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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2012

OR

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

For the transition period from to

Commission file number 001-35312

SUNSHINE HEART, INC.

Delaware	**No. 68-0533453**
(State or other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification Number)

12988 Valley View Road, Eden Prairie, MN 55344
(Address of Principal Executive Offices) (Zip Code)

(952) 345-4200
(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 x No o

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 x No o

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 o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

The number of shares outstanding of the Company's Common Stock on July 24, 2012 was 6,277,538.

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SUNSHINE HEART, INC.
Condensed Consolidated Balance Sheets
(Dollars in thousands, except share amounts)

	June 30, 2012 (unaudited)	December 31, 2011
Current assets		
Cash and cash equivalents	$ 1,772	$ 6,563
Other current assets	632	346
Total current assets	2,404	6,909
Property, plant and equipment, net	503	522
TOTAL ASSETS	$ 2,907	$ 7,431
Current liabilities		
Accounts payable	$ 1,643	$ 1,857
Accrued salaries, wages, and other compensation	619	978
Total current liabilities	2,262	2,835
Total liabilities	2,262	2,835
Commitments and contingencies	—	—
Stockholders' equity		
Preferred Stock as of June 30, 2012 and December 31, 2011, par value $0.0001 per share; authorized 40,000,000 shares	—	—
Common stock as of June 30, 2012 and December 31, 2011, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 6,277,538 and 6,019,663 shares, respectively	1	1
Additional paid-in capital	71,341	68,652
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	1,195	1,132
Retained earnings	(71,892)	(65,189)
Total stockholders' equity	645	4,596
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 2,907	$ 7,431

See notes to the condensed consolidated financial statements.

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SUNSHINE HEART, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Net sales	$ —	$ —	$ —	$ —
Cost of goods sold	—	—	—	—
Gross profit	—	—	—	—
Operating expenses				
Selling, general and administrative	1,569	1,178	3,509	1,820
Research and development	1,787	2,374	3,953	4,666
Total operating expenses	3,356	3,552	7,462	6,486
Loss from operations	(3,356)	(3,552)	(7,462)	(6,486)
Interest income	4	80	29	197
Loss before income taxes	(3,352)	(3,472)	(7,433)	(6,289)
Income tax benefit	(730)	—	(730)	—
Net loss	$ (2,622)	$ (3,472)	$ (6,703)	$ (6,289)
Basic and diluted loss per share	$ (0.42)	$ (0.68)	$ (1.08)	$ (1.24)
Weighted average shares outstanding — basic and diluted	6,277	5,088	6,223	5,083
Comprehensive loss	$ (2,610)	$ (3,352)	$ (6,640)	$ (6,104)

See notes to the condensed consolidated financial statements.

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SUNSHINE HEART, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	For the six months ended June 30,	
	2012	2011
Net loss	$ (6,703)	$ (6,289)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	63	30
Loss on disposal of plant and equipment	63	—
Stock-based compensation expense	621	42
Changes in assets and liabilities		
Accounts receivable	—	223
Other current assets	(286)	(15)
Accounts payable and accrued expenses	(573)	(203)
Net cash used in operating activities	(6,815)	(6,212)
Cash flows used in investing activities:		
Purchases of property and equipment	(107)	(43)
Net cash used in investing activities	(107)	(43)
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	2,068	183
Net cash provided by financing activities	2,068	183
Effect of exchange rate changes in cash	63	185
Net decrease in cash and cash equivalents	(4,791)	(5,887)
Cash and cash equivalents - beginning of period	6,563	12,350
CASH AND CASH EQUIVALENTS - END OF PERIOD	$ 1,772	$ 6,463

See notes to the condensed consolidated financial statements.

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SUNSHINE HEART, INC. AND SUBSIDIARY

Notes to Condensed Consolidated Financial Statements
(in thousands, except share and per share data)

Note 1 - Nature of Business and Significant Accounting Policies

Nature of Business: Sunshine Heart ("we" or the "Company") was founded in November 1999 and incorporated in Delaware in August 2002. The Company's headquarters are located in Eden Prairie, MN and the Company also has a wholly owned subsidiary, Sunshine Heart Company Pty Ltd, located in St Leonards, New South Wales, Australia. We are a medical device company developing innovative technologies for cardiac and coronary disease. The Company's primary product, the C-Pulse® Heart Assist System, or C-Pulse System, is an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure, which can be implanted using a minimally invasive procedure. The C-Pulse System is designed to relieve the symptoms of heart failure through the use of counter-pulsation technology by enabling an increase in cardiac output, an increase in coronary blood flow, and a reduction in the heart's pumping load. The Company received approval from the U.S. Food and Drug Administration, or FDA, to conduct a U.S. feasibility clinical trial with the C-Pulse System. Our shares of common stock in the form of CHESS Depositary Interests, or CDIs, have been publicly traded in Australia on the Australian Securities Exchange, or ASX, since September 2004.

Going Concern: The Company's financial statements have been prepared and presented on a basis assuming it continues as a going concern.

During the years ended December 31, 2011 and 2010 and through June 30, 2012, the Company incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively. At December 31, 2011, we had an accumulated deficit of $65,189 and we expect to incur losses for the foreseeable future. To date, the Company has been funded by private and public equity financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

The Company's ability to continue as a going concern is dependent on the Company's ability to raise additional capital based on the achievement of existing milestones as and when required. Should the future capital raising not be successful, the Company may not be able to continue as a going concern. Furthermore, the ability of the Company to continue as a going concern is subject to the ability of the Company to develop and successfully commercialize the product being developed. If the Company is unable to obtain such funding of an amount and timing necessary to meet its future operational plans, or to successfully commercialize its intellectual property, the Company may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company not continue as a going concern.

Basis of Presentation: The accompanying consolidated financial statements include the accounts of Sunshine Heart, Inc. and its wholly-owned subsidiary, Sunshine Heart Company Pty Ltd. (collectively, "Sunshine Heart" or the "Company"). All intercompany accounts and transactions between consolidated entities have been eliminated.

Unaudited Interim Consolidated Financial Information: The interim balance sheet as of June 30, 2012 and statements of operations and comprehensive loss and cash flows for the six months ended June 30, 2012 and 2011 and related interim information contained in the notes to these financial statements are unaudited. The accompanying condensed consolidated financial statements have been prepared in accordance with Regulation S-X of the Securities Act of 1933, as amended. In the opinion of management, such unaudited interim consolidated information has been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and includes all adjustments consisting of normal recurring accruals necessary for the fair presentation of this interim information when read in conjunction with the audited financial statements and notes thereto. Certain information and disclosures normally included in the financial statements have been condensed or omitted pursuant to such rules and regulations, although management believes that disclosures are adequate to make information presented not misleading. Results for the six months ended June 30, 2012 are not necessarily indicative of the results that may be expected for the year ending December 31, 2012 or any other interim period or for any other future year.

Use of Estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and disclosures in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Net Loss per Share: Basic net loss attributable to common stockholders, on a per share basis, is computed by

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dividing income available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) during the period. Shares issued during the period and shares reacquired during the period are weighted for the portion of the period that they were outstanding. The computation of diluted earnings per share, or EPS, is similar to the computation of basic EPS except that the denominator is increased to include the number of additional common shares that would have been outstanding if the dilutive potential common shares had been issued and computed in accordance with the treasury stock method. In addition, in computing the dilutive effect of convertible securities, the numerator is adjusted to add back the after-tax amount of interest recognized in the period associated with any convertible debt. Shares reserved for outstanding stock warrants and options totaling 2,457,291 and 1,233,845 for the six months ended June 30, 2012 and 2011, respectively, were excluded from the computation of loss per share as their effect was antidilutive due to the Company's net loss in each of those periods.

Fair Value of Financial Instruments: Our financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities. We believe that the carrying amounts of the financial instruments approximate their respective current fair values due to their relatively short maturities.

