
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

Form 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2011

Commission file number: 1-33818

ENTEROMEDICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

48-1293684
(IRS Employer
Identification No.)

2800 Patton Road, St. Paul, Minnesota 55113
(Address of principal executive offices, including zip code)

(651) 634-3003
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated Filer
Non-accelerated filer (Do not check if a smaller reporting entity) Smaller Reporting Company

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

As of April 30, 2011, 27,892,388 shares of the registrant's Common Stock were outstanding.

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Registered Trademarks and Trademark Applications: In the United States we have registered trademarks for VBLOC®, ENTEROMEDICS® and MAESTRO®, each registered with the United States Patent and Trademark Office, and have received a fifth 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, the European Community, Saudi Arabia and VBLOC is registered in Switzerland. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are registered in Mexico. The trademarks VBLOC, ENTEROMEDICS and MAESTRO SYSTEM ORCHESTRATING OBESITY SOLUTIONS are the subject of pending trademark applications in the United Arab Emirates. This Form 10-Q contains other trade names and trademarks and service marks of EnteroMedics and of other companies.

PART I – FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

ENTEROMEDICS INC.
(A development stage company)
Condensed Consolidated Balance Sheets
(Unaudited)

| | March 31, 2011 | December 31, 2010 |
|---|----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 29,955,310 | \$ 30,840,560 |
| Restricted cash | 200,000 | 6,527,031 |
| Short-term investments available for sale | 2,000,040 | — |
| Interest receivable | 333 | — |
| Prepaid expenses and other current assets | 718,584 | 436,538 |
| Total current assets | 32,874,267 | 37,804,129 |
| Property and equipment, net | 669,960 | 741,564 |
| Other assets | 133,170 | 141,572 |
| Total assets | <u>\$ 33,677,397</u> | <u>\$ 38,687,265</u> |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Current portion of notes payable | \$ 1,118,356 | \$ 921,998 |
| Accounts payable | 512,832 | 125,188 |
| Accrued expenses | 1,925,322 | 2,538,371 |
| Accrued interest payable | 403,386 | 411,492 |
| Total current liabilities | 3,959,896 | 3,997,049 |
| Notes payable, less current portion (net discounts of \$359,731 and \$421,874 at March 31, 2011 and December 31, 2010, respectively) | 4,481,756 | 4,983,159 |
| Total liabilities | <u>8,441,652</u> | <u>8,980,208</u> |
| Stockholders' equity: | | |
| Common stock, \$0.01 par value 85,000,000 shares authorized; 27,892,388 shares issued and outstanding at March 31, 2011 and December 31, 2010 | 278,924 | 278,924 |
| Additional paid-in capital | 180,757,786 | 180,143,120 |
| Accumulated other comprehensive income | 40 | — |
| Deficit accumulated during development stage | (155,801,005) | (150,714,987) |
| Total stockholders' equity | 25,235,745 | 29,707,057 |
| Total liabilities and stockholders' equity | <u>\$ 33,677,397</u> | <u>\$ 38,687,265</u> |

See accompanying notes to condensed consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Condensed Consolidated Statements of Operations
(Unaudited)

| | <u>Three months ended March 31,</u> | | <u>Period from</u> |
|---|-------------------------------------|-----------------------|-------------------------|
| | <u>2011</u> | <u>2010</u> | <u>December 19,</u> |
| | | | <u>2002</u> |
| | | | <u>(inception) to</u> |
| | | | <u>March 31, 2011</u> |
| Operating expenses: | | | |
| Research and development | \$ 2,788,252 | \$ 2,382,612 | \$ 102,896,588 |
| Selling, general and administrative | 2,068,554 | 1,966,175 | 41,654,177 |
| Total operating expenses | <u>4,856,806</u> | <u>4,348,787</u> | <u>144,550,765</u> |
| Other income (expense): | | | |
| Interest income | 7,234 | 1,000 | 4,031,256 |
| Interest expense | (231,600) | (363,562) | (11,071,511) |
| Change in value of warrant liability | — | (28,247) | (3,840,622) |
| Other, net | (4,846) | (8,371) | (238,395) |
| Net loss | <u>\$ (5,086,018)</u> | <u>\$ (4,747,967)</u> | <u>\$ (155,670,037)</u> |
| Net loss per share – basic and diluted | <u>\$ (0.18)</u> | <u>\$ (0.66)</u> | |
| Shares used to compute basic and diluted net loss per share | <u>27,892,388</u> | <u>7,213,555</u> | |

See accompanying notes to condensed consolidated financial statements.

ENTEROMEDICS INC.
(A development stage company)

Condensed Consolidated Statements of Cash Flows
(Unaudited)

| | <u>Three months ended March 31,</u> | | <u>Period from</u> |
|---|-------------------------------------|--------------------|-----------------------|
| | <u>2011</u> | <u>2010</u> | <u>December 19,</u> |
| | | | <u>2002</u> |
| | | | <u>(inception) to</u> |
| | | | <u>March 31, 2011</u> |
| Cash flows from operating activities: | | | |
| Net loss | \$(5,086,018) | \$(4,747,967) | \$(155,670,037) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 71,338 | 97,132 | 2,027,404 |
| Loss on sale of equipment | 266 | 3,819 | 73,124 |
| Employee stock-based compensation | 660,411 | 738,552 | 8,978,181 |
| Nonemployee stock-based compensation | — | 31,756 | 3,252,700 |
| Amortization of commitment fees, debt issuance costs and original issue discount | 70,545 | 112,846 | 3,722,428 |
| Amortization of short-term investment discount | — | — | (308,051) |
| Change in value of warrant liability | — | 28,247 | 3,840,622 |
| Change in operating assets and liabilities: | | | |
| Interest receivable | (333) | — | (333) |
| Other receivables | — | (4,517) | — |
| Prepaid expenses and other current assets | (282,046) | (114,800) | (718,584) |
| Other assets | — | (9,523) | (60,348) |
| Accounts payable | 387,644 | 40,972 | 321,293 |
| Accrued expenses | (613,049) | 158,687 | 1,925,322 |
| Accrued interest payable | (8,106) | 30,017 | 569,208 |
| Net cash used in operating activities | <u>(4,799,348)</u> | <u>(3,634,779)</u> | <u>(132,047,071)</u> |
| Cash flows from investing activities: | | | |
| Decrease (increase) in restricted cash | 6,327,031 | — | (200,000) |
| Purchases of short-term investments available for sale | (2,000,000) | — | (16,882,233) |
| Maturities of short-term investments available for sale | — | — | 14,854,414 |
| Purchases of short-term investments held to maturity | — | — | (22,414,130) |
| Maturities of short-term investments held to maturity | — | — | 22,750,000 |
| Purchases of property and equipment | — | (21,388) | (2,578,948) |
| Net cash provided by (used in) investing activities | <u>4,327,031</u> | <u>(21,388)</u> | <u>(4,470,897)</u> |
| Cash flows from financing activities: | | | |
| Proceeds from stock options exercised | — | 23,697 | 200,854 |
| Proceeds from warrants issued | — | — | 1,429,646 |
| 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, registered direct and public offerings | — | 4,834,894 | 54,455,501 |
| Common stock financing costs | (45,745) | (339,547) | (5,235,789) |
| Payment to shareholders for fractional shares upon reverse stock split | — | — | (355) |
| Proceeds from sale of Series A, B and C convertible preferred stock | — | — | 63,766,564 |
| Series A, B and C convertible preferred stock financing costs | — | — | (1,658,662) |
| Proceeds from convertible notes payable | — | — | 6,814,846 |
| Proceeds from notes payable | — | — | 35,831,121 |

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| | <u>Three months ended March 31,</u> | | <u>Period from December 19, 2002 (inception) to March 31, 2011</u> |
|---|-------------------------------------|---------------------|--|
| | <u>2011</u> | <u>2010</u> | |
| Repayments on notes payable | (367,188) | (926,786) | (29,871,278) |
| Debt issuance costs | — | — | (321,799) |
| Net cash (used in) provided by financing activities | <u>(412,933)</u> | <u>3,592,258</u> | <u>166,473,278</u> |
| Net (decrease) increase in cash and cash equivalents | (885,250) | (63,909) | 29,955,310 |
| Cash and cash equivalents: | | | |
| Beginning of period | 30,840,560 | 14,617,594 | — |
| End of period | <u>\$29,955,310</u> | <u>\$14,553,685</u> | <u>\$ 29,955,310</u> |
| Supplemental disclosure: | | | |
| Interest paid | \$ 169,121 | \$ 212,134 | \$ 6,771,270 |
| 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 | — | — | 3,196,933 |
| 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, registered direct and public offerings | — | — | 949,394 |
| Cashless exercise of warrants | — | — | 5,244,778 |
| Conversion of notes and interest payable to Series B and C convertible preferred shares | — | — | 6,980,668 |
| Options issued for deferred compensation | — | — | 10,898 |
| Common stock issued to Mayo Foundation and for deferred compensation | — | — | 1,770,904 |
| Reclassifications of warrant liability | — | — | 2,932,766 |
| Conversion of convertible preferred stock to common stock | — | — | 51,132 |

See accompanying notes to condensed consolidated financial statements.

EnteroMedics Inc.
(A development stage company)

Notes to Condensed Consolidated Financial Statements
(Unaudited)

(1) Summary of Significant Accounting Policies

Description of Business

EnteroMedics Inc. (formerly Beta Medical, Inc.) (the Company) is developing implantable systems to treat obesity and other gastrointestinal disorders. The Company was incorporated in the state of Minnesota on December 19, 2002 and was reincorporated in Delaware on July 22, 2004. The Company is in the development stage and since inception has devoted substantially all of its resources to recruiting personnel, developing its product technology, obtaining patents to protect its intellectual property and raising capital, and has not derived revenues from its primary business activity. The Company is headquartered in St. Paul, Minnesota. In January 2006, the Company established EnteroMedics Europe Sàrl, a wholly-owned subsidiary located in Switzerland.

Since inception, the Company has incurred losses through March 31, 2011 totaling approximately \$155.7 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.

Reverse Stock Split

The Company's Board of Directors and stockholders approved a 1-for-6 reverse split of the Company's outstanding common stock that became effective on July 9, 2010. The reverse stock split did not change the par value of the Company's stock or the number of common and preferred shares authorized by the Company's Fifth Amended and Restated Certificate of Incorporation. All share and per share amounts have been retroactively adjusted to reflect the stock split for all periods presented.

Basis of Presentation

The Company has prepared the accompanying condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America. The Company's fiscal year ends on December 31.

The accompanying condensed consolidated financial statements and notes thereto are unaudited. In the opinion of the Company's management, these statements include all adjustments, which are of a normal recurring nature, necessary to present a fair presentation. Interim results are not necessarily indicative of results for a full year. The condensed consolidated balance sheet as of December 31, 2010 was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America. The information included in this Form 10-Q should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2010.

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 months ended March 31, 2011 related entirely to net unrealized gains on short-term investments. There was no difference from reported net loss for the three months ended March 31, 2010.

EnteroMedics Inc.
(A development stage company)

Notes to Condensed Consolidated Financial Statements-(Continued)
(Unaudited)

Fair Value of Financial Instruments

Carrying amounts of certain of the Company's financial instruments, including cash and cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable and accrued liabilities approximate fair value due to their short maturities. The fair values of investments in debt and equity securities are disclosed in Note 2. The fair value of the Company's long-term debt is approximately \$5.5 million as of March 31, 2011 based on the present value of estimated future cash flows using a discount rate commensurate with borrowing rates available to the Company.

