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, 2008

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 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, 2008, 16,881,104 shares of the registrant's Common Stock were outstanding.

Table of Contents

INDEX

Registered Trademarks and Trademark Applications: EnteroMedics™, Maestro™, VBLOC™ vagal blocking therapy and the EnteroMedics logo are trademarks of EnteroMedics Inc. and we have applied to register these trademarks in the United States. This Quarterly Report on Form 10-Q contains other trade names and service marks of EnteroMedics and of other companies.

PART I – FINANCIAL INFORMATION

ITEM 1. ***CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)***

ENTEROMEDICS INC.
(A development stage company)

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 19,601,369	$ 48,732,309
Short-term investments available for sale	9,010,068	5,065,000
Short-term investments held-to-maturity	—	3,233,568
Interest receivable	46,554	53,177
Other receivables	39,236	43,135
Prepaid expenses and other current assets	263,618	426,718
Total current assets	28,960,845	57,553,907
Property and equipment, net	1,292,143	1,491,768
Other assets	75,000	5,000
Total assets	$ 30,327,988	$ 59,050,675
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of notes payable	$ 3,942,908	$ 5,081,025
Accounts payable	479,298	300,342
Accrued expenses	5,388,713	2,370,044
Total current liabilities	9,810,919	7,751,411
Notes payable, less current portion (net discounts of $301,238 and $575,889 at September 30, 2008 and December 31, 2007, respectively)	3,345,395	6,017,744
Total liabilities	13,156,314	13,769,155
Stockholders' equity:		
Common stock, $0.01 par value 50,000,000 shares authorized; 16,862,632 and 16,798,962 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively	168,626	167,990
Additional paid-in capital	110,535,376	108,588,601
Deferred compensation	(26,667)	(41,667)
Accumulated other comprehensive income	(19,959)	—
Deficit accumulated during development stage	(93,485,702)	(63,433,404)
Total stockholders' equity	17,171,674	45,281,520
Total liabilities and stockholders' equity	$ 30,327,988	$ 59,050,675

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, 2008
	2008	2007	2008	2007	
Operating expenses:					
Research and development	$ 8,192,624	$ 5,153,312	$ 23,286,790	$ 13,894,118	$ 71,641,798
Selling, general and administrative	1,869,094	1,678,988	6,516,088	5,462,648	21,195,152
Total operating expenses	10,061,718	6,832,300	29,802,878	19,356,766	92,836,950
Other income (expense):					
Interest income	205,047	327,871	986,777	1,089,448	3,823,924
Interest expense	(347,291)	(453,690)	(1,182,837)	(1,185,799)	(3,976,384)
Change in value of the convertible preferred stock warrant liability	—	—	—	(361,504)	(354,907)
Other, net	4,258	5,135	(53,360)	(14,592)	(141,385)
Net loss	$ (10,199,704)	$ (6,952,984)	$(30,052,298)	$(19,829,213)	$(93,485,702)
Net loss per share—basic and diluted	$ (0.61)	$ (11.40)	$ (1.79)	$ (33.01)	
Shares used to compute basic and diluted net loss per share	16,854,336	609,905	16,821,217	600,639	