Pursuant to the requirements of the Fair Value Measurements and Disclosures Topic of the Financial Accounting Standards Board, or FASB, Codification, the Company's financial assets and liabilities measured at fair value on a recurring basis are classified and disclosed in one of the following three categories:

Level 1: Financial instruments with unadjusted quoted prices listed on active market exchanges.

Level 2: Financial instruments lacking unadjusted, quoted prices from active market exchanges, including over the counter traded financial instruments. The prices for the financial instruments are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3: Financial instruments that are not actively traded on a market exchange. This category includes situations where there is little, if any, market activity for the financial instrument. The prices are determined using significant unobservable inputs or valuation techniques.

All cash and cash equivalents are considered Level 1 measurements for all periods presented. We do not have any financial instruments classified as Level 2 or Level 3 and there were no movements between these categories.

Recently Adopted Accounting Pronouncements

In May 2011, the FASB issued an update to accounting guidance for improved fair value measurement and disclosures. The update represents converged guidance between U.S. GAAP and IFRS, resulting in common requirements for measuring fair value and for disclosing information about fair value measurements. This new guidance was effective for our fiscal year beginning January 1, 2012 and the adoption of this guidance did not have an impact on our financial position, results of operations or cash flows.

In June 2011, the FASB issued amended disclosure requirements for the presentation of comprehensive income. The amended guidance eliminates the option to present components of other comprehensive income ("OCI") as part of the statement of changes in equity. Under the amended guidance, all changes in OCI are to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive financial statements. We adopted these changes effective January 1, 2012 and applied retrospectively for all periods. There was no impact to the consolidated results as the amendments related only to changes in financial statement presentation.

There was no other accounting pronouncement adopted during the three-month period ended June 30, 2012 that had a material impact on our financial position, operating results or disclosures.

Recent Accounting Pronouncements to be Adopted

There were no new accounting pronouncements issued during the three-month period ended June 30, 2012 that are expected to have material impacts on our financial position, operating results or disclosures.

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Note 2 — Equity

Private Placement

On February 8, 2012 we placed 256,875 shares of common stock (in the form of CDIs) at AU$8.00 per share, for proceeds, net of transaction costs, of $2,061.

Stock-Based Compensation

The Company recognizes all share-based payments, including grants of stock options and compensatory employee stock purchase plans, in the statement of operations as an operating expense, based on their fair value over the requisite service period. We recorded $402 and $219 of related compensation expense to selling, general and administrative expense and research and development expense, respectively, for the six months ended June 30, 2012, as compared to $31 and $11, respectively, of related compensation expense for the six months ended June 30, 2011. As of June 30, 2012, a total of $3,647 of unrecognized compensation costs related to non-vested stock option awards was outstanding and is expected to be recognized within the next 3.5 fiscal years.

The Company uses the Black-Scholes option pricing model to determine the weighted average fair value of options. The volatility factor used in the Black-Scholes option pricing model is based on historical stock price fluctuations. The current forfeiture rate is based on a reasonable estimate by management. Expected dividend yield is based upon the Company's historical and projected dividend activity and the risk free interest rate is based upon US Treasury rates appropriate for the expected term of the options. The expected term is based on estimates regarding projected employee stock option exercise behavior. Options for 31,875 shares were granted during the six months ended June 30, 2012, and the weighted average fair value of these options was $196, determined using an expected dividend yield of 0%, an expected stock price volatility ranging from 98.3% to 98.6%, risk-free interest rates ranging from 1.38% to 1.43% and expected option lives of 6.5 years. There were no options granted in the six months ended June 30, 2011.

The Company's stock options generally vest over four years of service and have a contractual life of 10 years. We have 1,019,856 shares authorized for grant under our Amended and Restated 2011 Equity Incentive Plan.

Warrants

Warrants to purchase 1,564,649 and 1,496,032 shares of common stock were outstanding at June 30, 2012 and December 31, 2011, respectively.

As part of the private placement on February 8, 2012, we issued 77,063 warrants to purchase common stock at an exercise price of AU$11.20 per share and a term of 4 years, and 8,553 warrants to purchase common stock at an exercise price of AU$8.00 per share with a term of 5 years.

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Note 3 - Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	June 30,	December 31,

	2012	2011
Library	$ 1	$ 1
Office Furniture & Fixtures	95	177
Leasehold Improvements	145	251
Software	9	37
Production Equipment	375	293
Computer Equipment	127	134
Total	752	893
Accumulated Depreciation	(249)	(371)
	$ 503	$ 522

Depreciation expense for the three and six month periods ended June 30, 2012 and 2011 was $32, $21, $63 and $30, respectively.

Note 4 — Income Taxes

We received a $730 research and development tax credit refund in the quarter ended June 30, 2012, based upon qualified research and development expenditures of our Australian subsidiary for its tax period ended June 30, 2011. The Australian research and development tax credit is paid as a refundable credit to small and medium enterprises. We have not completed the Australian tax return for the period ended June 30, 2012; therefore, we have not reflected a benefit related to the Australian research and development tax credit for that period.

Note 5 — Subsequent Events

Public Stock Offering

On July 17, 2012, we filed a registration statement on Form S-1 with the Securities and Exchange Commission ("SEC") for a public offering of our common stock for proceeds of up to $28.75 million before related commissions and expenses. We expect to complete the offering in the third quarter 2012 and use the net proceeds to fund our pivotal clinical trial and for general corporate purposes.

CE Mark

On July 23, 2012, we received CE Mark for our C-Pulse Heart Assist System. We expect to commence a post-market clinical trial in select countries in Europe beginning in the second half of 2012.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes included in Item 1 of Part I of this Quarterly Report and the audited consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations contained in our Annual Report on Form 10-K for the year ended December 31, 2011. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a variety of factors, including those discussed in Part I, Item 1A Risk Factors, in our Annual Report on Form 10-K for the year ended December 31, 2011 and in our subsequent filings with the SEC.

Overview

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse System for treatment of Class III and ambulatory Class IV heart failure. The C-Pulse System utilizes the scientific principles of intra-aortic balloon counter-pulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries.

We are in the process of pursuing regulatory approvals necessary to sell our system in the United States. We completed enrollment of our North American feasibility clinical trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the United States Food and Drug Administration, or FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an IDE application. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the potential market for our system in targeted countries in Europe in anticipation of commencing commercial sales. In order to gain additional clinical data and support reimbursement in Europe, we also expect to initiate a post-market trial in Europe that will evaluate endpoints similar to those for our U.S. pivotal trial.

Critical Accounting Policies and Estimates

Revenue Recognition: We recognize revenue when (i) persuasive evidence of a customer arrangement exists; (ii) the price is fixed or determinable and free of contingencies or uncertainties; (iii) collectability is reasonably assured; and (iv) product delivery has occurred, which is when product title transfers to the customer, or services have been rendered. Sales are not conditional based on customer acceptance provisions or installation obligations. Our C-Pulse System is not approved for commercial sale in the United States and we have not commenced sales of our system outside of the United States. Our revenue consists solely of sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial. For clinical trial implant revenue, the product title generally transfers on the date the system is implanted. We do not charge hospitals and clinics for shipping. We expense shipping costs at the time we report the related revenue and record such costs in cost of sales.

Foreign Currency Translation and Transactions: Foreign denominated monetary assets and liabilities are translated at the rate of exchange prevailing at the balance sheet date. Results of operations are translated using the average rates prevailing during the reporting period. Our Australian subsidiary's functional currency is the Australian Dollar. Translation adjustments result from translating the subsidiary's financial statements into our reporting currency, the U.S. Dollar. The translation adjustment has not been included in determining our net loss, but has been reported separately and is accumulated in a separate component of equity.