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

Restricted Cash

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

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

Derivative Instruments

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

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

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding during the period. Diluted net loss per share is based on the weighted-average 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.

EnteroMedics Inc.
(A development stage company)

Notes to Condensed Consolidated Financial Statements-(Continued)
(Unaudited)

The following table sets forth the computation of basic and diluted net loss per share for the three months ended March 31, 2011 and 2010:

| | Three months ended March 31, | |
|---|---------------------------------|----------------|
| | 2011 | 2010 |
| Numerator: | | |
| Net loss | \$ (5,086,018) | \$ (4,747,967) |
| Denominator for basic and diluted net loss per share: | | |
| Weighted-average common shares outstanding | 27,892,388 | 7,213,555 |
| Weighted-average unvested common shares subject to repurchase | — | — |
| Denominator for net loss per common share—basic and diluted | 27,892,388 | 7,213,555 |
| Net loss per share—basic and diluted | \$ (0.18) | \$ (0.66) |

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:

| | Three months ended March 31, | |
|-----------------------------------|---------------------------------|-----------|
| | 2011 | 2010 |
| Stock options outstanding | 1,828,360 | 911,869 |
| Warrants to purchase common stock | 22,224,718 | 1,358,814 |

Recently Issued Accounting Standards

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

(2) Short-term Investments and Fair Value Measurements

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

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

- Level 1—Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.
- Level 2—Quoted prices for similar assets and liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active or model-derived valuations for which all significant inputs are observable, either directly or indirectly.
- Level 3—Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable.

The Company's assets that are measured at fair value on a recurring basis are classified within Level 1 or Level 2 of the fair value hierarchy. The Company does not hold any assets that are measured at fair value using Level 3 inputs. The types of instruments the Company invests in that are valued based on quoted market prices in active markets include U.S. treasury securities. Such instruments are classified by the Company within Level 1 of the fair value hierarchy. U.S. treasuries are valued using unadjusted quoted prices for identical assets in active markets that the Company can access.

EnteroMedics Inc.
(A development stage company)

Notes to Condensed Consolidated Financial Statements-(Continued)
(Unaudited)

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 as of March 31, 2011. Assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

All short-term investments at March 31, 2011 are classified as Level 2 and are as follows:

| | <u>Significant Other Observable Inputs Level 2</u> |
|------------------------|--|
| U.S. agency securities | \$ 2,000,040 |
| Total | <u>\$ 2,000,040</u> |

The short-term investments available for sale at March 31, 2011 had effective maturities of less than one year. The amortized cost and fair value of short-term investments available for sale, and the related gross unrealized gains and losses, were as follows at March 31, 2011:

| | <u>Cost</u> | <u>Gross Unrealized</u> | | <u>Fair value</u> |
|------------------------|--------------------|-------------------------|---------------|--------------------|
| | | <u>Gains</u> | <u>Losses</u> | |
| U.S. agency securities | \$2,000,000 | \$ 230 | \$ 190 | \$2,000,040 |
| Total | <u>\$2,000,000</u> | <u>\$ 230</u> | <u>\$ 190</u> | <u>\$2,000,040</u> |

(3) Commitments

Operating Lease

The Company rents its office, warehouse and laboratory facilities under an operating lease, which expires on September 30, 2015. At March 31, 2011, future minimum payments under the lease are as follows:

| <u>Years ending December 31:</u> | |
|----------------------------------|--------------------|
| Remaining nine months in 2011 | \$ 206,264 |
| 2012 | 280,055 |
| 2013 | 285,656 |
| 2014 | 291,369 |
| 2015 | 221,789 |
| | <u>\$1,285,133</u> |

(4) Notes Payable

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

EnteroMedics Inc.
(A development stage company)

Notes to Condensed Consolidated Financial Statements-(Continued)
(Unaudited)

Warrants were issued with the November 18, 2008 Loan Agreement that contained down round protection provisions through May 18, 2010. As of March 31, 2011, Horizon had outstanding 141,025 common stock warrants with an exercise price of \$3.90 per share. The fair value of the warrant liability associated with these warrants was \$499,832 as of March 31, 2010. This Level 3 fair value was calculated using a weighted-average Black-Scholes valuation model and the following assumptions: volatility between 114.7% and 115.0%, dividend rate of 0%, risk-free interest rate of 3.83% and a remaining life between 8.64 and 9.08 years. The Company recorded an increase of \$28,247 in the change in value of the warrant liability for the quarter ended March 31, 2010 for the warrant liability. The warrants were reclassified from warrant liability to equity on May 18, 2010, the date on which the warrants' down round protection expired.

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

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

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

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

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

Scheduled debt principal payments are as follows as of March 31, 2011:

| <u>Years Ending December 31:</u> | |
|----------------------------------|--------------------|
| Remaining nine months in 2011 | \$ 554,810 |
| 2012 | 2,307,161 |
| 2013 | 2,458,599 |
| 2014 | 639,273 |
| | <u>5,959,843</u> |
| Less: Original issue discount | (359,731) |
| Notes payable, net | <u>\$5,600,112</u> |

EnteroMedics Inc.
(A development stage company)

Notes to Condensed Consolidated Financial Statements-(Continued)
(Unaudited)

(5) Stock-based Compensation

The fair value method of accounting for share-based payments is applied to all share-based payment awards issued to employees and where appropriate, nonemployees, unless another source of literature applies. When determining the measurement date of a nonemployee's share-based payment award, the Company measures the stock options at fair value and remeasures such stock options to the current fair value until the performance date has been reached.

Based on the application of these standards, stock-based compensation expense for stock-based awards under the Company's 2003 Stock Incentive Plan for the three months ended March 31, 2011 and 2010 was allocated to operating expenses as follows:

| | Three months ended March 31, | |
|-------------------------------------|---------------------------------|------------------|
| | 2011 | 2010 |
| Research and development | \$236,695 | \$277,286 |
| Selling, general and administrative | 423,716 | 493,022 |
| Total | <u>\$660,411</u> | <u>\$770,308</u> |

As of March 31, 2011 there was approximately \$5.1 million of total unrecognized compensation costs, net of estimated forfeitures, related to employee unvested stock option awards granted after January 1, 2006, which are expected to be recognized over a weighted-average period of 2.79 years.

The estimated grant-date fair values of the stock options were calculated using the Black-Scholes valuation model, based on the following assumptions for the three months ended March 31, 2011 and 2010:

| | Employees | | Nonemployees |
|--------------------------|------------------------------|------------|--------------------|
| | Three months ended March 31, | | Three months ended |
| | 2011 | 2010 | March 31, 2010 |
| Risk-free interest rates | 2.68% | 2.62% | 3.62%-3.81% |
| Expected life | 6.25 years | 6.25 years | 9.16-9.87 years |
| Expected dividends | 0% | 0% | 0% |
| Expected volatility | 124.40% | 117.43% | 115.28%-116.10% |

There was no nonemployee stock option expense for the three months ended March 31, 2011.

Option activity under the Company's 2003 Stock Incentive Plan for the three months ended March 31, 2011 was as follows:

| | Shares Available For Grant | Outstanding Options | |
|-----------------------------------|----------------------------------|---------------------|------------------------------------|
| | | Number of Shares | Weighted-Average Exercise Price |
| Balance, December 31, 2010 | 1,423,361 | 812,515 | \$ 5.60 |
| Shares reserved | — | — | — |
| Options granted | (1,048,464) | 1,048,464 | 2.58 |
| Options exercised | — | — | — |
| Options cancelled | 32,619 | (32,619) | 2.62 |
| Balance, March 31, 2011 | <u>407,516</u> | <u>1,828,360</u> | \$ 3.92 |

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, 2010. 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, its associated co-morbidities, and other gastrointestinal disorders. Our proprietary neuroblocking technology, which we refer to as VBLOC therapy, is designed to intermittently block the vagus nerve using high frequency, low energy, electrical impulses. We have a limited operating history and we currently have no products approved for sale. Our initial product under development is the Maestro System, which uses VBLOC therapy to limit the expansion of the stomach, help control hunger sensations between meals, reduce the frequency and intensity of stomach contractions and produce a feeling of early and prolonged fullness. We were formerly known as Beta Medical, Inc. and were incorporated in Minnesota on December 19, 2002. We later reincorporated in Delaware on July 22, 2004. Since inception, we have devoted substantially all of our resources to the development and commercialization of our Maestro System.

Based on our understanding of vagal nerve function and nerve blocking from our preclinical studies and the results of our initial clinical trials, we believe the Maestro System may offer obese patients a minimally-invasive treatment alternative that has the potential to result in significant and sustained weight loss. We believe that our Maestro System will allow bariatric surgeons to help obese patients who are concerned about the risks and complications associated with gastric banding and gastric bypass surgery. In addition, data from sub-group analyses demonstrate that VBLOC therapy may hold promise in improving the obesity-related co-morbidities of diabetes and hypertension. We are conducting, or plan to conduct, feasibility studies in each of these co-morbidities to assess VBLOC therapy's potential in addressing multiple indications.

We are currently evaluating the Maestro System in human clinical trials conducted in the United States, Australia, Mexico, Norway and Switzerland. To date, we have not observed any mortality related to our device or any unanticipated adverse device effects in these clinical trials. We have also not observed any long-term problematic clinical side effects in any patients, including in those patients who have been using the Maestro System for more than one year.

On October 2, 2009, we announced preliminary results from our first pivotal clinical study, the EMPOWER trial, a multi-center, randomized, double-blind, prospective, placebo-controlled pivotal study being conducted in the United States and selected international centers. Initial results from the trial indicated that the study did not meet its primary and secondary efficacy endpoints in that the weight loss for the treatment arm was not statistically different from the control arm in which therapy was turned off. The study did meet its safety endpoint. Our further review of the data suggests that: (i) patients that used the device for the prescribed amount of time (39 hours) had clinically meaningful weight-loss; (ii) both the treatment and control arm subjects experienced comparable, significant, dose-dependent excess weight loss (EWL) at 12 months; and (iii) there was an unanticipated therapeutic effect in which a low-intensity blocking signal introduced VBLOC therapy in human subjects in the control group. In January 2010, we met with the U.S. Food and Drug Administration (FDA) to discuss the EMPOWER trial results and the regulatory process going forward. Based on this discussion, in March 2010 we submitted an Investigational Device Exemption (IDE) for a pivotal trial of our second generation fully implantable Maestro Rechargeable (RC) System. In October 2010, we received an unconditional approval from the FDA for this trial, the ReCharge trial, a randomized, double-blind, parallel-group, multicenter pivotal clinical trial in 234 morbidly obese subjects enrolled at up to 12 U.S. centers. All patients in the study will receive an implanted device and will be randomized in a 2:1 allocation to treatment or control groups. The control group will receive a functional, but non-active device that will deliver no charge to the vagus nerve during the study period. All patients are expected to participate in a weight management program.

We have begun the enrollment process in the ReCharge trial and expect the first patient implant in the second quarter of 2011 with completion of all implants by year end. Assuming that we successfully enroll and implant the trial and achieve favorable results, we plan to use data from that trial to support a premarket approval (PMA) application for the Maestro System, which we expect to submit no earlier than the fourth quarter of 2012. We anticipate that we will be able to commercialize the Maestro System in the United States in late 2013 at the earliest.