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, 2008
	2008	2007	
Cash flows from operating activities:			
Net loss	$(30,052,298)	$(19,829,213)	$ (93,485,702)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	402,675	283,316	1,045,571
Loss on sale of equipment	4,186	—	14,458
Employee stock-based compensation	2,037,073	633,064	2,967,862
Nonemployee stock-based compensation	(122,910)	1,484,083	2,992,699
Amortization of commitment fees, debt issuance costs and original issue discount	274,651	623,268	1,393,400
Amortization of short-term investment discount	8,822	(112,046)	(296,454)
Change in carrying value of warrant liability	—	361,504	354,907
Change in operating assets and liabilities:			
Interest receivable	6,623	51,876	(46,554)
Other receivables	3,899	32,621	(39,236)
Prepaid expenses and other current assets	163,100	(177,259)	(263,618)
Other assets	(70,000)	(276,379)	(75,000)
Accounts payable	166,602	(440,352)	466,944
Accrued expenses	3,018,669	181,763	5,388,713
Accrued interest payable	—	—	165,822
Net cash used in operating activities	(24,158,908)	(17,183,754)	(79,416,188)
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	5,122,790	560,000	5,812,790
Purchases of short-term investments held-to-maturity	(1,185,838)	(4,331,856)	(22,414,130)
Maturities of short-term investments held-to-maturity	4,450,000	14,400,000	22,750,000
Purchases of property and equipment	(194,882)	(651,462)	(2,339,818)
Net cash provided by (used in) investing activities	(935,163)	9,976,682	(11,073,391)
Cash flows from financing activities:			
Proceeds from stock options exercised	48,248	21,187	122,481
Proceeds from warrants issued	—	—	15,657
Proceeds from warrants exercised	—	—	187,652
Proceeds from sale of common stock, net of underwriting fees of $3,074,315	—	—	40,874,977
Common stock financing costs	—	—	(1,752,663)
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	—	7,500,000	15,831,121
Repayments on notes payable	(4,085,117)	(1,965,985)	(8,241,580)
Debt issuance costs	—	—	(91,558)
Net cash provided by (used in) financing activities	(4,036,869)	5,555,202	110,090,948
Net increase (decrease) in cash and cash equivalents	(29,130,940)	(1,651,870)	19,601,369
Cash and cash equivalents:			
Beginning of period	48,732,309	17,536,472	—
End of period	$ 19,601,369	$ 15,884,602	$ 19,601,369
Supplemental disclosure:			
Interest paid	$ 873,952	$ 562,531	$ 2,407,709
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	—	479,052	966,830
Value of warrants issued for debt commitment	—	550,212	636,250
Value of warrants issued with Series C financing	—	—	735,438
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
Reclassification of convertible preferred stock warrant liability	—	—	1,090,345
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, 2008 totaling approximately $93.5 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, 2007 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 Quarterly Report on Form 10-Q should be read in conjunction with the Company’s Annual Report on Form 10-K for the year ended December 31, 2007.

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.

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, 2008 and 2007:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Numerator:				
Net loss	$(10,199,704)	$(6,952,984)	$(30,052,298)	$(19,829,213)
Denominator for historical basic and diluted net loss per share:				
Weighted-average common shares outstanding	16,854,336	610,368	16,821,217	603,954
Weighted-average unvested common shares subject to repurchase	—	(463)	—	(3,315)
Denominator for net loss per common share—basic and diluted	16,854,336	609,905	16,821,217	600,639
Net loss per share—basic and diluted	$ (0.61)	$ (11.40)	$ (1.79)	$ (33.01)

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,	
	2008	2007
Convertible preferred stock	—	10,313,842
Stock options outstanding	3,052,607	2,078,771
Warrants to purchase convertible preferred stock	—	495,908
Warrants to purchase common stock	683,235	170,336

Recently Issued Accounting Standards

In September 2006, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 was effective for the Company starting in fiscal 2008 with respect to financial assets and liabilities. The initial adoption of SFAS 157 on January 1, 2008 had no impact on the consolidated financial statements. With respect to non-financial assets and liabilities, SFAS 157 is effective for the Company starting in fiscal 2009. The Company has not determined the impact, if any, the adoption of this statement will have as it pertains to non-financial assets and liabilities on its consolidated financial statements.

In February 2007, FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The amendment to SFAS 115 applies to all entities with investments in available for sale or trading securities. SFAS 159 was effective for the Company starting on January 1, 2008, however, no assets or liabilities have currently been remeasured at fair value.

In May 2008, FASB issued Statement of Financial Accounting Standards No. 162 (SFAS 162), *The Hierarchy of Generally Accepted Accounting Principles*. This standard is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with generally accepted accounting principles in the United States for non-governmental entities. SFAS 162 is effective 60 days following approval by the U.S. Securities and Exchange Commission (SEC) of the Public Company Accounting Oversight Board's amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. The Company does not expect SFAS 162 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, 2008 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, 2007.

(2) Fair Value Measurement

Effective January 1, 2008, the Company adopted the fair value measurement and disclosure provisions of Statement of Financial Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*, for its financial assets as described below.