Effective January 1, 2011, we concluded that the functional currency of our U.S.-based parent company is the U.S. Dollar. We have concluded that the functional currency of the Australian subsidiary remains the Australian Dollar.

Comprehensive Income (Loss): The components of comprehensive income (loss) include net income (loss) and the effects of foreign currency translation adjustments.

Stock-Based Compensation: We recognize all share-based payments, including grants of stock options in the income statement as an operating expense based on their fair value over the requisite service period.

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We compute the estimated fair values of stock options using the Black-Scholes option pricing model. No tax benefit has been recorded due to the full valuation allowance on deferred tax assets that we have recorded.

Stock-based compensation expense is based on awards ultimately expected to vest and is reduced for estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Equity instruments issued to non-employees, and for services and goods, are shares of our common stock, warrants or options to purchase shares of our common stock. These shares, warrants or options are either fully-vested and exercisable at the date of grant or vest over a certain period during which services are provided. We expense the fair market value of these securities over the period in which the related services are received.

Going Concern: Our financial statements have been prepared and presented on a basis assuming we continue as a going concern.

During the years ended December 31, 2011 and 2010 and through June 30, 2012, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively.

Our ability to continue as a going concern is dependent on our ability to raise additional capital as and when required. Our directors, after due consideration, believe that we will be able to raise new equity capital as required to fund our business plan. Should our future efforts to raise capital not be successful, we may not be able to continue as a going concern. Furthermore, our ability to continue as a going concern is subject to our ability to develop and successfully commercialize our C-Pulse System being developed. If we are unable to obtain such funding of an amount and on a timeline necessary to meet our future operational plans, or to successfully commercialize our intellectual property, we may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we not continue as a going concern.

Accounting Standards Applicable to Emerging Growth Companies: We qualify as an "emerging growth company" pursuant to the provisions of the JOBS Act, enacted on April 5, 2012. Section 102(b)(1) of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An "emerging growth company" can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates for new or revised accounting standards for U.S. public companies.

Internal Controls and Procedures

Our independent registered public accounting firm is not yet required to formally attest to the effectiveness of our internal control over financial reporting, and will not be required to do so for as long as we are an "emerging growth company" pursuant to the provisions of the Jumpstart our Business Startups Act of 2012, or JOBS Act.

Recent Accounting Pronouncements

In May 2011, the FASB issued an update to accounting guidance for improved fair value measurement and disclosures. The update represents converged guidance between U.S. GAAP and IFRS, resulting in common requirements for measuring fair value and for disclosing information about fair value measurements. This new guidance was effective for our fiscal year beginning January 1, 2012 and the adoption of this guidance did not have an impact on our financial position, results of operations or cash flows.

In June 2011, the FASB issued amended disclosure requirements for the presentation of comprehensive income. The amended guidance eliminates the option to present components of OCI as part of the statement of changes in equity. Under the amended guidance, all changes in OCI are to be presented either in a single continuous statement of comprehensive income or in two separate but consecutive financial statements. We adopted these changes effective January 1, 2012 and applied retrospectively for all periods. There was no impact to the consolidated results as the amendments related only to changes in financial statement presentation.

Financial Overview

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse System for treatment of Class III and ambulatory Class IV heart failure. Our activities since inception have consisted principally of raising capital, performing research and development and conducting preclinical and clinical trials. At June 30, 2012, we had an accumulated deficit of $71.9 million and we expect to incur losses

for the foreseeable future. To date, we have been funded by private and public equity financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

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Results of Operations

Comparison of Three Months Ended June 30, 2012 to Three Months Ended June 30, 2011

Revenue

Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ —	$ —	$ —	N/A

Sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with the appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial historically have generated our revenue. We did not have any sales of our C-Pulse System device in the three month periods ended June 30, 2012 or 2011, as we completed enrollment in our feasibility trial in early 2011 and have not yet commenced enrollment in our pivotal clinical trial. We expect our revenue will be minimal until we begin enrolling patients in our North American pivotal clinical trial and initiate trials in select countries in Europe under our CE Mark, both expected to commence in the second half of 2012.

Research and Development Expense

Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 1,787,000	$ 2,374,000	$ (587,000)	(24.7)%

Our decrease in research and development expense for the three months ended June 30, 2012 compared to the prior year's period was primarily caused by the timing of certain outsourced development activities related to our C-Pulse System period to period. We expect our research and development expense will continue to be lower than the comparable prior year period in the third quarter 2012, then sequentially increase as we add personnel to support our pivotal clinical trial and pursue our development efforts.

Selling, General and Administrative Expense

Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 1,569,000	$ 1,178,000	$ 391,000	33.2%

Our increase in selling, general and administrative expense for the three months ended June 30, 2012 compared to the prior year was primarily caused by increased stock-based compensation expense resulting from current-year stock option grants, and increased professional fees and personnel additions in 2011 as we developed our infrastructure, and in preparation for European trials expected to commence in the second half of 2012. We expect our selling, general and administrative expense will continue to be above comparable prior year period levels in future periods as a result of the infrastructure recently put in place to support our growth.

Interest Income

Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 4,000	$ 80,000	$ (76,000)	(95)%

Our decrease in interest income for the three months ended June 30, 2012 compared to the prior year was primarily caused by lower average cash balances during the three months ended of June 30, 2012 as compared to June 30, 2011.

Income Tax Benefit

Three Months Ended June 30, 2012	Three Months Ended June 30, 2011	Increase (Decrease)	% Change
$ (730,000)	$ —	$ (730,000)	N/A%

Our income tax benefit for the three months ended June 30, 2012 resulted from a research and development tax

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credit in Australia. We completed our Australian tax return for the twelve-month period ended June 30, 2011 in the second quarter of 2012 and received a $730,000 research and development tax credit refund during the quarter. Assuming no further changes to the applicable Australian law for research and development tax credits, we expect to receive tax refunds in the future in amounts that vary based on research and development expenditures in Australia. At this time, we are working to complete our analysis of the potential research and development tax credit refund that may be available for the period ended June 30, 2012.

Comparison of Six Months Ended June 30, 2012 to Six Months Ended June 30, 2011

Revenue

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ —	$ —	$ —	N/A

Sales of the C-Pulse System to hospitals and clinics pursuant to research arrangements and with the appropriate regulatory approvals for sales in conjunction with our feasibility clinical trial historically have generated our revenue. We did not have any sales of our C-Pulse System device in the six month periods ended June 30, 2012 or 2011, as we completed enrollment in our feasibility trial in early 2011 and have not yet commenced enrollment in our pivotal clinical trial. We expect our revenue will be minimal until we begin enrolling patients in our North American pivotal clinical trial and initiate trials in select countries in Europe under our CE Mark, both expected to commence in the second half of 2012.

Research and Development Expense

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 3,953,000	$ 4,666,000	$ (713,000)	(15.3)%

Our decrease in research and development expense for the six months ended June 30, 2012 compared to the prior year's period was primarily caused by the timing of certain outsourced development activities related to our C-Pulse System period to period. We expect our research and development expense will continue to be lower than the comparable prior year period in the third quarter 2012, then sequentially increase as we add personnel to support our pivotal clinical trial and pursue our development efforts.

Selling, General and Administrative Expense

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 3,509,000	$ 1,820,000	$ 1,689,000	92.8%

Our increase in selling, general and administrative expense for the six months ended June 30, 2012 compared to the prior year was primarily caused by increased stock-based compensation expense resulting from current-year stock option grants, and increased professional fees and personnel additions in 2011 as we developed our infrastructure and prepared for our Nasdaq listing completed in February 2012, and in preparation for European trials expected to commence in the second half of 2012. We expect our selling, general and administrative expense will continue to be above comparable prior year period levels in future periods as a result of the infrastructure recently put in place to support our growth.