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We have begun to take the initial steps necessary to commercialize the Maestro RC System in Australia, which includes applying for European CE Mark certification and Australian Therapeutic Goods Administration (TGA) approval. During the first quarter of 2011, we received European CE Mark certification of the Maestro RC System and intend to use that approval to file an application for approval and listing of the Maestro RC System with the TGA and intend to commercialize the device following receipt of that approval during the second half of 2011.

On March 28, 2011, we entered into a multi-year distribution agreement with Device Technologies Australia Pty Limited (Device Technologies), effective as of March 8, 2011, appointing Device Technologies as our exclusive distributor of the Maestro RC System in Australia and New Zealand during the term of the agreement.

On October 21, 2010, we announced that we entered into a cooperation agreement with the Australian Institute of Weight Control (AIWC), a network of bariatric clinics specializing in laparoscopic weight loss surgery and clinical research for the morbidly obese. Under the cooperation agreement, we have designated AIWC and AIWC member clinics as authorized training and implantation centers for our products. AIWC will be the first clinics in Australia to implant the Maestro System when it has received approval by the TGA. The AIWC will work with us to provide research, communications, training and accreditation support related to the Maestro RC System in Australia and other international territories. In addition, the AIWC will work with us toward TGA approval of the Maestro RC System and collaborate on subsequent marketing and distribution efforts in Australia. The AIWC will also support our efforts in gaining reimbursement for the private sector through the Medical Services Advisory Committee (MSAC) in Australia.

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

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

To date, we have generated no revenue from the sale of products, and we have incurred net losses in each year since our inception. As of March 31, 2011, we had experienced net losses during the development stage of \$155.7 million. We expect our losses to continue as we continue our development activities. We have financed our operations to date principally through the sale of capital stock, debt financing and interest earned on investments.

Our board of directors and stockholders approved a 1-for-6 reverse split of our outstanding common stock that became effective on July 9, 2010. The reverse stock split did not change the par value of our stock or the number of common and preferred shares authorized by our Fifth Amended and Restated Certificate of Incorporation. All share and per share amounts have been retroactively adjusted to reflect the stock split for all periods presented.

Financial Overview

Revenue

To date, we have not commercialized any products and we have not generated any revenue. We received European CE Mark certification for our Maestro RC System in March 2011 and are continuing to take the necessary steps to commercialize the Maestro RC System in Australia which includes the filing of an application for approval and listing with the TGA. We hope to receive TGA approval during the second half of 2011. In October 2010 we received unconditional approval from the FDA of our IDE to complete a pivotal trial using the Maestro RC System. As such, we do not expect to generate revenue in the United States before late 2013 and then, only if we successfully enroll and implant the clinical trial, achieve favorable results and receive FDA approval of our Maestro System. Any revenue from initial sales of a new product in the United States or internationally is difficult to predict and in any event will only modestly reduce our continued losses resulting from our research and development and other activities.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development and clinical and regulatory expenses, incurred in the development of our Maestro System. Research and development expenses also include employee compensation, including stock-based compensation, consulting services, outside services, materials, supplies, depreciation and travel. We expense research and development costs as they are incurred. From inception through March 31, 2011, we have incurred a total of \$102.9 million in research and development expenses. We expect research and development expense to increase during 2011 in support of a new clinical trial, ReCharge, in addition to continued follow-up on existing trials, such as VBLOC-DM2 ENABLE and EMPOWER.

Selling, General and Administrative Expenses

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Our selling, general and administrative expenses consist primarily of compensation for executive, finance, market development and administrative personnel, including stock-based compensation. Other significant expenses include costs associated with attending medical conferences, professional fees for legal, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, and accounting services, cash management fees, consulting fees and travel expenses. From inception through March 31, 2011, we have incurred \$41.7 million in selling, general and administrative expenses.

Results of Operations

Comparison of the Three Months Ended March 31, 2011 and 2010

Research and Development Expenses. Research and development expenses were \$2.8 million for the three months ended March 31, 2011, compared to \$2.4 million for the three months ended March 31, 2010. The increase of \$406,000, or 17.0%, is primarily due to increases of \$447,000 and \$149,000 in device related costs and professional services, respectively. Device related costs are the result of starting to build devices in support of the ReCharge trial and international commercialization, while professional service related costs increased in support of our European CE Mark certification efforts. The increases were partially offset by decreases of \$104,000, \$41,000 and \$22,000 in compensation and benefits, stock-based compensation and travel, respectively.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were \$2.1 million for the three months ended March 31, 2011, compared to \$2.0 million for the three months ended March 31, 2010. The increase of \$102,000, or 5.2%, is primarily due to increases of \$60,000 and \$42,000 in professional services expense and travel, respectively, which are both a direct result of international commercialization efforts.

Interest Income. Interest income was \$7,000 for the three months ended March 31, 2011, compared to \$1,000 for the three months ended March 31, 2010. The increase of \$6,000 is primarily due to an increase in total cash available to invest. The cash, cash equivalents, restricted cash and short-term investments balance was \$32.2 million at March 31, 2011 compared to \$14.6 million at March 31, 2010.

Interest Expense. Interest expense was \$232,000 for the three months ended March 31, 2011, compared to \$364,000 for the three months ended March 31, 2010. The decrease of \$132,000, or 36.3%, is the result of a decrease in the gross principal balance outstanding from approximately \$7.3 million on March 31, 2010 to approximately \$5.9 million on March 31, 2011 and a modification to the loan agreement that reduced our annual interest rate from 11.0% to 6.25% effective March 1, 2011.

Change in Value of Warrant Liability. There was no warrant liability during the three months ended March 31, 2011. The value of the warrant liability increased \$28,000 during the three months ended March 31, 2010. For the three months ended March 31, 2010 the warrant liability consisted of warrants issued to Compass Horizon Funding Company LLC (Horizon). The fair market value of the remaining 141,025 warrants, with a weighted-average exercise price of \$3.90, was \$500,000 as of March 31, 2010. The fair market value for these remaining warrants was calculated using the Black-Scholes valuation model, which resulted in a \$28,000 increase for the three months ended March 31, 2010. While our stock price decreased from \$3.36 on December 31, 2009 to \$3.06 on March 31, 2010, the volatility used to calculate fair value increased from approximately 104% to 115% and the exercise price decreased from \$4.80 to \$3.90 per share as a result of a registered direct offering completed January 20, 2010.

Liquidity and Capital Resources

We have incurred losses since our inception in December 2002 and, as of March 31, 2011 we had experienced net losses during the development stage of \$155.7 million. We have financed our operations to date principally through the sale of capital stock, debt financing and interest earned on investments. Through December 31, 2010, we had received net proceeds of \$160.5 million from the sale of common stock and preferred stock, including \$39.1 million from our initial public offering in November 2007, \$58.2 million from public, private placement and registered direct offerings in 2010 and 2009, and \$35.8 million in debt financing, \$746,000 to finance equipment purchases and \$35.0 million to finance working capital.

As of March 31, 2011, we had \$32.2 million in cash, cash equivalents, restricted cash and short-term investments. Of this amount \$21.3 million was invested in short-term money market funds that are not considered to be bank deposits and are not insured or guaranteed by the federal deposit insurance company or other government agency. These money market funds seek to preserve the value of the investment at \$1.00 per share; however, it is possible to lose money investing in these funds. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. At times, such deposits may be in excess of insured limits. We have not experienced any losses on our deposits of cash and cash equivalents. We believe that the cash, cash equivalents, restricted cash and short-term investments balance as of March 31, 2011, together with any interest income we earn on these balances, will be sufficient to meet our anticipated cash requirements through 2012, assuming our planned commercialization and we do not receive any other additional funds.

On March 3, 2011 we entered into a Fourth Amendment (the Fourth Amendment) to the Loan Agreement with SVB. The Fourth Amendment modified the repayment terms of the Term Loan such that beginning April 1, 2011 through September 30, 2011, we are

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

Net Cash Used in Operating Activities

Net cash used in operating activities was \$4.8 million and \$3.6 million for the three months ended March 31, 2011 and 2010, respectively. Net cash used in operating activities primarily reflects the net loss for those periods, which was partially offset by depreciation and amortization, change in the carrying value of warrant liability, stock-based compensation and changes in operating assets and liabilities.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$4.3 million for the three months ended March 31, 2011 compared to net cash used in investing activities of \$21,000 for the three months ended March 31, 2010. Net cash provided by investing activities for the three months ended March 31, 2011 is primarily attributable to a \$6.3 million decrease in the restricted cash balance as a result of the Fourth Amendment offset by purchases of \$2.0 million in short-term investments available for sale. Net cash used in investing activities for the three months ended March 31, 2010 is primarily attributable to the purchase of property and equipment.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities was \$413,000 for the three months ended March 31, 2011 compared to net cash provided by financing activities of \$3.6 million for the three months ended March 31, 2010. Net cash used in financing activities was due to \$367,000 in principal repayments on our long-term debt and common stock financing costs of \$46,000. Net cash provided by financing activities for the three months ended March 31, 2010 is primarily attributable to a registered direct offering that resulted in gross proceeds of \$4.8 million, offset by \$340,000 in financing costs and \$927,000 of repayments on our long-term debt.

Operating Capital and Capital Expenditure Requirements

To date, we have not commercialized any products and we have not generated any operating revenues. We received European CE Mark certification for our Maestro RC System in March 2011 and are continuing to take the necessary steps to commercialize the Maestro RC System in Australia which includes the filing of an application for approval and listing with the TGA. We hope to receive TGA approval during the second half of 2011. In October 2010 we received unconditional approval from the FDA of our IDE to complete a pivotal trial using the Maestro RC System. As such, we do not expect to generate revenue in the United States before late 2013 and then, only if we successfully enroll and implant the clinical trial, achieve favorable results and receive FDA approval of our Maestro System. We anticipate that we will continue to incur substantial net losses for the next several years as we develop our products, prepare for the potential commercial launch of our Maestro RC System, develop the corporate infrastructure required to sell our products, operate as a publicly-traded company and pursue additional applications for our technology platform.

We believe that our cash, cash equivalents, restricted cash and short-term investments balance of \$32.2 million as of March 31, 2011, and any interest income we earn on these balances will be sufficient to meet our anticipated cash requirements through 2012, assuming our planned commercialization and we do not receive any other additional funds. If our available cash, cash equivalents, restricted cash 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. 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

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in Part I, Item 1A, *Risk Factors*, of our Annual Report on Form 10-K for the year ended December 31, 2010. 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, timing and uncertainty of any 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 Maestro System or our future products; and
- the extent to which we invest in products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Critical Accounting Policies and Estimates

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

Our significant accounting policies are fully described in Note 2 to our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2010 filed with the U.S. Securities and Exchange Commission (SEC).

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Contractual Obligations

During the three months ended March 31, 2011, there were no material changes to our contractual obligation disclosures as set forth under the caption, “Contractual Obligations” in Part II, Item 7, *Management’s Discussion and Analysis of Financial Condition and Results of Operations*, of our Annual Report on Form 10-K for the year ended December 31, 2010.

