have entered into account control agreements in order to perfect the lender's first security interest in our cash and investment accounts. In the event we have less than five remaining months of liquidity, we are required to grant a temporary lien on our intellectual property. The number of remaining months of liquidity is calculated by dividing cash and cash equivalents as of the end of any particular month by the sum of our total operating expenses for each of the immediately preceding five months. The debt financing agreement also requires us to (1) maintain a cash and cash equivalents balance that exceeds our aggregate operating expenses for the most recent five calendar month period ending prior to the determination date and (2) secure aggregate net proceeds of at least $20.0 million by January 9, 2010 from new capital transactions, of which $10.0 million was required by June 30, 2009. On February 24, 2009, we completed a private placement transaction with several accredited investors, receiving gross proceeds of $15.9 million less a placement agent fee of $617,000 and on October 7, 2009, we completed a registered direct offering transaction, receiving gross proceeds of $4.9 million before deducting estimated offering expenses. There are no additional liquidity covenants that we are required to maintain under the terms of our debt financing agreements.

Net Cash Used in Operating Activities

Net cash used in operating activities was $17.4 million and $24.2 million for the nine months ended September 30, 2009 and 2008, 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 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 $5.1 million for the nine months ended September 30, 2009 compared to net cash used in investing activities of $935,000 for the nine months ended September 30, 2008. Net cash provided by investing activities for the nine months ended September 30, 2009 is primarily related to the proceeds from the maturity of short-term investments slightly offset by the purchase of property and equipment. Net cash used in investing activities for the nine months ended September 30, 2008 is primarily related to purchases of short-term investments and, to a lesser extent, the purchase of property and equipment, partially offset by the maturity of short-term investments.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $18.3 million for the nine months ended September 30, 2009 compared to net cash used in financing activities of $4.0 million for the nine months ended September 30, 2008. Net cash provided by financing activities for the nine months ended September 30, 2009 is primarily attributable to the completion of a private placement transaction that resulted in gross proceeds of $15.9 million for the issuance of common stock and common stock warrants, offset by $806,000 in financing costs incurred through September 30, 2009 and debt funding proceeds of $5.0 million automatically funded on April 28, 2009 per the terms of the $20.0 million debt facility we entered into on November 18, 2008, offset by repayments on long-term debt. Net cash used in financing activities for the nine months ended September 30, 2008 is primarily attributable to the repayments of long-term debt.

Operating Capital and Capital Expenditure Requirements

To date, we have not commercialized any products and we have not earned any operating revenues. 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 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 do not expect to generate any product revenue from sales in the United States unless we successfully obtain FDA approval for our Maestro System. We believe the net proceeds from our IPO in November 2007, the credit facility entered into November 2008, the private placement closed February 24, 2009 and the registered direct offering closed October 7, 2009, together with our pre-existing cash, cash equivalents and short-term investment balances and interest income we earn on these balances will be sufficient to meet our anticipated cash requirements into 2010. If our available cash, cash equivalents and investment balances are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities or enter into an additional 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 Part I, Item 1A, *Risk Factors*, of our Annual Report on Form 10-K for the year ended December 31, 2008 and in Part II, Item 1A, *Risk Factors*, of this Quarterly Report on Form 10-Q. 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 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 future products; and

- the extent to which we acquire or invest in businesses, 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.

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, 2008 filed with the U.S. Securities and Exchange Commission (SEC).

Contractual Obligations

During the nine months ended September 30, 2009, 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, 2008, other than the funding of a $5.0 million term loan on April 28, 2009 as discussed in Note 3 to our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

The following table summarizes our contractual obligations as of September 30, 2009 and the effect those obligations are expected to have on our financial condition and liquidity position in future periods:

	Payments Due By Period				
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating lease	$ 1,661,267	$ 239,536	$ 551,859	$ 574,154	$ 295,718
Long-term debt, including interest	21,710,743	9,204,775	12,505,968	—	—
Other long-term liabilities	50,000	50,000	—	—	—
Total contractual cash obligations	$ 23,422,010	$ 9,494,311	$ 13,057,827	$ 574,154	$ 295,718

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. Other long-term liabilities consist of obligations required under the terms of our license agreements with the Mayo Foundation for Medical Education and Research (Mayo Foundation).