Interest Income

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ 29,000	$ 197,000	$ (168,000)	(85.3)%

Our decrease in interest income for the six months ended June 30, 2012 compared to the prior year was primarily caused by lower average cash balances during the six months ended June 30, 2012 as compared to the six months ended June 30, 2011.

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Income Tax Benefit

Six Months Ended June 30, 2012	Six Months Ended June 30, 2011	Increase (Decrease)	% Change
$ (730,000)	$ —	$ (730,000)	N/A

Our income tax benefit for the six months ended June 30, 2012 resulted from a research and development tax credit in Australia. We completed our Australian tax return for the twelve-month period ended June 30, 2011 in the second quarter of 2012 and received a $730,000 research and development tax credit refund during the quarter. Assuming no further changes to the applicable Australian law for research and development tax credits, we expect to receive tax refunds in the future in amounts that vary based on research and development expenditures in Australia. At this time, we are working to complete our analysis of the potential research and development tax credit refund that may be available for the period ended June 30, 2012.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through a series of equity issuances, including the issuance of common shares in the form of CDIs for net proceeds of $7.6 million in 2011, $11.9 million in 2010 and $2.1 million in the six months ended June 30, 2012. As of June 30, 2012 and December 31, 2011 and 2010, cash and cash equivalents were $1.8 million, $6.6 million, and $12.4 million, respectively.

On July 17, 2012, we filed a registration statement on Form S-1 with the SEC for a public offering of our common stock for proceeds of up to $28.75 million before related commissions and expenses. We expect to complete the offering in the third quarter 2012 and use the net proceeds to fund our pivotal clinical trial and our operations.

We believe, based on our current operating plan, that the net proceeds from our public offering, together with our cash balances, cash generated from our clinical trial and interest income, will be sufficient to meet our anticipated cash requirements through at least the next 12 months. From time to time we may seek to sell additional equity or convertible debt securities or enter into credit facilities. The sale of additional equity or convertible debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible debt or enter into credit facilities, these securities and debt holders could have rights senior to those of our common stock, and this debt could contain covenants that would restrict our operations and would require us to use cash for debt service rather than our operations. We may require additional capital beyond our currently forecasted amounts. Although we

have successfully financed our operations through the issuance of common stock and warrants to date, any such required additional capital may not be available to us on acceptable terms, or at all.

Cash Flows from Operating Activities

Net cash used in operating activities was $13.1 million in 2011, $7.2 million in 2010, and $6.8 million and $6.2 million in the six months ended June 30, 2012 and 2011, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by depreciation, and stock-based compensation and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $451,000 in 2011, $7,000 in 2010, and $107,000 and $43,000 in the six months ended June 30, 2012 and 2011, respectively. The majority of cash used in investing activities in first half of 2012 and in 2011 was for leasehold improvements, furniture and equipment associated with the relocation of our headquarters. Cash used in investing activities in the first half of 2011 and in 2010 related to purchases of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $7.6 million in 2011, $11.9 million in 2010, and $2.1 million and $183,000 in the six months ended June 30, 2012 and 2011, respectively. Net cash provided by financing activities was primarily attributable to proceeds from sales of our common stock and warrants.

Capital Resource Requirements

As of June 30, 2012, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

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Forward-Looking Statements and Risk Factors

This report contains forward-looking statements. In some cases, you can identify forward-looking statements by the following words: “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are not a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time the statements are made and involve known and unknown risks, uncertainties and other factors that may cause our results, levels of activity, performance or achievements to be materially different from the information expressed or implied by the forward-looking statements in this report. These factors include:

- our ability to obtain additional financing;
- our dependence on a single product candidate;
- the cost, timing and results of our clinical trials, regulatory submissions and approvals;
- our dependence on a single or limited number of manufacturers and suppliers for critical components of our system;
- our ability to effectively manage our expected growth;
- our ability to develop sales, marketing and distribution capabilities;
- commercial acceptance of our system, if approved for sales and marketing;
- our estimates regarding our capital requirements and our need for additional financing;
- our ability to obtain adequate reimbursement from governments or other third-party payors;
- regulatory risks affecting us;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights or that our system is defective;
- our ability to protect and enforce our intellectual property rights; and
- other risk factors included under “Risk Factors” in our SEC and ASX filings and in this report.

You should read the matters described in “Risk Factors” and the other cautionary statements made in this report as being applicable to all related forward-looking statements wherever they appear in this report. We cannot assure you that the forward-looking statements in this report will prove to be accurate and therefore you are encouraged not to place undue reliance on forward-looking statements. You should read this report completely. Other than as required by law, we undertake no obligation to update or revise these forward-looking statements, even though our situation may change in the future.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of June 30, 2012, to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and (ii) accumulated and communicated to the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely

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decisions regarding required disclosure.

Changes in Internal Controls

There have been no changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the period covered by this report that have materially affected, or are reasonably likely to materially affect, internal control over financial reporting.

PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

This report describes various risks and uncertainties to which the Company is or may become subject. The risks described in this report are not the only risks facing the Company. Although we are not aware of any other facts that we currently anticipate will cause our forward-looking statements to differ materially from our future actual results or materially affect the Company's financial condition or future results, additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might also materially adversely affect our financial condition or future results.

Risks Relating to Our Business

We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses for the foreseeable future.

We are an early-stage company with a history of incurring net losses. We have incurred net losses since our inception, including net losses of $16.2 million and $7.6 million for the years ended December 31, 2011 and 2010, respectively, and $6.7 million for the six months ended June 30, 2012. As of June 30, 2012, our accumulated deficit was $71.9 million. We do not have any products that have been approved for marketing in the United States, we have not established any sales capability outside of the United States, and we continue to incur research and development and general and administrative expenses related to our operations. We expect to continue to incur significant and increasing operating losses for the foreseeable future as we incur costs associated with the conduct of clinical trials, continue our research and development programs, seek regulatory approvals, expand our sales and marketing capabilities, increase manufacturing of our system and comply with the requirements related to being a U.S. public company listed on the ASX and the Nasdaq Capital Market. To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to succeed in a range of challenging activities, including conducting clinical trials, obtaining regulatory approvals, manufacturing products and marketing and selling commercial products. There can be no assurance that we will succeed in these activities, and we may never generate revenues sufficient to achieve profitability. If we do achieve profitability, we may not be able to sustain it.

We will need additional funding to continue operations, which may not be available to us on favorable terms or at all.

We have no products currently available for commercial sale, and to date we have generated only limited revenue from our feasibility study. In addition, the report of our independent registered public accounting firm includes an explanatory paragraph with regard to our ability to continue as a going concern in connection with its audit of our financial statements for the fiscal year ended December 31, 2011. We expect to continue to incur significant and increasing operating losses for the foreseeable future as we incur costs associated with the conduct of clinical trials, continue our research and development programs, seek regulatory approvals, expand our sales and marketing capabilities, increase manufacturing of our system and comply with the requirements related to being a U.S. public company listed on the ASX and the Nasdaq Capital Market. Additional funding will likely be needed even if we complete a public offering and may not be available on terms favorable to us, or at all. If we raise additional funding through the issuance of equity securities, our stockholders may suffer dilution and our ability to use our net operating losses to offset future income may be limited. If we raise additional funding through debt financing, we may be required to accept terms that restrict our ability to incur additional indebtedness, require us to use our cash to make payments under such indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions. If we are unable to secure additional funding, our development programs and our commercialization efforts would be delayed, reduced or eliminated, our relationships with our suppliers and manufacturers may be harmed, and we may not be able to continue our operations.

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Our near-term prospects are highly dependent on the development of a single product, our C-Pulse System. If we fail to obtain the regulatory approvals necessary to sell the C-Pulse System or fail to successfully commercialize this system, our business and prospects would be harmed significantly.