The following table summarizes our contractual obligations as of March 31, 2011 and the effect those obligations are expected to have on our financial condition and liquidity position in future periods:

| Contractual Obligations | Payments Due By Period | | | | |
|------------------------------------|------------------------|---------------------|--------------------|------------------|----------------------|
| | Total | Less Than 1 Year | 1-3 Years | 3-5 Years | More than 5 Years |
| Operating lease | \$1,285,133 | \$ 275,930 | \$ 568,525 | \$440,678 | \$ — |
| Long-term debt, including interest | 7,150,935 | 1,482,494 | 5,668,441 | — | — |
| Total contractual cash obligations | <u>\$8,436,068</u> | <u>\$1,758,424</u> | <u>\$6,236,966</u> | <u>\$440,678</u> | <u>\$ —</u> |

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

Off-Balance Sheet Arrangements

As of March 31, 2011, we did not have any off-balance sheet arrangements.

Recent Accounting Pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk is confined to our cash, cash equivalents, restricted cash and short-term investments. As of March 31, 2011, we had \$32.2 million in cash, cash equivalents, restricted cash and short-term investments. The goals of our investment policy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we may maintain a portfolio of cash equivalents and investments in a variety of securities of high credit quality. The securities in our investment portfolio, if any, are not leveraged, are classified as either available for sale or held-to-maturity and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our cash equivalents and investments, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio. We have no investments denominated in foreign currencies and therefore our investments are not subject to foreign currency exchange risk.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), defines the term “disclosure controls and procedures” as those controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation as of March 31, 2011, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any litigation and we are not aware of any pending or threatened litigation against us that could have a material adverse effect on our business, operating results or financial condition. The medical device industry in which we operate is characterized by frequent claims and litigation, including claims regarding patent and other intellectual property rights as well as improper hiring practices. As a result, we may be involved in various legal proceedings from time to time.

ITEM 1A. RISK FACTORS

There have been no material changes during the three months ended March 31, 2011 to the risk factors set forth in Part I, Item 1A, *Risk Factors*, of our Annual Report on Form 10-K for the year ended December 31, 2010.

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

Unregistered Sales of Equity Securities

None.

Uses of Proceeds from Sale of Registered Securities

None.

Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. RESERVED

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The list of exhibits on the accompanying Exhibit Index are filed or incorporated by reference (as stated therein) as part of this Quarterly Report on Form 10-Q.

EXHIBIT INDEX

| <u>Exhibit Number</u> | <u>Description of Document</u> |
|-----------------------|--|
| 3.1 | Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.2 to Amendment No. 6 to the Company's Registration Statement on Form S-1 filed on November 9, 2007 (File No. 333-143265)). |
| 3.2 | Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.2 to the Company's Quarterly Report on Form 10-Q filed on August 7, 2009 (File No. 1-33818)). |
| 3.3 | Certificate of Amendment to the Fifth Amended and Restated Certificate of Incorporation of the Company. (Incorporated herein by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed on July 13, 2010 (File No. 1-33818)). |
| 3.4 | Amended and Restated Bylaws of the Company, as currently in effect. (Incorporated herein by reference to Exhibit 3.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed on July 6, 2007 (File No. 333-143265)). |
| 4.1 | Amended and Restated Investors' Rights Agreement, dated as of July 6, 2006, by and between the Company and the parties named therein. (Incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-1 filed on May 25, 2007 (File No. 333-143265)). |
| 10.1 | Fourth Amendment to Loan and Security Agreement, dated as of March 3, 2011, by and between Silicon Valley Bank and the Company. (Incorporated herein by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K filed on March 7, 2011 (File No. 1-33818)). |
| 10.2*# | Distribution Agreement, dated as of March 28, 2011, by and between Device Technologies Australia Pty Limited and the Company. |
| 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.

Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

DISTRIBUTION AGREEMENT

THIS DISTRIBUTION AGREEMENT (the “Agreement”), dated as of 28th March, 2011 (the “Operative Date”), is by and between Enteromedics, Inc. a Minnesota corporation located at 2800 Patton Road, St. Paul MN 55113 (“Supplier”) and Device Technologies Australia Pty Limited, located at Unit 8, 25 Frenchs Forest Road, Frenchs Forest, New South Wales 2086 Australia, with ABN 40 058 091 973 (“Distributor”).

WHEREAS, Supplier is engaged in the Business and wishes to engage Distributor to sell the Products.

WHEREAS, Distributor has certain experience relevant to the distribution of the Products in the Territory.

WHEREAS, Supplier wishes to appoint Distributor, and Distributor agrees to be appointed, as Supplier’s exclusive distributor of the Products in the Territory on the terms set out in this Agreement.

1 INTERPRETATION

1.1 Definitions

In this Agreement:

“**Agreement**” means this Distribution Agreement and includes any annexes, schedules and exhibits;

“**Business**” means Supplier’s business of, among other things, manufacturing and distributing the Products;

“**Business Day**” means a day on which banks are open for general banking business in Sydney, Australia but does not include a Saturday, Sunday or public holiday;

“**Competitive Product**” means any implanted product approved for implant for six (6) months or longer by any of the TGA, US FDA or CE Mark authorities which has a clinical indication for use in patients with obesity who have a BMI between 30 and 45.

“**Confidential Information**” means information of every kind contained in or concerning:

(a) the past, present or future business, operations or affairs of the disclosing Party;

(b) the possibilities, procedures, operations, practices, studies, feasibilities, evaluations, processes, organization and procedures of the disclosing Party directly or indirectly touching or concerning the disclosing Party’s business;

- (c) written reports, memoranda and other writings and papers or computer records or electronic databases including any technical data files relating to the disclosing Party's business;
 - (d) prices and cost information relating to the disclosing Party's business;
 - (e) any intellectual or industrial property owned or otherwise available for use by the disclosing Party;
 - (f) the business transactions, business methods, records, forms costings, charges, financial affairs and trade secrets of the disclosing Party;
 - (g) all manuals, records, computer files and software, documents and materials generated or arising directly or indirectly out of any disclosure by the disclosing Party;
 - (h) all other documents and things whether recorded or not and however recorded, supplied or made available by the disclosing Party to the other;
- and
- (i) this Agreement;

whether or not such information is described as confidential;

“Control” of a corporation includes the power (whether it is legally enforceable or not) to control, whether directly or indirectly, a composition of the board of directors of that corporation, the voting rights of the majority of the voting shares of the corporation or the management of the affairs of the corporation;

“Cooperative Contractor” means Australian Institute of Weight Control Pty Limited, or other such entity as may be nominated by Supplier from time to time.

“Corporations Act” means Corporations Act 2001 and the Corporations Regulations in each Australian jurisdiction and (where the context so permits) includes any prior corresponding legislation;

“Distributor's Business” means that part of Distributor's business that relates to this Agreement;

“Delivery” means delivery of the Products by Supplier to Distributor or any agent, employee or representative of Distributor in accordance with **clause 5.1**;

“GST” means any goods and services tax or similar tax imposed in Australia;

“Initial Order” means the first stocking order from the Distributor;

“Initial Term” means the period commencing on the Operative Date and ending on the fourth anniversary of the TGA approval date;

“Insolvency Event” with respect to an entity means the happening of any one or more of the following events:

- (a) an order is made that the entity be wound up;
- (b) an order is made appointing a liquidator, receiver, receiver and manager or other administrator in respect of any of the assets or undertaking of the entity;
- (c) the entity enters into, or resolves to enter into, a scheme of arrangement or composition with, or assignment for the benefit of, all or any class of its creditors, or its proposes a reorganization, moratorium or other administration involving any of them;
- (d) the entity resolves to appoint an administrator to itself, wind itself up, or otherwise dissolves itself, or gives notice of intention to do so, or is otherwise wound up or dissolved;
- (e) the entity is, or states that it is, unable to pay its debts when they fall due or is presumed to be insolvent within the meaning of the Corporations Act;
- (f) the entity takes any step to obtain protection, or is granted protection, from its creditors under any applicable legislation; and
- (g) anything having a substantially similar effect to any of the events specified in paragraphs (a) to (g) above happens under the law of any applicable jurisdiction;

“Intellectual Property” means any industrial or intellectual property throughout the world, including without limitation:

- (a) any patent, trademark (whether registered or unregistered) or service mark, copyright, design, business name, or any right to register such rights; and
- (b) all present and future rights in an invention, discovery, trade secret, confidential information, know-how, concept, idea, data or formula and rights in information, including any serendipitous discoveries, granted by law or equity from time to time under the law of any jurisdiction;

“Liability” means all liability, however arising, including but not limited to liability in tort (including liability as to negligence) and liability in contract;

“Nominated Representative” means the President of Supplier and the Managing Director of Distributor, unless otherwise notified by a Party in writing;

“Operative Date” means the date set forth in the preamble above;

“Party” means a party to this Agreement and **“Parties”** means the parties to this Agreement;

“Products” means, subject to clause 2.4, the products described in **Exhibit A** and such other products which are agreed in writing between Supplier and Distributor from time to time;

“Product Warranty” means the warranty for a Product offered in writing by Supplier;

“Related Company” means a related body corporate (as defined in the Corporations Act);

“Reportable Events” means an event in relation to a Product that is required to be reported under the United States Food and Drug Administration’s Adverse Event Reporting System and any equivalent system in the Territory, and includes adverse events;

“Supplier” means Enteromedics, Inc.;

“Tax” means all duties, stamp and other taxes, value added taxes, goods and services tax, levies, imposts, deductions, charges and withholdings whatsoever (excluding income tax), any interest or penalty, and any charges, fees or other amounts made on, or in respect of, the same, relating to the export or import of Products;

“Term” means the period from the Operative Date until termination of this Agreement under **clause 14**;

“Territory” means Australia and New Zealand;

“TGA” means Therapeutic Goods Administration;

“Trademarks” means Supplier’s trademarks as listed (and in the form set out) in **Exhibit C**.

1.2 Construction

Unless expressed to the contrary:

- (a) if a word or phrase is defined cognate words and phrases have corresponding definitions;
- (b) a reference to:
 - (i) a person includes a firm, unincorporated association, corporation and a government or statutory body or authority;
 - (ii) a statute, ordinance, code or other law includes regulations and other statutory instruments under it and consolidations, amendments, re-enactments or replacements of any of them;
 - (iii) time is to local time in Sydney,
 - (iv) “\$” or “dollars” is a reference to the lawful currency of Australia;

- (c) this or any other document includes the document as varied or replaced and notwithstanding any change in the Identity of the parties;
 - (i) writing includes any mode of representing or reproducing words in tangible and permanently visible form, and includes facsimile transmission; and
 - (ii) any thing (including, without limitation, any amount) is a reference to the whole or any part of it and a reference to a group of things or persons is a reference to any one or more of them.

1.3 Headings

Clause headings do not affect the interpretation of this Agreement.

2 APPOINTMENT

2.1 Exclusive distribution

- (a) Supplier appoints Distributor as its exclusive distributor in the Territory for the Products for the Term subject to the terms of this Agreement.
- (b) Distributor accepts the appointment referred to in paragraph (a).

2.2 Restricted supply by Supplier

Subject to **clause 14.2(c)**, Supplier shall not appoint any other person to act as its distributor in the Territory for the Products during the Term without Distributor's prior written approval.

2.3 Distribution outside the Territory

Distributor shall:

- (a) not distribute, resell or otherwise supply Products to:
 - (i) any person outside the Territory; or
 - (ii) any person who Distributor knows or could reasonably be expected to know intends to distribute or resell or otherwise supply Products to any person outside the territory;
- (b) impose on all its purchasers of the Products and enforce a condition of sale to the effect that the Products are supplied for use only within the Territory and may not be on-sold outside the Territory or for use outside the Territory; and
- (c) promptly inform Supplier of any inquiries that Distributor receives for the supply of Products outside the Territory.