SFAS 157 defines fair value 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, and establishes a framework for measuring fair value. It also establishes a fair value hierarchy 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 under SFAS 157 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.

A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

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 in to 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 under SFAS 157 as of September 30, 2008. As required by SFAS 157, 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, 2008 are classified as Level 2 in connection with our adoption of SFAS 157 and are as follows:

	Significant Other Observable Inputs Level 2
U.S. agency securities	$ 4,593,655
U.S. corporate bonds	1,390,687
Commercial paper	2,487,344
Asset-backed securities	538,382
Total	$ 9,010,068

(3) Commitments

Operating Lease

The Company rents its office, warehouse and laboratory facilities under an operating lease, which expired on September 30, 2008. Effective October 1, 2008, the Company entered into a seven-year non-cancelable operating lease agreement for office/warehouse space. The leased space will continue to include furnished office space and various research and development labs. The lease expires on September 30, 2015 with monthly base rent ranging from $19,570 to $24,643. At September 30, 2008, future minimum payments under the new lease are as follows:

Years Ending December 31:	
Remaining three months in 2008	$ 58,710
2009	236,013
2010	247,951
2011	274,564
2012	280,055
2013	285,656
2014	291,369
2015	221,788
	$1,896,106

(4) Notes Payable

The Company entered into a loan agreement on December 1, 2004 that provided for equipment loans and growth capital loans up to an aggregate original principal amount of $250,000 and $3,000,000, respectively, through September 30, 2005. The loan agreement was amended on September 29, 2005 providing for additional lender commitments for equipment loans and growth capital loans to the Company up to an aggregate original principal amount of $500,000 and $2,000,000, respectively.

On May 17, 2007 the Company entered into a $15.0 million debt facility with the same lender of the other notes payable. The initial commitment under the debt facility was for $10.0 million and allowed for two $5.0 million draw periods, the first of which was required upon closing. The loan agreement was amended on August 28, 2007 to provide for two draw periods on the second $5.0 million that was available to the Company under the terms of the original agreement. As amended, $2.5 million was available to the Company through August 31, 2007 and the remaining $2.5 million was available to the Company through October 31, 2007. The final $5.0 million commitment is available to the Company through the end of 2008. The final $5.0 million commitment is dependent upon the negotiation of mutually agreed terms between the parties.

The aggregate amount funded by the lender, and the amount outstanding, under the two debt facilities was $15,746,121 and $7,589,541, respectively, at September 30, 2008.

Scheduled debt principal payments are as follows as of September 30, 2008:

Years Ending December 31:	
Remaining three months in 2008	$ 995,907
2009	3,972,771
2010	2,620,863
	7,589,541
Less: Original issue discount	(301,238)
Notes payable, net	$7,288,303

(5) Stock-based Compensation

As of September 30, 2008, the Company has adopted the EnteroMedics Inc. 2003 Stock Incentive Plan (the Plan) that includes both incentive stock options and nonqualified stock options to be granted to employees, officers, consultants, independent contractors, directors and affiliates of the Company. Prior to January 1, 2006, the Company accounted for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Board Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*, and related interpretations, and followed the minimum value disclosure provisions of Statement of Financial Accounting Standards No. 123 (SFAS 123), *Accounting for Stock-Based Compensation*. Under APB 25, compensation expense is based on the difference, if any, on the date of the grant, between the fair value of the Company's stock and the exercise price. Employee stock-based compensation determined under APB 25 is recognized over the option vesting period. Accordingly, for those grants made through December 31, 2005, we recognized compensation expense pursuant to APB 25 for stock options granted to employees with an exercise price below the estimated fair value of our common stock on the date of grant. For disclosure purposes pursuant to SFAS 123, we estimated the date of grant fair value using the minimum value option-pricing model.