Our near-term prospects are highly dependent on the development of a single product, our C-Pulse System, and we have no other product candidates in active development at this time. We are in the process of pursuing regulatory approvals necessary to sell our system in the United States. We completed

enrollment of our North American feasibility clinical trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an IDE application. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. We expect to complete enrollment of our pivotal trial by the end of 2015 and do not anticipate marketing our system in the United States before 2017.

There can be no assurance that we will be able to obtain the regulatory approvals necessary to sell our system. In addition, even if we obtain such regulatory approvals, there can be no assurance that we will be able to successfully commercialize our system. If we fail to obtain the regulatory approvals necessary to sell our system or fail to successfully commercialize our system, our business and prospects would be harmed significantly.

We currently have no sales, marketing or distribution operations and will need to expand our expertise in these areas.

We currently have no sales, marketing or distribution operations and, in connection with the expected commercialization of our system, will need to expand our expertise in these areas. To increase internal sales, distribution and marketing expertise and be able to conduct these operations, we would have to invest significant amounts of financial and management resources. In developing these functions ourselves, we could face a number of risks, including:

- we may not be able to attract and build an effective marketing or sales force;
- the cost of establishing, training and providing regulatory oversight for a marketing or sales force may be substantial; and
- there are significant legal and regulatory risks in medical device marketing and sales that we have never faced, and any failure to comply with applicable legal and regulatory requirements for sales, marketing and distribution could result in an enforcement action by the FDA, European regulators or other authorities that could jeopardize our ability to market the system or could subject us to substantial liability.

We plan to commercialize our system outside of the United States, which will expose us to risks associated with international operations.

We plan to commercialize our system outside of the United States and expect to commence clinical trials in certain European countries in addition to the United States. Conducting international operations subjects us to risks, including:

- costs of complying with varying regulatory requirements and potential, unexpected changes to those requirements;
- fluctuations in and management of currency exchange rates;
- potentially adverse tax consequences, including the complexities of foreign value added tax systems and restrictions on the repatriation of earnings;
- government-imposed pricing controls on sales of our system;
- longer payment cycles and difficulties in collecting accounts receivable;
- difficulties in managing and staffing international operations;
- the burdens of complying with a wide variety of non-U.S. laws and legal standards;
- increased financial accounting and reporting burdens and complexities; and
- reduced or varied protection for intellectual property rights in some countries.

The occurrence of any one of these risks could negatively affect our international operations. Additionally, operating in international markets also requires significant management attention and financial resources. We cannot be certain that our

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operations in other countries will produce desired levels of revenues or profitability.

We depend on a limited number of manufacturers and suppliers of various critical components for our C-Pulse System. The loss of any of these manufacturer or supplier relationships could delay future clinical trials or prevent or delay commercialization of our C-Pulse System.

We rely entirely on third parties to manufacture our C-Pulse System and to supply us with all of the critical components of our C-Pulse System, including the balloon, driver, cuff and interface lead. We primarily purchase our components and products on a purchase order basis and do not “second source” any components of our system. If one or more of the suppliers of the components used in our system were unable or unwilling to meet our demand for such components or faced financial or business difficulties in general, or if the components or finished products provided by any of our suppliers do not meet quality and other specifications, clinical trials or commercialization of our system could be delayed and our expenses could increase. Moreover, if any of the suppliers were unable or unwilling to perform, we would be required to find alternative sources for the components provided by such supplier, and there can be no assurance that we would be able to find a replacement supplier on a timely basis, or at all. In particular, the balloon used in our system is highly specialized and is currently solely available from a single supplier. If the manufacturer of the balloon were unable or unwilling to supply this component for any reason, we would have to locate and qualify another supplier and such supplier and its balloon product would have to be qualified with the FDA. Since there is currently no other supplier in the industry, locating and qualifying another supplier could cause significant production delays, causing us to lose revenues and market share and to potentially suffer increased costs and damage to our reputation. Additionally, even if we are able to find a replacement supplier of any of the components used in our system, we may face additional regulatory delays, and the manufacture and delivery of our C-Pulse System could be interrupted for an extended period of time and become significantly more expensive. This could delay completion of future clinical trials or commercialization of our C-Pulse System and adversely affect our results of operations. In addition, we may be required to use different suppliers or components to obtain regulatory approval from the FDA.

If our manufacturers or our suppliers are unable to provide an adequate supply of our system following the start of commercialization, our growth could be limited and our business could be harmed.

In order to produce our C-Pulse System in the quantities that we anticipate will be required to meet market demand, we will need our manufacturers to increase, or scale-up, the production process by a significant factor over the current level of production. There are technical challenges to scaling-up manufacturing capacity and developing commercial-scale manufacturing facilities that may require the investment of substantial additional funds by our manufacturers and hiring and retaining additional management and technical personnel who have the necessary manufacturing experience. If our manufacturers are unable to do so, we may not be able to meet the requirements for the launch of the system or to meet future demand, if at all. We also may represent only a small portion of our supplier's or manufacturer's business, and if they become capacity constrained they may choose to allocate their available resources to other customers that represent a larger portion of their business. We currently anticipate that we will continue to rely on third-party manufacturers and suppliers for the production of our C-Pulse System following commercialization. If we develop and obtain regulatory approval for our system and are unable to obtain a sufficient supply of our system, our revenue, business and financial prospects would be adversely affected.

If we are unable to manage our expected growth, we may not be able to commercialize our system.

We have expanded, and expect to continue to expand, our operations and grow our research and development, product development, regulatory, manufacturing, sales, marketing and administrative operations. This expansion has placed, and is expected to continue to place, a significant strain on our management and operational and financial resources. To manage any further growth and to commercialize our system, we will be required to improve existing and implement new operational and financial systems, procedures and controls and expand, train and manage our growing employee base. In addition, we will need to manage relationships with various manufacturers, suppliers and other organizations. Our ability to manage our operations and growth will require us to improve our operational, financial and management controls, as well as our internal reporting systems and controls. We may not be able to implement such improvements to our management information and internal control systems in an efficient and timely manner and may discover deficiencies in existing systems and controls. Our failure to accomplish any of these tasks could materially harm our business.

We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include:

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- the time and resources required to develop, conduct clinical studies and obtain regulatory approvals for the products we develop;
- the expenses we incur for the research and development required to maintain and improve our system;
- the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation;
- the expenses we incur in connection with commercialization activities, including marketing, sales and distribution;
- our sales strategy and whether the revenues from sales of our system will be sufficient to offset our expenses;
- the costs to attract and retain personnel with the skills required for effective operations; and
- the costs associated with being a public company.

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of our C-Pulse System. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected shortfall in revenue. Accordingly, a significant shortfall in demand for our system could have an immediate and material impact on our business and financial condition.

We compete against many companies, some of which have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.

Competition from medical device companies and medical device divisions of health care companies, as well as pharmaceutical companies and gene- and cell-based therapies is intense and is expected to increase. Our system will compete against therapies, including pharmacological therapies, as well as other medical device competitors that treat or may treat in the future Class III or ambulatory Class IV heart failure patients, including AbioMed, Inc., Berlin Heart GmbH, CardioKinetix, Inc., CircuLite, Inc., HeartWare International Inc., Jarvik Heart, Inc., MicroMed Technology, Inc., SynCardia Systems, Inc., Terumo Heart, Inc. and Thoratec Corporation, as well as a range of other specialized medical device companies with devices at varying stages of development. Some of these competitors have significantly greater financial and human resources than we do and have established reputations, as well as worldwide distribution channels and sales and marketing capabilities that are larger and more established than ours. Additional competitors may enter the market, and we are likely to compete with new companies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could harm our business.

Our ability to compete effectively depends upon our ability to distinguish our company and our system from our competitors and their products. Factors affecting our competitive position include:

- financial resources;
- product performance and design;
- product safety;

- acceptance of our system in the marketplace;
- sales, marketing and distribution capabilities;
- manufacturing and assembly costs;
- pricing of our system and of our competitors' products;
- the availability of reimbursement from government and private health insurers;
- success and timing of new product development and introductions;

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- regulatory approvals in the United States; and
- intellectual property protection.