2.4 Changes in production

Supplier may cease to manufacture the Products or make material changes in the design, production, packaging or finish of the Products from time to time, upon giving not less than 60 days' written notice to Distributor. In the event that such changes require additional Regulatory or Reimbursement action by the Distributor, consideration to any agreed Order Forecasts or Sales Performance Objectives will be given accordingly by the Supplier.

2.5 Import into Territory

Supplier shall not supply Products to a person outside the Territory if Supplier knows or could reasonably be expected to know that the person intends to resell the Products in the Territory.

2.6 No agency

Distributor shall not hold itself out as Supplier's agent for sales of the Products or as being entitled to bind Supplier in any way.

2.7 Resale by Distributor

Distributor is entitled to resell the Products to Distributor's customer at such prices as it determines.

2.8 Reimbursement

Supplier will negotiate with any relevant government authority in the Territory to determine the level of any applicable governmental funded customer reimbursement in relation to the Products. Distributor shall do all things necessary, including complying with Supplier's directions, to assist Supplier in such negotiations.

3 SUPPLY OF PRODUCTS AGAINST ORDERS

3.1 Order forecast

- (a) To facilitate Supplier's production schedule, Distributor shall provide Supplier with a written forecast of Distributor's anticipated quarterly requirements for Products for the following two quarters, to be submitted at least 90 days prior to commencement of the forecast period ("**Order Forecast**"). The first two months of each Order Forecast shall constitute a binding commitment of Distributor to purchase the quantities of Products described therein once the Distributor has obtained TGA approval and after the first six (6) months of subsequent sales into the Territory.
- (b) The Distributor will place an Initial Order, for a quantity of Products to be mutually agreed between the Supplier and the Distributor, for stocking purposes six (6) weeks post the TGA submission. In the event that the TGA approval is

delayed, the Supplier agrees that the payment time of this Initial Order will be correspondingly adjusted by the same TGA delayed approval time.

(c) Distributor shall:

- (i) use its best efforts to ensure the Order Forecasts are as accurate as possible; and
- (ii) promptly notify Supplier if it becomes aware that a submitted Order Forecast is not an accurate prediction of its requirement for Products in the relevant period.

3.2 Supply

Supplier shall make delivery of Products under orders that Supplier accepts in writing according to the delivery terms in the relevant order.

3.3 Separate contracts

Each shipment which Supplier makes of Products in response to Distributor's orders is a separate contract of sale.

3.4 Orders in writing

Orders for the Products shall be provided by Distributor to Supplier in writing. Supplier shall examine each order and confirm whether it accepts or declines each order in writing no later than 10 Business Days from its receipt of Distributor's order. No order shall be final and binding until expressly accepted by Supplier in writing. Distributor is, in respect of each order for the Products to be supplied under this Agreement, responsible for ensuring the accuracy of the order.

4 PRICE AND PAYMENT

4.1 Price

The prices payable by Distributor to Supplier for each of the Products are set out in **Exhibit B** and are inclusive of packaging but exclusive of delivery costs and Tax (subject to adjustment in accordance with **clause 16**).

4.2 Review of price

The prices for the Products are fixed for 6 months from the Operative Date and for the Initial Order, after which time Supplier may increase or decrease the price of the Products from time to time upon 180 days' written notice to Distributor. The new prices shall apply to all Products ordered by Distributor from Supplier after the date that the written notice takes effect.

4.3 Payment

- (a) Distributor shall pay Supplier the prices for all Products ordered and accepted by it within forty five(45) days of the date of Seller's invoice which will accompany the delivery of the Products, by direct wire transfer to the nominated bank account. Any payment not made when due will accrue interest at a rate of 1.5% per month or part thereof.
- (b) If Distributor owes any amount to Supplier under this Agreement which is outstanding by more than fourteen (14) days, Supplier may, at its sole discretion and without prejudice to any of its other rights under this Agreement, do any or all of the following:
 - (i) withhold some or all future supplies of Products until the amount has been paid in full;
 - (ii) require Distributor to furnish security for payment acceptable to Supplier;
 - (iii) set-off that amount against any amount owing by Supplier to Distributor; and
 - (iv) require payment for all future supplies of Products to be made in cash either before, or immediately upon, the delivery of those Products to Distributor.

5 DELIVERY

5.1 Delivery

Delivery of the Products to Distributor's premises or nominated address is to be taken to constitute delivery to Distributor and Supplier's obligation in respect of delivery satisfied. Shipping, insurance, customs duties, etc. are the responsibility of the Distributor.

5.2 Returns

- (a) All Products shall be received subject to inspection. Signed delivery dockets shall not mean acceptance by Distributor of Products delivered but only confirmation of the number of packages or cartons delivered.
- (b) Distributor will notify Supplier of any defective Products within 30 days of receipt of the Products and hold such Products for Supplier's instructions for a reasonable period (not exceeding 60 days). If Supplier's instructions are not received within such period Distributor may return the defective Products to Supplier's premises at Supplier's expense and any expense incurred by Distributor in such return will be payable forthwith by Supplier and may be set off by Distributor against any moneys otherwise due by Distributor to Supplier.

- (c) If Distributor can verify to Supplier's reasonable satisfaction that a Product was defective at the time it was delivered to Distributor, Supplier shall use reasonable endeavors to repair or replace that defective Product with a Product which is free of defects within thirty (30) days.
- (d) If Supplier is not able to repair or replace the defective Product as required under **clause 5.2(c)**, it shall refund the cost of the defective Product to Distributor.

6 RISK AND TITLE

6.1 Distributor's risk

The Products are at Distributor's risk from the time of Delivery, and in the case of returned Products, risk passes to Supplier upon its receipt of the returned Products.

6.2 Title

Property in and ownership of the Products passes to Distributor at the time when full payment for the Products is made.

7 SUPPLIER'S AND DISTRIBUTOR'S OBLIGATIONS

7.1 Reports and database

- (a) At the end of each three (3) month period commencing at the end of the first calendar quarter following the Operative Date, Distributor shall render to Supplier a report of sales and marketing information concerning each type of Product.
- (b) Distributor shall maintain a database containing details of customers to whom it sells Products during the Term (including the type and quantity of Product purchased by each customer), and Distributor shall grant Supplier reasonable access to this database upon Supplier's request.

7.2 Promotions

Distributor shall use its best efforts to offer the Products as part of its existing product range and promote and extend and increase the sale of the Products throughout the Territory. Distributor will use its best endeavors to promote the Products in the relevant markets for the Product and where appropriate include the Products in any electronic promotion (including any Internet-related promotion) that Distributor may conduct from time to time.

7.3 No representations

Distributor shall not make any representations or give any warranties or other benefits in favor of any proposed purchaser or to the detriment of Supplier beyond those authorized in writing by Supplier.

7.4 Applicable regulations

Distributor shall report to Supplier regularly during the Term to enable it to ensure that the Products meet regulations applicable in the Territory relating to safety and labeling, but this obligation to report shall in no way derogate from Supplier's obligations under **clause 7.14(b)**.

7.5 Description of Distributor as authorized distributor

In all correspondence, commercial documents and on any name plate or sign on any premises, on vehicles or in directories and similar media, Distributor shall describe itself as "authorized distributor" of the Products and take any other necessary steps as required by Supplier or otherwise to make clear the extent of the limitation of Distributor's authority to act on behalf of Supplier.

7.6 Applications for applicable licenses

- (a) The Distributor shall obtain and maintain all certificates, licenses, authorizations or registrations as required to import, promote, sell, use or distribute the Products in the Territory. Each Party shall provide reasonable aid or assistance as may be required by the other Party to obtain the same. Unless otherwise required by law, all certificates, licenses, authorizations and registrations that relate to the Products shall be in Supplier's name.
- (b) Upon receipt by Distributor of any document or approval set out in **clause 7.6(a)**, Distributor shall provide a copy to Supplier.
- (c) At the expiration or termination of this Agreement, or at any time on Supplier's direction, Distributor will transfer, or assist to transfer all certificates, licenses, authorizations and registrations set out in **clause 7.6(a)** that are in its name to the Supplier's Australian entity nominee at no charge.

7.7 Referrals on inquiries

Distributor shall refer promptly to Supplier any inquiries made by persons regarding sales or potential sales of Products outside the Territory.

7.8 Further development

Distributor shall regularly meet with Supplier to consider new opportunities and markets for the Products, and will work with Supplier and the Cooperative Contractor to develop the market for the Products in the Territory.

7.9 Sub-Distributors

Distributor may appoint sub-distributors, agents or other intermediaries to perform its obligations under this Agreement provided that Distributor will be responsible for any act or omission by the sub-Distributor, agent or intermediary, and subject to any terms that Supplier may impose in its sole discretion.

7.10 Competitive products

Distributor shall not, during the Initial Term and any renewal terms thereafter, without mutual agreement between the parties, manufacture, import, sell, supply, develop, provide, promote or market "Competitive Products" in the Territory.

7.11 Cooperative Contractor terms

Distributor shall offer the Cooperative Contractor reasonable commercial terms of supply for Products which are no less favorable than the terms of supply for Products that are offered by Distributor to its other customers.

7.12 Distributor's further obligations

In addition to fulfilling the other obligations imposed by this Agreement, Distributor shall:

- (a) pay all Taxes payable with respect to Products delivered to Distributor;
- (b) only provide Products to customers that have an acceptable level of training or resources and have been accredited, as mutually determined by the Distributor and the Supplier;
- (c) nominate an officer to sit on a steering committee (to join the nominee from Supplier and the nominee from the Cooperative Contractor), which committee Distributor agrees shall receive and make recommendations to the parties regarding surgeon training, bariatric center accreditation and technical materials;
- (d) provide such customer support services and assistance as may be necessary for purchasers of Products to obtain satisfactory results from their use of the Products;
- (e) refrain from practicing medicine or giving medical treatment or advice in Supplier's name or on Supplier's behalf;
- (f) comply with Supplier's business standards as notified by Supplier;
- (g) at all times during the Term, observe all laws (including privacy laws) and standards and maintain all accreditations applicable to the conduct of its business and carrying out its obligations under this Agreement (including in respect of the storage, transportation and sale of the Products in the Territory);
- (h) assist Supplier to discharge its regulatory obligations by providing requested information to Supplier regarding Product traceability in accordance with generally accepted industry standards, including customer by Product and Product by customer tracking;

- (i) follow the same quality control standards with respect to the storage, preservation, sale and use of the Products as followed by Supplier and communicated to Distributor by Supplier and not remove Products from packages designated for delivery to end-user customers when such removal may affect the quality of the Products or destroy any trademark identity; and
- (j) promptly notify Supplier all Reportable Events, product defects, adverse events and customer complaints that come to its attention, including such detail as Supplier may reasonably require.

7.13 Good faith

Each Party shall at all times during the Term act towards the other Party dutifully and in good faith.

7.14 Compliance with laws

- (a) Supplier shall at all times comply with all the applicable laws and regulations in the Territory relating to the nature, method of manufacture, packaging and labeling of the Products.
- (b) If Distributor is aware that changes are required to the Product labeling in order to comply with the laws and regulatory requirements in the Territory, Distributor shall immediately notify Supplier of the required changes.
- (c) Distributor shall not modify, remove or replace any Product labeling, package inserts, warnings, instructions for use or other similar materials under any circumstances without Supplier's prior written consent.