Effective January 1, 2006, the Company adopted the fair value provisions of Statement of Financial Accounting Standards No. 123R (SFAS 123R), *Share-Based Payment*, which supersedes its previous accounting under APB 25. SFAS 123R requires the recognition of compensation expense, using a fair-value-based method, for costs related to all share-based payments including stock options. SFAS 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The Company adopted SFAS 123R using the prospective transition method, which requires that for nonpublic entities that used the minimum value method for either pro forma or financial statement recognition purposes, SFAS 123R shall be applied to option grants or modifications to existing options after the required effective date. For options granted prior to the new SFAS 123R effective date and for which the requisite service period has not been performed as of January 1, 2006, the Company continues to apply the intrinsic value provisions of APB 25 on the remaining unvested awards. All option grants valued after January 1, 2006 are expensed on a straight-line basis over the vesting period.

The provisions of SFAS 123R 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 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 Plan for the three and nine months ended September 30, 2008 and 2007 was allocated to operating expenses as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Research and development	$ 154,826	$ 228,719	$ 665,155	$ 632,416
Selling, general and administrative	419,105	364,173	1,249,008	1,484,731
Total	$ 573,931	$ 592,892	$ 1,914,163	$ 2,117,147

As of September 30, 2008 there was $5,920,426 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 2.74 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, 2008 and 2007:

	Employees Three months ended September 30,		Employees Nine months ended September 30,	
	2008	2007	2008	2007
Risk-free interest rates	4.01%	4.48%-4.60%	3.49%-4.01%	4.48%-4.79%
Expected life	6.25 years	6.25 - 6.50 years	5.00 - 6.25 years	6.00 - 6.50 years
Expected dividends	0%	0%	0%	0%
Expected volatility	67.75%	55.25%-56.13%	67.63%-69.38%	55.25%-58.63%

	Nonemployees Three months ended September 30,		Nonemployees Nine months ended September 30,	
	2008	2007	2008	2007
Risk-free interest rates	3.83%	4.58%-4.60%	3.43%-3.98%	4.58%-5.03%
Expected life	10 years	10 years	10 years	10 years
Expected dividends	0%	0%	0%	0%
Expected volatility	72.88%	60.75%	72.88%-75.25%	60.75%-63.25%

Option activity under the Plan for the nine months ended September 30, 2008 was as follows:

		Outstanding Options	
	Shares Available For Grant	Number of Shares	Weighted-Average Exercise Price
Balance, December 31, 2007	1,647,462	2,101,926	$ 3.24
Shares reserved	—	—	—
Options granted	(1,322,308)	1,322,308	7.63
Options exercised	—	(63,671)	.75
Options cancelled	307,956	(307,956)	7.12
Balance, September 30, 2008	633,110	3,052,607	$ 4.80

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, 2007. 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.

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 within the United States and internationally. Preliminary results from a feasibility study conducted outside the U.S., which includes 33 patients, indicates that the Maestro System may provide durable and ongoing weight-loss for people with obesity. Follow up data show excess weight loss, or EWL, of 29.1% in 12 patients at 12 months of VBLOC therapy, 27.4% in 17 patients at nine months of therapy and 21.4% in 28 patients at six months of therapy. We have completed enrollment and implantation of subjects in our first U.S. pivotal trial, the EMPOWER trial. We plan to review the data from our EMPOWER trial to support our premarket approval, or PMA, application in the middle of 2009 and submit the application for the Maestro System shortly thereafter. We anticipate commercialization in the United States beginning in 2010 if and when the FDA grants us approval. 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.

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, 2008, we had a deficit accumulated during the development stage of $93.5 million. We expect our losses to continue and to increase as we continue our development activities and 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 until 2010 and then, only if 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, and travel. We expense research and development costs as they are incurred. From inception through September 30, 2008, we have incurred a total of $71.6 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, 2008, we have incurred $21.2 million in selling, general and administrative expenses.