The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial personnel. We face intense competition for such personnel, and we may not be able to attract, retain and motivate these individuals. We compete for talent with numerous companies, as well as universities and nonprofit research organizations. Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations and maintain a cohesive and stable environment. We do not maintain key man life insurance on the lives of any of the members of our senior management. The loss of key personnel for any reason or our inability to hire, retain and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

Product defects could harm our results of operations.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of a product or inadequate disclosure of risks relating to the use of the product can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to a product (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. Any recall of our system could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our system. Personal injuries relating to the use of our system could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals. Any one of these factors could substantially harm our business and results of operations.

We may be sued for product liability, which could adversely affect our business.

The design, manufacture and marketing of medical devices carries a significant risk of product liability claims. Our system treats Class III and ambulatory Class IV heart failure for patients who typically have serious medical issues. As a result, our exposure to product liability claims may be heightened because the people who use our system have a high risk of suffering adverse outcomes, regardless of the safety or efficacy of our system. In addition, because our system has been implanted in a limited number of patients to date, we cannot assure you that we are currently aware of all material risks related to use of our system or that could lead to products liability claims against us.

We may be held liable if any product we develop and commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. The safety studies we must perform and the regulatory approvals required to commercialize our system will not protect us from any such liability. We carry product liability insurance with a $10 million aggregate limit. However, if there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any of our approved products. If such insurance is insufficient to protect us, our results of operations will be harmed. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. Even if a product liability claim against us is without merit or if we are not found liable for any damages, a product liability claim could result in decreased demand for our system, injury to our reputation, diversion of management's attention from operating our business, withdrawal of clinical trial participants, significant costs of related litigation, loss of revenue or the inability to commercialize the C-Pulse System.

Risks Relating to Regulation

We do not have FDA approval for our system and our success will depend heavily on the success of our pivotal trial for our C-Pulse System. Any failure or significant delay in successfully completing our pivotal trial or obtaining regulatory approvals could harm our financial results and our prospects and require us to seek additional funding.

Upon completion of the six-month follow-up period for our feasibility trial, we submitted the trial's clinical data to the FDA in November 2011. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. Completion of the pivotal trial could be delayed, and adverse events during the trial could cause us to modify the existing design, repeat or terminate the trial. If the trial is delayed, if it must be repeated or if it is terminated, our costs associated with the trial will increase, and it will take us longer to obtain regulatory approvals and commercialize the C-Pulse System, if we are able to do so at all. Our pivotal trial also may be suspended or terminated at any time by

regulatory authorities or by us. FDA scrutiny of IDE applications has intensified in recent years, increasing the risk of delay or failure.

If we commence and complete our pivotal clinical trial, we must demonstrate the safety and efficacy of the C-Pulse System by meeting the trial's endpoints before we can commercialize the C-Pulse System in the United States. Our inability to achieve the safety or efficacy endpoints in the pivotal trial could delay our timeline for obtaining regulatory approval to commercialize our system or prevent us from obtaining such regulatory approval altogether.

In addition to successfully completing our pivotal trial, we will need to receive approval from regulatory agencies in each country in which we seek to sell our system. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval varies from country to country and approval in one country does not ensure regulatory approval in another. In addition, a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. We cannot assure you when, or if, we will be able to commence sales in any jurisdiction within or outside the United States.

If we are unable to complete our pivotal trial, or experience significant delays in the trial, or if the results of the trial do not meet its safety and efficacy endpoints, our ability to obtain regulatory approval to commercialize our system and to generate revenues will be harmed.

Even if we obtain foreign regulatory approvals, we will need to obtain FDA approval to commercialize our system in the United States.

Even if we obtain foreign regulatory approvals, we will need to obtain FDA approval to commercialize our system in the United States, which will require us to receive FDA approval to conduct clinical trials in the United States and to complete those trials successfully. If we fail to obtain approval from the FDA, we will not be able to market and sell our system in the United States. We do not currently have the necessary regulatory approvals to commercialize our C-Pulse System in the United States, which we believe is the largest potential market for our C-Pulse System. We can offer no assurance that our IDE application will be approved, that our clinical trials will be successful or that we will ever obtain FDA approval of the C-Pulse System or any future products.

In order to obtain FDA approval for our C-Pulse System, we will be required to receive a Premarket Approval, or PMA, from the FDA. A PMA must be supported by pre-clinical and clinical trials to demonstrate safety and efficacy. A clinical trial will be required to support an application for a PMA, and we will be seeking FDA approval of our IDE application that will allow us to commence a clinical trial in the United States. We intend to commence our U.S. pivotal trial in 2012, but there can be no assurance that our U.S. pivotal trial will begin or be completed on schedule or at all. Even if completed, we do not know if this trial will meet its objectives or end-points to show the safety and efficacy of our system so as to support an application for a PMA.

The process of obtaining a PMA from the FDA for our C-Pulse System, or any future products or enhancements or modifications to any products, could:

- take a significant period of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing;
- require changes to the product; and
- result in failure to support approval of the product or limitations on the indicated uses of the product.

Increased attention to safety and oversight issues in light of recent, widely publicized events concerning the safety of certain food, drug and medical device products could cause the FDA to take a more cautious approach in connection with approvals for devices such as ours, which could delay or prevent FDA approval of our C-Pulse System.

There can be no assurance that we will receive the required approvals from the FDA or, if we do receive the required approvals, that we will receive them on a timely basis. The failure to receive product approval by the FDA would significantly harm our business, financial condition or results of operations.

We may be unable to enroll and complete our planned U.S. pivotal trial for the C-Pulse System or other clinical trials, which could prevent or delay regulatory approval of the C-Pulse System and impair our financial position.

We intend to commence our U.S. pivotal trial in 2012. The trial will be designed to be a randomized trial that includes approximately 380 patients and is expected to involve approximately 40 sites. Conducting a clinical trial of this size is a complex and uncertain process.

The commencement of our trial could be delayed for a variety of reasons, including:

- reaching agreement on acceptable terms with prospective clinical trial sites;
- manufacturing sufficient quantities of our C-Pulse System;
- obtaining institutional review board approval to conduct the trial at a prospective site; and
- obtaining sufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the trial.

Once the trial has begun, the completion of the trial, and our other ongoing clinical trials, could be delayed, suspended or terminated for several reasons, including:

- ongoing discussions with regulatory authorities regarding the scope or design of our preclinical results or clinical trial or requests for supplemental information with respect to our preclinical results or clinical trial results;
- our failure or inability to conduct the clinical trials in accordance with regulatory requirements;
- sites currently participating in the trial may drop out of the trial, which may require us to engage new sites or petition the FDA for an expansion of the number of sites that are permitted to be involved in the trial;
- patients may not achieve the required clinical end-points of the trial;
- patients may not remain in or complete clinical trials at the rates we expect;
- patients may experience serious adverse events or side effects during the trial, which, whether or not related to our system, could cause the FDA or other regulatory authorities to place the clinical trial on hold; and
- clinical investigators may not perform clinical trials on our anticipated schedule or consistent with the clinical trial protocol and good clinical practice requirements.

If our pivotal trial is delayed, it will take us longer to ultimately commercialize a product or the delay could result in our being unable to do so. Our development costs will also increase if we have material delays in our pivotal trial or if we need to perform more or larger clinical trials than planned. Moreover, there can be no assurance that we will be able to successfully complete, or achieve the desired clinical end-points from, our pivotal trial at all, which could prevent us from receiving regulatory approval for the C-Pulse System altogether. Any of the foregoing could harm our financial results and our prospects and cause us to seek additional funding.