7.15 Insurance

(a) Supplier's insurance

- (i) Supplier shall take out and maintain appropriate and adequate insurance during the Term in relation to any Liability that may arise from the manufacture, sale or use of the Products. Such insurance will include, as a minimum, public liability and product liability insurance.
- (ii) Supplier shall make all insurance policies available to Distributor for inspection.

(b) Distributor's insurance

- (i) Distributor shall effect and maintain for the Term, at its own expense and with an insurer of repute and good standing, a comprehensive public liability insurance policy against any Liability related to personal injury and property damage resulting from acts or omissions of Distributor, its

officers, employees, agents or third party contractors. The insurance policy shall meet the following insurance level requirements:

| <u>Claim type</u> | <u>Minimum insurance level</u> |
|--|--|
| Personal injury arising from public liability | Aust\$20,000,000 per person Aust\$20,000,000 per occurrence |
| Property damage arising from product liability | Aust\$20,000,000 aggregate claims each year. |

- (c) **Certificates.** Distributor and Supplier shall furnish each other with copies of all insurance certificates within thirty (30) days of the execution of this Agreement. For the avoidance of doubt, nothing in this **clause 7.15(b)** limits either Party's liability under this Agreement.

8 PROMOTION AND TECHNICAL MATERIALS

8.1 Promotion

- (a) Distributor shall conduct promotional exercises and promotions in relation to the Products including direct marketing from time to time to medical conferences and medical practitioners, and advertise the Products in the Territory from time to time.
- (b) Distributor shall ensure that all advertising and promotional materials it wishes to use comply with the laws and regulatory requirements of the countries within the Territory in which they will be used.
- (c) Distributor shall not use, publish, broadcast or disseminate any advertising and promotional materials without Supplier's approval. When submitting the materials to Supplier for approval, Distributor shall give details of when, where and in which medium the materials will be used. Supplier shall take reasonable steps to promptly respond to Distributor's request for approval upon receipt of the materials.

8.2 Technical materials

Supplier shall, at its cost and upon request by Distributor, supply to Distributor reasonable quantities of masters of such technical data sheets, manuals and drawings relating to the Products as the Parties determine are reasonably required to facilitate Distributor's performance of its obligations under this Agreement.

9 SUPPORT AND TRAINING

9.1 Samples and catalogues

- (a) Supplier shall, as mutually agreed and at reasonable cost, provide samples of the Products to Distributor for marketing purposes.

- (b) Supplier shall, at its cost, from time to time provide Distributor with such catalogues, brochures and up to date information concerning the Products as Supplier may consider appropriate or as Distributor may reasonably require in order to assist Distributor in the sale of the Products in the Territory, and Supplier shall endeavor to answer as soon as practicable any technical enquiries concerning the Products which are made by Distributor or its customers.

9.2 Keep Distributor Informed

Supplier shall supply to Distributor any information which may come into its possession which Supplier considers is likely to be relevant in relation to the marketing of the Products in the Territory and which may assist Distributor to effect sales.

9.3 Market strategies

Each Party shall keep the other informed from time to time as to its market strategies for the Products and intended marketing positioning.

9.4 Training

As agreed by the Parties from time to time, taking into account the role of the Cooperative Contractor in marketing and providing training for the Products in the Territory:

- (a) Supplier shall provide Distributor (at such time as may be agreed and for a period not exceeding 5 Business Days in each year of the Term) with the services of a suitably qualified employee of Supplier or of an associate or contractor of Supplier at no charge, to assist Distributor in the marketing of the Products; and
- (b) Supplier will provide or arrange training for up to 3 suitably qualified employees of Distributor in relation to matters relating to the Products and their marketing at such time as may be agreed and for a period not exceeding 5 Business Days in each year of the Term.

10 AFTER SALES SERVICE

10.1 Warranty Labor Support

Distributor will, at its cost, provide to third parties labor and telephone support including that required under the Product Warranty, and if there is a dispute as to the level of support required, as reasonably determined by Supplier.

10.2 Warranty Product Support

Supplier at its cost will provide all non-labor items (such as replacement components) as reasonably required by Distributor to complete the warranty service set out in clause 10.1.

11 TRADEMARKS AND INTELLECTUAL PROPERTY

11.1 License of Trademarks

- (a) Supplier grants Distributor a non-exclusive, non-transferable license to use the Trademarks in connection with the distribution, sale, promotion and/or advertising of the Products in the Territory in accordance with Supplier's standards and instructions. Distributor shall acquire no other right, title or interest in the Trademarks, and Distributor shall not use any Trademark as part of Distributor's corporate or trade name or permit any third party to do so without the prior written consent of Supplier.
- (b) Distributor acknowledges Supplier's proprietary rights in and to the Trademarks, and Distributor waives in favor of Supplier all rights to any trademarks or trade names now or hereafter originated by Supplier. Distributor shall not at any time adopt, use or register any words, phrases or symbols which are identical or confusingly similar to any of Trademark.

11.2 Intellectual property

- (a) Distributor shall only be permitted to use Supplier's Intellectual Property in connection with the distribution, sale, promotion and/or advertising of the Products as provided in this Agreement, and then only in the form and manner approved by Supplier.
- (b) Except for the limited trademark license in **clause 11.1** and use rights granted in this **clause 11.2**, this Agreement does not grant to Distributor any rights in any Intellectual Property.

11.3 Developed materials

The Distributor and the Supplier shall develop marketing materials which may be used by the Supplier outside of the Territory. The Supplier will be responsible for developing all manufactured related materials such as Instructions for Use and Operating and Technical manuals.

11.4 Infringement of rights

Distributor shall report forthwith to Supplier any infringement or suspected infringement by third parties of Supplier's Intellectual Property which come to the notice of Distributor and Supplier has the exclusive right to determine whether any action is brought, maintained or disposed of in respect of any infringement or suspected infringement. The Distributor will provide all reasonable assistance to the Supplier in this event but shall not have any financial involvement.

11.5 No challenge by Distributor

Distributor shall not challenge the validity or ownership of Supplier's Intellectual Property. Distributor acknowledges that the use of Supplier's Intellectual Property by Distributor is only on behalf of Supplier as a licensee under its control.

12 CONFIDENTIALITY

Each Party shall treat Confidential Information disclosed to it by the other Party as confidential and to this end (but without limiting the generality of the obligation hereunder) each Party shall:

- (a) initiate a system for the safe custody of the Confidential Information and for the control of the making of copies of it and their safe custody;
- (b) not, without the prior written consent of the disclosing Party, disclose Confidential Information belonging to the disclosing Party to any other person except for:
 - (i) those of its employees involved in performance of this Agreement and who need to know the Confidential Information in question; and
 - (ii) in the case of Supplier, its Related Companies;
- (c) instruct each and every employee who will be required to use the Confidential Information to the effect that it is to be treated as confidential and kept in safe custody;
- (d) use the Confidential Information belonging to the Disclosing Party solely in connection with performing, or receiving the benefit of this Agreement, and not for its own benefit or the benefit of any third party; and
- (e) allow each Party to inspect the premises and method of administration of these provisions by the other at any reasonable time.

The obligation of confidentiality imposed by this clause does not extend to any part of the Confidential Information:

- (f) which is in the public domain other than as a result of any breach of this Agreement;
- (g) which was disclosed by a third party other than in breach of an obligation of confidentiality; or
- (h) to the extent that disclosure is necessary for a Party to comply with any applicable law, any court proceedings, the requirements of any regulatory body or the rules of any stock exchange on which the shares of that Party are listed.

The obligation of confidentiality under this clause shall continue for the Term and shall survive termination or expiration unless it is agreed by both parties that any such Confidential Information is in the public domain or is otherwise sufficiently public as to negate this obligation.

13 WARRANTIES AND INDEMNITY

13.1 Supplier's warranties

- (a) Supplier warrants to Distributor that:
- (i) all Products supplied to Distributor shall be free from defects in construction, material and workmanship for a minimum period of one (1) year from the date of the Distributor's invoice accompanying the delivery of the Products to the customer;
 - (ii) all Products supplied to Distributor will correspond to Supplier's descriptions of them and will comply with any specification stipulated by Distributor to Supplier and expressly agreed to in writing by Supplier;
 - (iii) all the Intellectual Property in and related to the Products that is required for use by Distributor under this Agreement is owned by or licensed to Supplier or a Related Company of Supplier and that Supplier has the right to allow Distributor to use such Intellectual Property in accordance with the terms of this Agreement; and
 - (iv) Supplier is not aware of any rights of any third party in the Territory which would or might render the sale of the Products, or the use of any of the Trademarks on or in relation to the Products, unlawful.
- (b) If a Product proves to be defective in regards to sub-clause 13.1 above, Supplier will, at its option, replace the Product at its own expense within thirty (30) days of notice by the Distributor or refund the purchase price paid by Distributor for the Product, unless the product defect was not caused by Supplier. Such replacement or refund shall be Supplier's sole obligation and Distributor's sole remedy for breach of warranty hereunder.
- (c) ALL CLAIMS UNDER THIS CLAUSE 13.1 SHALL BE MADE BY DISTRIBUTOR AND MAY NOT BE MADE DIRECTLY BY DISTRIBUTOR'S CUSTOMERS. THE WARRANTIES SET FORTH ABOVE ARE IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHICH ARE HEREBY DISCLAIMED AND EXCLUDED BY SUPPLIER, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR USE.

13.2 Distributor's warranties

- (a) Distributor warrants in favor of Supplier that:
 - (i) it has the necessary skills, knowledge, expertise and ability to perform its obligations under this Agreement;
 - (ii) it will perform its obligations under this Agreement in a competent and professional manner;
 - (iii) it has full corporate power and lawful authority to execute and deliver this Agreement and to perform its obligations under this Agreement;
 - (iv) this Agreement constitutes a legal, valid and binding obligation enforceable in accordance with its terms by appropriate legal remedy; and
 - (v) there is no claim, action, proceeding, demand or investigation pending or threatened against it or by, against or before any person in relation to it which may have a material effect on the subject matter of this Agreement.

13.3 Indemnity

Subject to **clause 13.4 and clause 13.5**, each Party (the **Indemnifying Party**) indemnifies the other Party against all losses, damages, Liabilities, claims, charges and expenses (including legal costs on an indemnity basis) incurred or suffered by the other Party (including claims by an injured patient or third party) arising out of or in connection with any third-party claim based on:

- (a) any breach by the Indemnifying Party of its obligations under this Agreement;
- (b) any negligent act, omission or willful misconduct of the Indemnifying Party or any of its respective officers, employees, agents or third party contractors; and
- (c) any claim by a person that a Party's use of any Intellectual Property or material provided by the Indemnifying Party pursuant to this Agreement infringes a third party's intellectual property rights, except to the extent that the claim arises through a breach by the Party of its obligations under this Agreement.