Results of Operations

Comparison of the Three Months Ended September 30, 2008 and 2007

Research and Development Expenses. Research and development expenses were $8.2 million for the three months ended September 30, 2008, compared to $5.2 million for the three months ended September 30, 2007. The increase of $3.0 million, or 59.0%, is primarily due to increases of $390,000 and $3.2 million in compensation expense and professional services, respectively, to support the EMPOWER clinical study and completion of the Maestro RC System development efforts, offset by a decrease of $767,000 in device costs which were required in 2007 as the EMPOWER clinical study began ramping up. Employee stock-based compensation increased $92,000 due to new options granted since the third quarter of 2007. Nonemployee stock compensation charges decreased $166,000 due to a drop in the fair value of our common stock compared to the third quarter of 2007.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $1.9 million for the three months ended September 30, 2008, compared to $1.7 million for the three months ended September 30, 2007. The increase of $190,000, or 11.3%, is primarily due to increases of $323,000, $182,000 and $12,000 in employee stock-based compensation from new options granted since the third quarter of 2007, compensation expense due to increased headcount and professional services, respectively, offset by a decrease of $268,000 in nonemployee stock compensation charges due to a drop in the fair value of our common stock compared to the third quarter of 2007.

Interest Income. Interest income was $205,000 for the three months ended September 30, 2008, compared to $328,000 for the three months ended September 30, 2007. The decrease of $123,000, or 37.5%, is primarily due to a decrease in the short-term interest rate environment despite an increase in the average cash, cash equivalents and short-term investment balance from $24.3 million during the third quarter of 2007 to $31.9 million during the third quarter of 2008. The increased average cash, cash equivalents and short-term investments balance is the result of the net $39.1 million raised in our initial public offering in November 2007 and $10.0 million of debt funding received in 2007. We expect our quarterly interest income to continue decreasing in the future as we continue to use the proceeds of our initial public offering to fund our operations.

Interest Expense. Interest expense was $347,000 for the three months ended September 30, 2008, compared to $454,000 for the three months ended September 30, 2007. The decrease of $106,000, or 23.5%, was primarily due to the third quarter of 2007 including amortization expense of $132,000 for commitment warrants issued in conjunction with the $10.0 million debt agreement entered into on May 17, 2007.

Comparison of the Nine Months Ended September 30, 2008 and 2007

Research and Development Expenses. Research and development expenses were $23.3 million for the nine months ended September 30, 2008, compared to $13.9 million for the nine months ended September 30, 2007. The increase of $9.4 million, or 67.6%, is primarily due to increases of $1.2 million, $7.1 million and $159,000 in compensation expense, professional services and device costs, respectively, to support the EMPOWER clinical study and completion of the Maestro RC System development efforts. Employee stock based compensation increased $537,000 over the first nine months of 2007 due to new options granted during that period. Nonemployee stock compensation charges decreased $504,000 due to a drop in the fair value of our common stock and an increase in fully vested options compared to the first nine months of 2007.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $6.5 million for the nine months ended September 30, 2008, compared to $5.5 million for the nine months ended September 30, 2007. The increase of $1.1 million, or 19.3%, is primarily due to a $494,000 increase in professional services expense for public relations, investor relations and legal fees. Additionally, there was a $466,000 increase in compensation expense associated with increased headcount and a $151,000 increase associated with the cost of being a public company, including travel for attendance at investor conferences and meetings and

insurance. Employee stock based compensation increased $867,000 over the first nine months of 2007 due to new options granted. Nonemployee stock based compensation decreased $1.1 million due to a drop in the fair value of our common stock compared to the first nine months of 2007.

Interest Income. Interest income was $987,000 for the nine months ended September 30, 2008, compared to $1.1 million for the nine months ended September 30, 2007. The decrease of $103,000, or 9.4%, is primarily due to a decrease in the short-term interest rate environment despite an increase in the average cash, cash equivalents and short-term investment balance from $27.3 million during the nine months ended September 30, 2007 to $41.5 million during the nine months ended September 30, 2008. The increased average cash, cash equivalents and short-term investments balance is the result of the net $39.1 million raised in our initial public offering in November 2007 and $10.0 million of debt funding received in 2007. We expect our quarterly interest income to continue decreasing in the future as we continue to use the proceeds of our initial public offering to fund our operations.

Interest Expense. Interest expense was flat at $1.2 million for the nine months ended September 30, 2008 and for the nine months ended September 30, 2007. The slight decrease of $3,000, or 0.2%, was primarily due to $10.0 million of debt funding obtained throughout 2007 under the terms of a debt agreement entered into on May 17, 2007 offset by the amortization expense of $525,000 for commitment warrants issued in conjunction with the same debt agreement.