We depend on clinical investigators and clinical sites to enroll patients in our clinical trials, and on other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.

We have and plan to continue to rely on clinical investigators and clinical sites to enroll patients in our clinical trials, including our planned U.S. pivotal trial, and other third parties to manage the trials and to perform related data collection and analysis. However, we have limited oversight over these entities and cannot control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials, to ensure compliance by patients with clinical protocols or comply with regulatory requirements, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for our system. Our agreements with clinical investigators and clinical trial sites for clinical testing place substantial responsibilities

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on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, or the clinical data may be rejected by the FDA, and we may be unable to obtain regulatory approval for, or successfully commercialize, our system.

Our manufacturers and suppliers might not meet regulatory quality standards applicable to manufacturing and quality processes, which could harm our financial results and prospects.

Even if our system receives marketing approval, product approvals by the FDA can be withdrawn due to failure to comply with regulatory standards. We rely entirely on third parties to manufacture our C-Pulse System and those manufacturers are required to demonstrate and maintain compliance with the FDA's Quality System Regulation, or QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our system. The FDA enforces the QSR through periodic unannounced inspections. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. A failure by our manufacturers to comply with the QSR or to take satisfactory corrective action in response to an adverse QSR inspection could cause a significant delay in our ability to have our system manufactured and to complete our clinical trials and could significantly increase our costs, which would harm our financial results and our prospects. In addition, suppliers of components of, and products used to manufacture, our system must also comply with FDA and foreign regulatory requirements, which often require significant time, money and record-keeping and quality assurance efforts and subject us and our suppliers to potential regulatory inspections and stoppages.

We plan to operate in multiple regulatory environments that require costly and time consuming approvals.

Even if we obtain regulatory approvals to commercialize the C-Pulse System or any other product that we may develop, sales of our system in other jurisdictions will be subject to regulatory requirements that vary from country to country. The time and cost required to obtain approvals from these countries may be longer or shorter than that required for FDA approval, and requirements for licensing may differ from those of the FDA. Laws and regulations regarding the manufacture and sale of our system are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable foreign, federal, state or local market laws or regulations or administrative interpretations and policies of regulatory agencies, we could be precluded from commercializing our system in those countries and could become subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals and civil and criminal penalties, which in each case would harm our business.

The C-Pulse System may never achieve market acceptance even if we obtain regulatory approvals.

Even if we obtain regulatory approvals to commercialize the C-Pulse System or any other product that we may develop, our products may not gain market acceptance among physicians, patients, third-party health care payors or the medical community. The degree of market acceptance of any of the devices that we may develop will depend on a number of factors, including:

- the perceived effectiveness and price of the product;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

If our C-Pulse System, or any other product that we may develop, is approved but does not achieve an adequate level of acceptance by physicians, patients, third-party health care payors and the medical community, we may not generate product revenue and we may not become profitable or be able to sustain profitability.

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If we fail to obtain an adequate level of reimbursement for our system by third-party payors, there may be no commercially viable markets for our system or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payors significantly affect the market for our system. Reimbursement by third-party payors in the United States typically is based on the device's perceived benefit and whether it is deemed medically reasonable and necessary. Reimbursement levels of third-party payors in the United States are also based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed. We cannot assure you the level of reimbursement we might obtain in the United States, if any, for our system. If we do not obtain adequate levels of reimbursement for our system by third-party payors in the United States, which we believe is largest potential market for our system, our financial condition, results of operations and prospects would be harmed.

Reimbursement and health care payment systems in international markets vary significantly by country, and include both government-sponsored health care and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce additional clinical data, which may involve one or more additional clinical trials, that compares the cost-effectiveness of our system to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our system in the international markets in which those approvals are sought.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for the C-Pulse System and limit our ability to sell the C-Pulse System or any future products on a profitable basis. In addition, third-party payors continually attempt to contain or reduce the costs of health care by challenging the prices charged for health care products and services. If reimbursement for our system is unavailable in any market or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our system would be significantly impaired and our future revenues, if any, would be significantly harmed.

We may be subject, directly or indirectly, to U.S. federal and state health care fraud and abuse and false claims laws and regulations. Prosecutions under such laws have increased in recent years and we may become subject to such litigation. If we are unable to, or have not fully complied with such laws, we could face substantial penalties.

If we are successful in achieving regulatory approval to market our C-Pulse System, our operations will be directly, or indirectly through our customers and health care professionals, subject to various U.S. federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, federal False Claims Act, and federal Foreign Corrupt Practices Act, or the FCPA. These laws may impact, among other things, our proposed sales, and marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal health care program such as the Medicare and Medicaid programs. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the statute has been violated. The Anti-Kickback Statute is broad and, despite a series of narrow safe harbors, prohibits many arrangements and practices that are lawful in businesses outside of the health care industry. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil and administrative sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal health care programs. An alleged violation of the Anti-Kickback Statute may be used as a predicate offense to establish liability pursuant to other federal laws and regulations such as the federal False Claims Act. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for health care items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Suits filed under the False Claims Act, known as "*qui tam*" actions, can be brought by any individual on behalf of the government and such individuals, commonly known as "relators" or "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of medical device, pharmaceutical and health care companies to have to defend a False Claim Act action. The federal Patient Protection and Affordable Care Act includes provisions expanding the ability of certain relators to bring actions that would have been previously dismissed under prior law. When an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. The Deficit Reduction Act of 2005 encouraged states to enact or modify their state false claims act to

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be at least as effective as the federal False Claims Act by granting states a portion of any federal Medicaid funds recovered through Medicaid-related actions. Most states have enacted state false claims laws, and many of those states included laws including *qui tam* provisions. States have until March 31, 2013 to enact or amend their false claims laws modeled after the federal False Claims Act for review and approval to receive a greater portion of any recovery.

The federal Patient Protection and Affordable Care Act includes provisions known as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid starting in 2012 to record any transfers of value to physicians and teaching hospitals and to report this data beginning in 2013 to the Centers for Medicare and Medicaid Services for subsequent public disclosure. Manufacturers must also disclose investment interests held by physicians and their family members. Failure to submit the required information may result in civil monetary penalties of up to $1 million per year for knowing violations and may result in liability under other federal laws or regulations. Similar reporting requirements have also been enacted on the state level in the United States, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. In addition, some states such as Massachusetts and Vermont impose an outright ban on certain gifts to physicians. If we receive FDA clearance to market our system in the United States, these laws could affect our promotional activities by limiting the kinds of interactions we could have with hospitals, physicians or other potential purchasers or users of our system. Both the disclosure laws and gift bans will impose administrative, cost and compliance burdens on us.

We are unable to predict whether we could be subject to actions under any of these laws, or the impact of such actions. If we are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, or an administrative action of suspension or exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations.

In addition, to the extent we commence commercial operations overseas, we will be subject to the FCPA and other countries' anti-corruption/anti-bribery regimes, such as the U.K. Bribery Act. The FCPA prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, sales agents or distributors may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

Risks Relating to our Intellectual Property

We may not be able to protect our intellectual property rights effectively, which could have an adverse effect on our business, financial condition or results of operations.

Our success depends in part on our ability to obtain and maintain protection in the United States and other countries of the intellectual property relating to or incorporated into our technology and system. As of June 30, 2012, we owned 12 issued patents in the United States and 8 patent applications in the United States, as well as 23 issued patents and 15 patent applications in foreign jurisdictions. We estimate that the U.S. patents expire between approximately 2020 and 2024. Our pending and future patent applications may not issue as patents or, if issued, may not issue in a form that will provide us any competitive advantage. Even if issued, existing or future patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of terms of patent protection we may have for our system. Changes in patent laws or their interpretation in the United States and other countries could also diminish the value of our intellectual property or narrow the scope of our patent protection. In addition, the legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. In order to preserve and enforce our patent and other intellectual property rights, we may need to make claims or file lawsuits against third parties. This can entail significant costs to us and divert our management's attention from developing and commercializing our system.