13.4 Exclusion for consequential loss or damage

EXCEPT FOR BREACHES OF CLAUSE 7.10 (COMPETITIVE PRODUCTS), CLAUSE 12 (CONFIDENTIALITY) AND ANY INDEMNIFICATION OBLIGATIONS UNDER CLAUSE 13.3, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY KIND OF SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL LOSSES OR DAMAGES, INCLUDING LOST PROFITS, LOSS OF REVENUE, LOSS OF USE, LOSS OF CONTRACT, LOSS OF GOODWILL OR INCREASED COST OF WORKING, EVEN IF THE PARTY SHALL HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH POTENTIAL LOSS OR DAMAGE

13.5 Notifying claim

The indemnity in **clause 13.2** is subject to the condition that the Party seeking the indemnity shall promptly notify the Indemnifying Party on becoming aware of any potential loss, damage, Liability, claim, charge or expense.

14 TERM AND TERMINATION

14.1 Term

This Agreement commences on the Operative Date and subject to **clause 14.2** continues for the Initial Term. At the expiry of the Initial Term this Agreement will continue for successive further 12-month terms unless either a new contract is then negotiated subject to mutual agreement or it is terminated at any time during any such successive further term by either Party giving to the other not less than 3 months' written notice.

14.2 Termination for breach

- (a) Either Party may terminate this Agreement by written notice to the other if the other Party commits any substantial breach of the provisions contained in this Agreement and does not remedy the breach within 60 days after receipt of written notice requiring it to do so. If the breach is not capable of being remedied, the Party not in breach is entitled to terminate this Agreement with immediate effect by written notice to the other.
- (b) In addition to the right of termination granted by **clause 14.2** either Party may terminate this Agreement with immediate effect by written notice to the other Party in any of the following events;
 - (i) if any moneys payable under this Agreement are in arrears and one Party fails to pay the same within 45 days of a written notice to pay from the other Party;
 - (ii) if the other Party assigns or attempts to assign its rights under this Agreement without the consent of the other Party under **clause 23.5**;
 - (iii) if at any time there is any majority change in the organization, management, direction, Control or constitution of a Party without the prior written notice of the other Party;
 - (iv) if an Insolvency Event occurs in relation to a Party;
 - (v) if either Party is prohibited by any law, regulation or requirement of any government or governmental authority in any part of the Territory from complying with this Agreement;

- (vi) if a force majeure event causes delay to performance for a continuous period of 3 months or for a period of 3 months out of any 6-month period; and
 - (vii) if either Party ceases to carry on business in the normal course.
- (c) **Sales performance objective**
- (i) A sales performance objective will be determined by agreement by both Parties for the first year of the trading Term within 30 days following TGA approval and will be reviewed and amended by mutual agreement on an annual basis.
 - (ii) If the Parties fail to reach agreement on the sales performance objective after the period defined in (i):
 - (A) for the second year of the trading Term, it will be determined by agreement by both Parties; and
 - (B) for subsequent years, it will be set at the sales performance objective level of the previous year plus 5%.
 - (iii) Distributor acknowledges and agrees that (i) it has participated to fix these sales performance objectives, (ii) these sales performance objectives are reasonable in view of Distributor's capabilities and market conditions in the Territory, and (iii) the provisions of this **clause 14.2(c)** are essential to this Agreement as stating the minimum amount of Product sales which justify Supplier's grant to Distributor of exclusive distribution rights for the Products.
 - (iv) If the sales performance objective is not met by Distributor, a 3-month period will be allowed for remediation. Product purchases during this remediation period that are counted toward the sales performance objective for the previous year shall not be counted toward the sales performance objective for the then current year. If after this remediation period the sales objective is not obtained and an agreement is not reached between the Parties for a revised sales objective, Supplier may at its sole election:
 - (A) terminate this Agreement with immediate effect; or
 - (B) (1) amend the appointment of Distributor under this Agreement to a non-exclusive distributor, and/or (2) limit the Territory and/or sales channels in which Distributor has distribution rights and/or (3) limit the Products to which Distributor has distribution rights, by giving written notice to Distributor.

- (v) Any termination under this **clause 14** is without prejudice to the rights and remedies of either Party against the other in respect of any antecedent claim or breach of any of the provisions of this Agreement.

14.3 Consequences of termination or expiration of this Agreement

(a) Cease promotions

Subject to **clause 14.3(e)**, Distributor shall not, from the date of termination or expiration of this Agreement, promote or market the Products or use Supplier's Intellectual Property without the written consent of Supplier.

(b) Actions following determinations

Subject to **clause 14.3(e)**, upon termination or expiration of this Agreement, Distributor, its employees, agents and third party contractors shall immediately:

- (i) refrain from using any of the Trademarks, or any name or names deceptively similar to the Trademarks alone or in connection with any other names;
- (ii) refrain from representing orally or in writing to members of the public that its business has a sponsorship, approval or affiliation with Supplier;
- (iii) refrain from advertising whether by the issue of booklets, leaflets, brochures or otherwise representing that its business or goods is or are in any way connected with Supplier; and
- (iv) pay to Supplier any amounts due under this Agreement.

(c) Details of Products

Distributor shall within 60 days of termination or expiration of this Agreement furnish Supplier with details of:

- (i) all partially completed contracts sale with customers for the Products; and
- (ii) all Products held by Distributor in store or in transit.

(d) Buy back of Products

Supplier shall buy back any current and saleable Products held by Distributor, provided it is packaged in the original undamaged wrap and has a minimum of six months expiry. The purchase price will be the same as the invoiced price (excluding associated shipping and importing costs).

(e) Orders

Supplier shall fulfill all orders from Distributor to Supplier to the extent to which they are unfulfilled at the time of termination or expiration of this Agreement unless Distributor cancels those orders prior to Delivery of the Products. Distributor may use any labels, wraps, containers, advertising and other items bearing the Trademarks to enable it to sell Products delivered after termination of this Agreement.

(f) Return of records and Confidential Information

Subject to clause 14.3(e), upon termination or expiration of this Agreement:

- (i) Distributor shall forthwith return to Supplier all records of information and documents supplied to Distributor under this Agreement;
- (ii) each Party shall, at the other Party's direction, either return or destroy all documents in its possession or control containing (and any other records of) the other Party's Confidential Information, and provide to the other Party a signed certificate stating that this obligation has been complied with; and
- (iii) the Distributor shall provide the Supplier with all customer sales information and any marketing material developed for the purpose of representing the Products.

(g) No rights other than as this Agreement

Subject as otherwise provided in this Agreement and to any rights or obligations which have accrued prior to termination or expiration, neither Party has any further obligation to the other under this Agreement.

15 COMPENSATION FOR LOSS OF DISTRIBUTORSHIP

If this Agreement is terminated for any reason (including a change of control in the ownership of Supplier or its ultimate parent company) other than as a result of a breach of this Agreement by Distributor, a force majeure event or an Insolvency Event involving Distributor, then Supplier shall, within 60 days of termination of this Agreement provide the following compensation:

- (a) all costs associated with the Regulatory and Reimbursement approvals; and
- (b) in the event that the Agreement is terminated during the first twelve (12) month trading period following TGA approval, payment will be made by the Supplier to the Distributor of [*], for the remaining months of the twelve (12) month period; or
- (c) in the event that Termination is after the first twelve (12) month trading period and until the end of the agreed Initial Term, [*] for the previous twelve (12) months trading period, from the date of the termination notice, will be paid by the Supplier to the Distributor.

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

16 GOODS AND SERVICES TAX

- (a) Unless otherwise expressly stated, all prices or other sums payable or consideration to be provided under this document are exclusive of GST.
- (b) If:
 - (i) a Party incurs a liability to pay GST on any supply it makes to the other Party under this Agreement;
 - (ii) the Party making the supply certifies that it has not priced the supply to include GST; and
 - (iii) the Party making the supply is registered for GST purposes, the Party receiving the supply agrees to pay the Party making the supply, at the same time and in addition to any other consideration payable for that supply under this Agreement, an amount calculated by multiplying the amount payable by the Party receiving the supply by the prevailing GST rate, provided always that such amount will not become payable until a valid tax invoice is issued by the Party making the supply.
- (c) Notwithstanding any other provision in this Agreement if imposition of a GST or any subsequent change in the GST law is accompanied by or undertaken in connection with the abolition of or reduction in any existing taxes, duties or statutory charges (in this **clause 16** "Non-GST Taxes"), the consideration (excluding any GST) payable by Distributor for any supply made under this Agreement will be varied as a consequence of the abolition of or reduction in Non-GST Taxes, whether directly by way of a variation in Non-GST Taxes paid or payable by Supplier to its suppliers or to any government or indirectly by way of a variation in the prices (excluding any GST) charged by suppliers to Supplier. The parties agree that:
 - (i) the relevant proportion will be the subject of negotiations made in good faith between them at the relevant time; and
 - (ii) those negotiations may, without limitation, deal with the extent to which any Non-GST Taxes are relevant to this clause (for example, income tax).

17 ANCILLARY PROVISIONS

The relationship between the Parties is that of seller and buyer and is not that of employer/employee, principal/agent, joint venture, partnership or otherwise. Distributor is not authorized to act on behalf of Supplier purporting to bind Supplier, or to extend any warranty, commitment or representation on behalf of Supplier, but acts as an independent contractor buying for itself and selling in Distributor's own name and at Distributor's own risk.

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

18 FORCE MAJEURE

- 18.1 No Party will be liable nor deemed to be liable to the other Party for failure or delay in meeting any obligation which it had the duty to perform to the extent that, and for the period of time during which performance of the obligation is effected by strikes and/or lockouts (whether of their own employees or those of others and whether or not the Party against whom such action is taken could have avoided the same by acceding to the demands of the employees responsible for such action) acts of God, war, fire, flood, embargo, acts of government or any agency instrumentality or any political subdivision hereof or any other cause beyond the reasonable control of the Party but does not include for example, economic problems such as insufficient funds or substantial price rises, ordinarily foreseeable events like bad weather or accidents due to miscalculation.
- 18.2 In any such event, the time for performance of the obligations under this Agreement will be extended by the same period or periods (as the case may be) for which performance is delayed by the event. The Party so affected will use its best endeavors to avoid or remove such causes of non-performance and will continue performance hereunder with the utmost dispatch as soon as such causes are removed. Nothing in this clause will be construed as requiring the affected Party to settle any industrial dispute.
- 18.3 A Party affected by a force majeure event must immediately upon becoming aware of the occurrence of the event, notify the other Party of the occurrence, its cause and the steps which the notifying Party is taking to resume performance of its obligations under this Agreement.
- 18.4 Neither Party may invoke grounds for relief pursuant to a force majeure event unless such Party can prove that it has taken all reasonable measures to limit the effects of the delay, and after the impediment has ceased to exist, attempted to make up for the lost time.

19 PRODUCT RECALL

- (a) If Supplier wishes to recall any Product, or if any government or authority requires the recall of any Product for any reason, Distributor shall effect the recall in accordance with all relevant legal and regulatory requirements and directions by Supplier.
- (b) The Parties shall consult closely and Distributor shall keep Supplier fully informed from time to time as to the status of any Product recall.
- (c) Distributor shall not communicate with the news media, consumers, government or regulatory authorities in relation to any Product recall without Supplier's prior written approval (which shall not be unreasonably withheld) or as directed by the TGA, and shall only communicate to those parties on terms reasonably directed by Supplier or the TGA.
- (d) Each Party shall provide assistance reasonably requested by the other Party in connection with the implementation of a Product recall.