Change in Value of the Convertible Preferred Stock Warrant Liability. The change in value of the convertible preferred stock warrant liability was zero for the nine months ended September 30, 2008, compared to $362,000 for the nine months ended September 30, 2007. This is the result of a convertible preferred stock warrant liability being recorded on December 11, 2006 when we sold an additional 123,569 shares of Series C convertible preferred stock. Upon closing the sale, we had insufficient authorized and unissued shares of Series C convertible preferred stock available to share settle outstanding warrants to purchase Series C convertible preferred stock, resulting in the warrants being reclassified as a liability at the estimated fair value of $735,000 on December 11, 2006 and subsequently remeasured as of December 31, 2006 and March 31, 2007. The fair market value of the warrants as of March 31, 2007 and December 31, 2006 was $973,000 and $729,000, respectively. On May 14, 2007 we filed an amended certificate of incorporation to increase the number of authorized shares of Series C convertible preferred stock. As a result of the amendment, we had sufficient authorized and unissued shares of Series C convertible preferred stock available to share settle the warrants. The warrants were marked-to-market on May 14, 2007 and the convertible preferred stock liability was reclassified to additional paid-in capital. The fair market value of the warrants on May 14, 2007 was determined to be $1.1 million.

Liquidity and Capital Resources

We have incurred losses since our inception in December 2002 and, as of September 30, 2008 we had a deficit accumulated during the development stage of $93.5 million. We have financed our operations to date principally through sale of capital stock, debt financing and interest earned on investments. Prior to our initial public offering of stock in November 2007, we had received net proceeds of $63.2 million from the sale of common stock and preferred stock and $15.8 million in debt financing from a lender that provided $746,000 to finance equipment purchases and $15.0 million to finance working capital. Through our initial public offering we received net proceeds of $39.1 million after expenses and underwriters' discounts and commissions and including the exercise of the underwriters' over-allotment option.

As of September 30, 2008, we had $28.6 million in cash, cash equivalents and short-term investments. Of this amount $15.8 million was invested in short-term money market funds that are not considered to be bank deposits and are not insured or guaranteed by the federal deposit insurance company or other government agency. These money market funds seek to preserve the value of the investment at $1.00 per share; however, it is possible to lose money investing in these funds. Our cash and investment balances are held in a variety of interest bearing instruments, including obligations of U.S. government agencies, U.S. corporate bonds, commercial paper, asset-backed securities and money market 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 fair value of our short-term investment holdings are based on security prices from one or multiple industries established pricing sources. Examples of these pricing sources are Bloomberg, Interactive Data Corporation, Reuters, JJ Kenny, and Merrill Lynch. Each pricing source uses a different confidential method for pricing securities using various inputs, such as interest rates, known historical trades, yield curve information, benchmark data, prepayment speeds, credit quality, or broker/dealer quotes. Management regularly reviews the pricing methodology used by our third party asset managers to ensure consistency of the fair-value determination with SFAS 157 and proper classification of the underlying assets and liabilities within that standard's fair-value hierarchy. We also review each of our short-term investment positions and assess whether there is any other-than temporary impairment as well as the reasonableness of the fair market values being reported.

The remaining unpaid balance of the $7.6 million in debt financing 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 four 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 four months. There are no additional 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 $24.2 million and $17.2 million for the nine months ended September 30, 2008 and 2007, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, which was partially offset by depreciation and amortization, stock-based compensation and changes in operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities was $935,000 for the nine months ended September 30, 2008 and is primarily related to purchases of short-term investments and, to a lesser extent, the purchase of property and equipment, partially offset by proceeds from the maturity of short-term investments. Net cash provided by investing activities was $10.0 million for the nine months ended September 30, 2007 and is primarily related to the proceeds from the maturity of short-term investments partially offset by the purchase of short-term investments and, to a lesser extent, the purchase of property and equipment.

Net Cash Used in Financing Activities

Net cash used in financing activities was $4.0 million for the nine months ended September 30, 2008 and is primarily attributable to the repayments of long-term debt. Net cash provided by financing activities was $5.6 million for the nine months ended September 30, 2007 and is primarily attributable to debt proceeds of $7.5 million partially offset by 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 and operate as a publicly-traded company as well as pursue additional applications for our technology platform.