Off-Balance Sheet Arrangements

As of September 30, 2009, we did not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) approved the FASB Accounting Standards Codification (ASC or the Codification) as the single source of authoritative, nongovernmental accounting principles generally accepted in the United States of America (GAAP), excluding the guidance issued by the Securities and Exchange Commission (SEC). FASB approved an Exposure Draft that replaced SFAS 162 and modified GAAP by establishing only two levels of GAAP, authoritative and nonauthoritative. This was accomplished by authorizing the Codification to become the single source of authoritative U.S. accounting and reporting standards, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other nongrandfathered, non-SEC accounting literature not included in the Codification has become nonauthoritative. The Codification is effective for us during the quarter ended September 30, 2009. The adoption of the Codification did not have a material impact on our consolidated financial statements.

In June 2008, FASB issued ASC subtopic 815-40 (ASC 815-40), *Derivatives and Hedging: Contracts in Entity's Own Equity*, or Emerging Issues Task Force No. 07-5, *Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock.* ASC 815-40 requires entities to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock by assessing the instrument's contingent exercise provisions and settlement provisions. Instruments not indexed to their own stock fail to meet the scope exception of ASC 815, *Derivatives and Hedging*, or Statement of Financial Accounting Standards No. 133, *Accounting for Derivative Instruments and Hedging Activities*, paragraph 11(a), and should be classified as a liability and marked-to-market. The statement is effective for fiscal years beginning after December 15, 2008 and is to be applied to outstanding

instruments upon adoption with the cumulative effect of the change in accounting principle recognized as an adjustment to the opening balance of retained earnings. We adopted ASC 815-40 on January 1, 2009 and assessed any outstanding equity-linked financial instruments and concluded that effective January 1, 2009 warrants issued 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.

There have been no other significant changes in recent accounting pronouncements during the nine months ended September 30, 2009 as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

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

Our exposure to market risk is confined to our cash, cash equivalents and short-term investments. As of September 30, 2009, we had $27.1 million in cash, cash equivalents 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 maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio 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 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 4T. *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, 2009 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, 2009 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, 2009 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, 2008 other than those identified below.

The preliminary results of the blinded segment of our EMPOWER trial may not be sufficient to support approval of a PMA application, and this will likely prevent or delay regulatory approval of our Maestro System and impair our financial position.

In September 2009, we completed the blinded segment of our EMPOWER pivotal trial, a randomized, prospective, placebo-controlled multi-center trial of our Maestro System in the United States. Based on our initial analysis, the EMPOWER trial did not meet its primary and secondary efficacy endpoints; however, we are currently conducting a thorough analysis of the EMPOWER study data. The inability to achieve our primary and secondary efficacy endpoints in the EMPOWER trial means that it will take us longer to ultimately commercialize a product and generate revenue, our financial projections may be impaired, and we may never be able to produce sufficient data to support a premarket approval (PMA) application with the U.S. Food and Drug Administration or commercialize a product.

If we are unable to comply with the continued listing requirements of the NASDAQ Global Market, our common stock could be delisted, which could affect its market price and liquidity and reduce our ability to raise capital.

We are required to meet certain qualitative and financial tests to maintain the listing of our common stock on the NASDAQ Global Market. On October 19, 2009, we received a notice from the NASDAQ Stock Market (NASDAQ) advising that for the prior ten consecutive business days, the market value of the our listed securities had been below the minimum $50,000,000 requirement for continued listing on the NASDAQ Global Market pursuant to NASDAQ Listing Rule 5450(b)(2)(A) (the MVLS Rule). We are monitoring our Market Value of Listed Securities (MVLS) and have until January 19, 2010, the end of the 90 calendar day grace period, to regain compliance with the MVLS Rule by having our MVLS close at $50,000,000 or more for a minimum of ten consecutive business days. If we are unable to regain compliance with the MVLS Rule or are unable to maintain compliance with the other continued listing requirements of the NASDAQ Global Market within specified periods and subject to permitted extensions, our common stock may be recommended for delisting (subject to any appeal we would file or application to transfer our common stock to the NASDAQ Capital Market, if approved). If our common stock were delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting would also impair our ability to raise capital.