20 NOTICES

20.1 Manner of service

A notice or other communication required or permitted to be given by a Party to another shall be in writing and either—

- (a) delivered personally;
- (b) sent to an address in Australia by security post or registered mail, postage prepaid;
- (c) sent to an address outside Australia by registered prepaid first class airmail; or
- (d) sent by facsimile transmission with acknowledgment of receipt from the addressee, to the address for service, or to the facsimile number of the sender.

20.2 Notice given

A notice or other communication is taken to have been given if:

- (a) personally delivered, upon delivery;
- (b) mailed to an address in the Commonwealth of Australia, on actual delivery to the addressee, as evidenced by documentation of the relevant postal authority;
- (c) mailed to an address outside the Commonwealth of Australia, 7 days after posting; and
- (d) sent by facsimile, upon the sender receiving acknowledgment of receipt from the address.

20.3 Acknowledgment of receipt

A Party who receives a notice or the communication by facsimile shall immediately acknowledge receipt to the sender.

20.4 Address

A notice or other communication is taken to be duly given if given in the manner specified in this clause and if delivered or posted to the Party to whom the same is addressed to the address set forth on the first page of this Agreement or to such other address as shall have been furnished.

21 NON SOLICITATION

Without the prior written consent of Distributor, Supplier shall not, directly or indirectly, hire or otherwise engage, or seek to hire or engage or cause, aid or assist any other person or entity (including any related body corporate of Supplier) to hire or otherwise engage, any employee of Distributor or employee who leaves the employment of Distributor during the Term

of this Agreement until the earlier to occur of 12 months after the termination of this Agreement or 12 months after the termination of the individual's employment with Distributor. This clause will survive termination of this Agreement.

22 DISPUTE RESOLUTION

- 22.1 Arbitration.** Subject to the rights of the parties set forth in clause 22.3 below, all disputes, claims or controversies arising out of or in connection with this Agreement shall be finally settled through binding arbitration conducted in Honolulu, Hawaii under the auspices of JAMS in accordance with the JAMS International Arbitration Rules (the "Rules"), as modified herein. Such arbitration shall be conducted by a single arbitrator who shall be independent and neutral. The award of the arbitrator shall be final and binding, and judgment upon the award rendered by the arbitrators may be entered in any court of competent jurisdiction. The arbitration shall be conducted in the English language.
- 22.2 Procedures.** Within thirty (30) days following the appointment of the arbitrator, each party shall provide to the other party copies of all documents relevant to the issues raised by any claim or counterclaim. Within thirty (30) days following the date upon which documents are exchanged the parties may take up to five depositions of up to five hours each. Discovery disputes shall be resolved upon application to arbitrator, the arbitrator's resolution to be final. Hearings shall be on four successive days within 150 days after the arbitrator is appointed, and the award of the arbitrator shall be issued within 200 days after the arbitrator is appointed. It is the intent of the parties that the above time limits be strictly enforced, unless extended by the mutual agreement of the parties. The parties agree that the arbitrator shall agree to comply with the above modifications to the Rules prior to accepting appointment.
- 22.3 Equitable Relief.** Each Party expressly reserves the right to seek emergency injunctive relief from a court of competent jurisdiction with respect to the enforcement of its rights hereunder and waives any bond, surety or other security that might be required of the other Party with respect to any such action.

23 MISCELLANEOUS

23.1 Costs

Subject to any express provision in this Agreement to the contrary, each Party shall bear its own legal and other costs and expenses relating directly or indirectly to the preparation of, and performance of its obligations under, this Agreement.

23.2 Amendment

This Agreement may only be varied or replaced by a document duly executed by both Parties.

23.3 Waiver and exercise of rights

- (a) A single or partial exercise or waiver of a right relating to this Agreement does not prevent any other exercise of that right or the exercise of any other right.
- (b) A Party is not liable for any loss, cost or expense of any other Party caused or contributed to by the waiver, exercise, attempted exercise, failure to exercise or delay in the exercise of a right.

23.4 Approvals and consent

Subject to any express provision in this Agreement to the contrary, a Party may conditionally or unconditionally give or withhold any consent to be given under this Agreement and is not obliged to give its reasons for doing so.

23.5 Assignment

Neither Party shall assign any rights under this Agreement without the prior written consent of the other Party, provided that, a successor in interest by merger, operation of law, assignment, purchase or otherwise of the entire business of either Party shall acquire all interest of such Party hereunder unless such successor is a competitor of the other Party.

23.6 Further assurance

Each Party shall promptly execute all documents and do all things that another Party from time to time reasonably requires of it to effect, perfect or complete the provisions of this Agreement.

23.7 Counterparts

This Agreement may consist of a number of counterparts and if so the counterparts taken together constitute one and the same instrument.

23.8 Governing law

In the event that any legal action is initiated by the Supplier this Agreement shall be governed by and interpreted in accordance with the laws of the State of Minnesota, U.S.A. excluding (a) any conflict of law rules or principle therein contained under which any other law would be made applicable and (b) the United Nations Convention on Contracts for the International Sales of Goods.

In the event that any legal action is initiated by the Distributor this Agreement shall be governed by and interpreted in accordance with the laws of the State of New South Wales, AUSTRALIA excluding (a) any conflict of law rules or principle therein contained under which any other law would be made applicable and (b) the United Nations Convention on Contracts for the International Sales of Goods.

Products

| <u>Model</u> | <u>Name</u> | <u>AIMD/MDD Class</u> | <u>Code description</u> |
|--------------|---------------------------------|-----------------------|--|
| 200 | Maestro Rechargeable System Kit | AIMD | System Kit, Neuroregulator, vagus nerve, rechargeable: An assembly of devices intended to treat obesity through the application of electrical stimuli to the vagus nerve below the gastric junction. It is typically implanted in the abdomen and consists of a rechargeable battery-operated neuroregulator, implantable lead(s), torque wrench, components for external charging, and a clinician programmer used to modify operating parameters. The battery is recharged externally. |
| 2004 | Implant Kit | AIMD | Implant Kit, Neuroregulator, vagus nerve, rechargeable: An assembly of devices intended to treat obesity through the application of electrical stimuli to the vagus nerve below the gastric junction. It is typically implanted in the abdomen and consists of a rechargeable battery-operated neuroregulator, implantable lead(s), torque wrench, and components for external charging. The battery is recharged externally. |
| 2002 | Rechargeable Neuroregulator | AIMD | Neuroregulator, vagus nerve, rechargeable: A device intended to treat obesity through the application of electrical stimuli to the vagus nerve below the gastric junction. It is typically implanted in the abdomen and consists of a rechargeable battery-operated neuroregulator and torque wrench. The battery is recharged externally. |

| <u>Model</u> | <u>Name</u> | <u>AIMD/MDD Class</u> | <u>Code description</u> |
|--------------|-------------------------|-----------------------|--|
| 2200A-47E | Anterior Lead | III | A lead, insulated with non-conductive material except at the electrode(s), that is implanted in the neurological tissue. It is used to make an electrical connection between the stimulator and the vagus nerve. |
| 2200P-47E | Posterior Lead | III | A lead, insulated with non-conductive material except at the electrode(s), that is implanted in the neurological tissue. It is used to make an electrical connection between the stimulator and the vagus nerve. |
| 2403-300 | Clinician transmit coil | III | Transmit coil - An electronic device that provides radio-frequency connection between an implanted Vagus Nerve Electrical Blocking Neuroregulator and an external Mobile Recharger for transmission of power to charge the battery in the implanted device and to provide information transfer to and from the implant and the Mobile Recharger. This device may be operated by a clinician or patient. |
| 31810 | Sterile sleeve | I sterile | Cover, cable/lead/sensor/probe |
| 80118 | Medical adhesive | 1 (sterile) | Medical device adhesive, sterile |
| 2404 | Patient kit | III | Recharging Kit, Neuroregulator, vagus nerve, rechargeable - An assembly of devices used to transcutaneously recharge the battery of a rechargeable implanted neuroregulator. Typically includes mobile charger, transmit coil, AC recharger and transmit coil belt. |

| Model | Name | AIMD/MDD Class | Code description |
|--------------|----------------------------|-----------------------|--|
| 2402 | Mobile charger | III | Recharger, Neuroregulator, vagus nerve, rechargeable - A device used to transcutaneously communicate with a rechargeable implanted neuroregulator for recharging the battery of a rechargeable implanted neuroregulator, or review and modification of neuroregulator operating parameters. |
| 2403-60 | Patient transmit coil | III | Transmit Coil - An electronic device that provides radio-frequency connection between an implanted Vagus Nerve Electrical Blocking Neuroregulator and an external Mobile Recharger for transmission of power to charge the battery in the implanted device and to provide information transfer to and from the implant and the Mobile Recharger. This device may be operated by a clinician or patient. |
| 1660 | Patient transmit coil belt | I | A device used for keeping electrodes in place. This is typically used for reusable electrodes which do not stick to the body surface or for electrodes that may require extra securing. This is a reusable device. |
| 2403-60A | Patient transmit coil | III | Transmit Coil - An electronic device that provides radio-frequency connection between an implanted Vagus Nerve Electrical Blocking Neuroregulator and an external Mobile Recharger for transmission of power to charge the battery in the implanted device and to provide information transfer to and from the implant and the Mobile Recharger. This device may be operated by a clinician or patient. |

| Model | Name | AIMD/MDD Class | Code description |
|--------------|----------------------------|---------------------------|---|
| 1660A | Patient transmit coil belt | I | A device used for keeping electrodes in place. This is typically used for reusable electrodes which do not stick to the body surface or for electrodes that may require extra securing. This is a reusable device. |
| 1620 | AC recharger | I | A device designed to supply an electrical charge to rechargeable batteries, restoring the battery to an appropriate working condition. This device is typically connected to the building's electrical power supply and can be used to either charge the batteries by themselves (removed from the device) or whilst they are still inside the parent device (in situ), e.g., a defibrillator or ophthalmoscope. This device usually has current and voltage controls to meet the charge needs of different types of batteries. |
| 2502 | Clinician programmer | III | Programmer, Implantable Neuroregulator - A device used to change, noninvasively, one or more of the operating parameters of an implanted neuroregulator. The programmer reads recorded information from the implanted device, and provides the clinician with information on device performance and patient compliance. The programmer also allows for firmware revision upgrades of the implanted device. |
| 1600 | Programmer cable | I | A device that provides a connection between two or more devices for the purpose of transmitting an energy that may, or may not, contain information. |
| 1680 | Torque wrench | I (sterile) | Wrench, surgical |

Prices

[*]

*Confirmation of pricing and minimum purchase requirements will be mutually agreed within
3 months of signing this agreement.*

[*] Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

Trademarks

VBLOC[®] vagal blocking therapy and VBLOC[®]Therapy (Australian registered trade mark number 1178307)

Maestro[®] System (Australian registered trade mark number 1079091)

EnteroMedics[®] (Australian registered trade mark number 1079090)

CERTIFICATION

I, Mark B. Knudson, Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of EnteroMedics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ MARK B. KNUDSON, PH.D.

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

Date: May 6, 2011

CERTIFICATION

I, Greg S. Lea, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of EnteroMedics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ GREG S. LEA

Greg S. Lea
Senior Vice President and Chief Financial Officer

Date: May 6, 2011

CERTIFICATION

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

1. The Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011 to which this Certification is attached as Exhibit 32.1 (the Report) fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and the results of operations of EnteroMedics Inc. as of, and for, the periods covered by the Report.

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

Date: May 6, 2011