We do not expect to generate significant product revenue until 2010. We do not anticipate generating any product revenue in the United States unless and until we successfully obtain FDA approval for our Maestro System. We believe the net proceeds from our initial public offering, 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 through the end of 2009. 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 a credit facility agreement. 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, 2007. 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, 2007 filed with the SEC.

Contractual Obligations

During the nine months ended September 30, 2008, 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, 2007, other than those described below.

Effective October 1, 2008 the Company entered into a seven-year non-cancelable operating lease agreement for office/warehouse space. The leased space will continue to include furnished office space and various research and development labs. The lease expires on September 30, 2015 with monthly base rent ranging from $19,570 to $24,643.

The following table summarizes our contractual obligations as of September 30, 2008 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	$ 1,896,106	$ 234,839	$ 512,733	$ 562,896	$ 585,638
Long-term debt	8,492,263	4,609,313	3,882,950	—	—
Other long-term liabilities	350,000	300,000	50,000	—	—
Total contractual cash obligations	$ 10,738,369	$ 5,144,152	$ 4,445,683	$ 562,896	$ 585,638

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 agreement with the Mayo Foundation for Medical Education and Research, or Mayo Foundation.

Off-Balance Sheet Arrangements

As of September 30, 2008, we did not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

In September 2006, FASB issued Statement of Financial Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*, which defines fair value, establishes guidelines for measuring fair value and expands disclosures regarding fair value measurements. SFAS 157 does not require any new fair value measurements but rather eliminates inconsistencies in guidance found in various prior accounting pronouncements. SFAS 157 was effective for us starting in fiscal 2008 with respect to financial assets and liabilities. The

initial adoption of SFAS 157 on January 1, 2008 had no impact on our consolidated financial statements. With respect to non-financial assets and liabilities, SFAS 157 is effective for us starting in fiscal 2009. We have not yet determined the impact, if any, the adoption of this statement will have as it pertains to non-financial assets and liabilities on our consolidated financial statements.

In February 2007, FASB issued Statement of Financial Accounting Standards No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115*. SFAS 159 permits entities to choose to measure many financial instruments and certain other items at fair value. The amendment to SFAS 115 applies to all entities with investments in available for sale or trading securities. SFAS 159 was effective for us starting on January 1, 2008; however, no assets or liabilities have currently been remeasured at fair value.

In May 2008, FASB issued Statement of Financial Accounting Standards No. 162 (SFAS 162), *The Hierarchy of Generally Accepted Accounting Principles*. This standard is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with generally accepted accounting principles in the United States for non-governmental entities. SFAS 162 is effective 60 days following approval by the SEC of the Public Company Accounting Oversight Board's amendments to AU Section 411, *The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles*. We do not expect SFAS 162 to have a material impact on the preparation of our consolidated financial statements.

There have been no other significant changes in recent accounting pronouncements during the nine months ended September 30, 2008 as compared to the recent accounting pronouncements described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

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, 2008, we had $28.6 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 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, 2008 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, 2008 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, 2008 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, 2007.

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.

As of September 30, 2008, approximately $28.6 million of the aggregate net proceeds from our initial public offering remained invested in a variety of interest bearing instruments, including obligations of U.S. government agencies, corporate bonds, commercial paper, and money market funds or in operating cash accounts.

Purchases of Equity Securities

None.

ITEM 3. *DEFAULTS UPON SENIOR SECURITIES*

None.

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

None.

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 7, 2008

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	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 for the quarter ended September 30, 2008 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 condensed 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)) 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. 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
    c. 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.

By: /s/ Mark B. Knudson, Ph.D.
Mark B. Knudson, Ph.D.
President and Chief Executive Officer

Date: November 7, 2008

Exhibit 31.2

CERTIFICATION

I, Greg S. Lea, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 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 condensed 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)) 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. 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
    c. 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.

By: /s/ Greg S. Lea
Greg S. Lea
Senior Vice President and Chief Financial Officer

Date: November 7, 2008

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, 2008 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 7, 2008

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, 2008 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 7, 2008