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

Unregistered Sales of Equity Securities

None.

Uses of Proceeds from Sale of Registered Securities

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-143265), that was declared effective by the SEC on November 14, 2007. We registered 5,750,000 shares of our common stock with a proposed maximum aggregate offering price of $46.0 million, of which we sold 5,489,849 shares with gross proceeds to the Company of approximately $43.9 million. The offering was completed after the sale of the 5,489,849 shares. J.P. Morgan Securities Inc. and Morgan Stanley & Co. Incorporated acted as joint book-running managers of the offering and, together with Cowen and Company, LLC and Leerink Swann LLC, who acted as the managing underwriters of the offering. Of this amount, $3.1 million was paid in underwriting discounts and commissions, and an additional $1.7 million of expenses were incurred, all of which was incurred during the fiscal year ended December 31, 2007. None of the expenses were paid, directly or indirectly, to directors, officers or persons owning 10% or more of our common stock, or to our affiliates.

We currently intend to use the aggregate net proceeds of $39.1 million from our initial public offering as follows:

- approximately $20.0 million for achieving regulatory approval of our product;
- approximately $10.0 million for research and product development activities;
- approximately $5.0 million for initiating sales and marketing efforts; and
- the remainder for working capital and other general corporate purposes.

Management has broad discretion over the uses of the proceeds of the initial public offering. As of September 30, 2009, none of the aggregate net proceeds from our initial public offering remained.

Purchases of Equity Securities

None.

ITEM 3. *DEFAULTS UPON SENIOR SECURITIES*

None.

ITEM 4. ***SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS***

At a Special Meeting of Stockholders held on July 2, 2009 in St. Paul, Minnesota our stockholders voted on the following matter set forth in our Proxy Statement, which was filed with the SEC pursuant to Regulation 14A of the Exchange Act and mailed to stockholders on June 1, 2009:

Amend Article IV, Section 1 of the Company's Fifth Amended and Restated Certificate of Incorporation to increase the number of shares of common stock authorized for issuance by 35 million shares from 50 million to 85 million.

Based on the following results of voting, an increase to the number of shares of common stock authorized for issuance was approved:

FOR	AGAINST
23,272,029	119,533

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 16, 2009

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1	Amended and Restated Certificate of Incorporation of the Company, as currently in effect. (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, dated as of July 2, 2009. (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	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	Specimen certificate for shares of common stock (Incorporated herein by reference to Exhibit 4.1 to Amendment No. 2 to the Company's Registration Statement on Form S-1 filed on August 14, 2007 (File No. 333-143265)).
4.2	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)).
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.

* Filed herewith

Exhibit 31.1

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 16, 2009

Exhibit 31.2

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 16, 2009

Exhibit 32.1

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009 to which this Certification is attached as Exhibit 32.1 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act, and
2. That the information contained in the Report fairly presents, in all material respects, the financial condition and the results of operations of EnteroMedics Inc. as of, and for, the periods covered by the Report.

By: /s/ Mark B. Knudson, Ph.D.

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

Date: November 16, 2009

Exhibit 32.2

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2009 to which this Certification is attached as Exhibit 32.2 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act, and
2. That the information contained in the Report fairly presents, in all material respects, the financial condition and the results of operations of EnteroMedics Inc. as of, and for, the periods covered by the Report.

By: /s/ Greg S. Lea

Greg S. Lea
Senior Vice President and Chief Financial Officer

Date: November 16, 2009