Intellectual property litigation could be costly and disruptive to us.

In recent years, there has been significant litigation involving medical device patents and other intellectual property rights. From time to time, third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in our business. Any claims, with or without merit, could be time-consuming, result in costly litigation, divert the efforts of our technical and management personnel or require us to pay substantial damages. If we are

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unsuccessful in defending ourselves against these types of claims, we may be required to do one or more of the following:

- stop clinical trials or delay or abandon commercialization of our system;
- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or
- redesign our system.

In the event a claim against us was successful and we could not obtain a license to the relevant technology on acceptable terms or license a substitute technology or redesign our system to avoid infringement, our business would be significantly harmed.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and system could be adversely affected.

In addition to patented technology, we rely on our unpatented proprietary technology, trade secrets, processes and know-how. We generally seek to protect this information by confidentiality agreements with our employees, consultants, scientific advisors and third parties. These agreements may be breached, and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently developed by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Our system could infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our system.

Our commercial success depends on our ability to develop, manufacture and market our system and technology without infringing the patents and other proprietary rights of third parties. As our industry expands and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our system and technologies of which we are not aware or that we must challenge to continue our operations as currently contemplated. Our system may infringe or may be alleged to infringe these patents.

In addition, some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Another party may have filed, and may in the future file, patent applications covering our system or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in our industry, we employ individuals who were previously employed at other medical device companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risk Factors Related to Ownership of Our Common Stock

An active trading market for our shares of common stock in the United States may not develop.

Our common stock has been listed for trading on the Nasdaq Capital Market only since February 16, 2012 and has experienced limited trading volume. Our common stock has been listed on the ASX in the form of CDIs since 2004 and has

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also experienced limited trading volume on that exchange. The average daily trading volume in our common stock on the Nasdaq Capital Market for the three-month period ended June 30, 2012 was approximately 950 shares. The reported average daily trading volume in our common stock on the ASX for the three-month period ended June 30, 2012, was approximately 430,591 CDIs (equivalent to approximately 2,513 shares). There can be no assurance that an active public market for our shares will continue to develop in the United States. If an active trading market does not continue to develop in the United States, the market price and liquidity of shares of our common stock would be adversely affected.

Future sales of our common stock could cause our stock price to decline.

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that we or our stockholders might sell shares of our common stock or CDIs could also depress the market price of our common stock. A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

We also plan to file with the SEC registration statements on Form S-8 covering approximately 1 million shares of our common stock issuable under our equity plans. Once registered with the SEC, these shares of common stock would be freely tradable in the United States when issued pursuant to our equity plans and the related award agreements. In addition, we may sell additional shares of common stock in subsequent offerings to raise additional funding.

The price of our common stock may fluctuate significantly.

Our common stock has been traded on the Nasdaq Capital Market since February 16, 2012 and on the ASX in the form of CDIs since 2004. The price of our common stock has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. For example, the per share price of our common stock traded on the Nasdaq Capital Market ranged from $2.50 to $22.90 from February 16, 2012 to June 30, 2012. Our CDI closing price on the ASX ranged from A$0.020 (equivalent to approximately $4.09 per share using a conversion rate of A$1 to $1.0231) to A$0.055 (equivalent to approximately $11.25 per share using a conversion rate of A$1 to $1.0231) for the six months ended June 30, 2012. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;
- regulatory developments, disclosure regarding completed, ongoing or future clinical trials and enforcement actions bearing on advertising, marketing or sales;
- reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports;
- introduction of new products;
- acquisition or loss of significant manufacturers, distributors or suppliers or an inability to obtain sufficient quantities of materials needed to manufacture our system;

- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- business acquisitions or divestitures;
- changes in governmental or third-party reimbursement practices;
- fluctuations of investor interest in the medical device sector; and
- fluctuations in the economy, world political events or general market conditions.

In addition, stock markets in general and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years, fluctuations that frequently have been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our

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shares may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

Our directors and executive officers hold substantial control over us and could limit your ability to influence the outcome of key transactions, including changes of control.

As of June 30, 2012, our executive officers and directors and entities affiliated with them beneficially owned, in the aggregate (including options or warrants exercisable currently or within 60 days of June 30, 2012), approximately 52.0% of our outstanding common stock. Our executive officers, directors and affiliated entities, if acting together, would be able to control all matters requiring approval by our stockholders, including the election of directors and the approval of mergers, financings or other significant corporate transactions. The concentration of ownership of our common stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our stockholders and CDI holders of an opportunity to receive a premium for their common stock and CDIs as part of a sale of our company and may affect the market price of our common stock and CDIs. This significant concentration of stock ownership may adversely affect the trading price of our common stock and CDIs due to investors' perception that conflicts of interest may exist or arise.

Our ability to use U.S. net operating loss carryforwards or Australian tax losses might be limited.

As of December 31, 2011, we had U.S. net operating loss carryforwards of approximately $14.6 million for U.S. income tax purposes, which expire in 2023 through 2031. To the extent these net operating loss carryforwards are available, we intend to use them to reduce any corporate income tax liability associated with our operations we might have in the future. Section 382 of the U.S. Internal Revenue Code generally imposes an annual limitation on the amount of net operating loss carryforwards that might be used to offset taxable income when a corporation has undergone significant changes in stock ownership. As a result, prior or future changes in ownership could put limitations on the availability of our U.S. net operating loss carryforwards. In addition, our ability to utilize the current net operating loss carryforwards might be further limited by the issuance of common stock in any future public offerings.

As of December 31, 2011, we had tax losses in the Commonwealth of Australia of approximately $54.1 million. Continuing utilization of carry forward tax losses in Australia may also be affected by the issuance of our common stock in any public offerings that we conduct. This is because one test for carrying forward tax losses in Australia from year to year requires continuity of ultimate ownership (subject to the relevant tests in the Australian tax law) of more than 50% between the loss year and the income year in which the loss is claimed.

To the extent our use of our net operating loss carryforwards or tax losses is limited, our income could be subject to corporate income tax earlier than it would if we were able to use net operating loss carryforwards, which could result in lower profits.

We may be subject to arbitrage risks.

Investors may seek to profit by exploiting the difference, if any, between the price of our CDIs on the ASX and the price of shares of our common stock on the Nasdaq Capital Market. Such arbitrage activities could cause our share price in the market with the higher value to decrease to the price set by the market with the lower value and could also lead to significant volatility in the price of our common stock.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We have never declared or paid any cash dividends on our common stock, and we currently do not anticipate paying any cash dividends in the foreseeable future. We intend to retain any earnings to finance the development and expansion of our products and business. Accordingly, our stockholders and CDI holders will not realize a return on their investment unless the trading price of our common stock and CDIs appreciate.

We will continue incur increased costs as a result of being a U.S. reporting company and we have limited experience as a U.S. reporting company.

In connection with the effectiveness of our registration statement on Form 10, as of February 14, 2012, we became subject to the periodic reporting requirements of the Exchange Act. Although we have been listed on the ASX for several years and have been required to file financial information and make certain other filings with the ASX, our status as a U.S. reporting company under the Exchange Act has caused us to incur additional legal, accounting and other expenses that we did not previously incur, including costs related to compliance with the requirements of the Sarbanes-Oxley Act of 2002 and the listing requirements of the Nasdaq Capital Market. We expect these rules and regulations will continue to increase our

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legal and financial compliance costs and to make some activities more time-consuming and costly, and these activities may increase general and administrative expenses and divert management's time and attention away from revenue-generating activities. We also expect these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers.

Investors could lose confidence in our financial reports, and the value of our common stock may be adversely affected, if our internal controls over financial reporting are found not to be effective by management or by an independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

In connection with becoming a company required to file reports with the SEC, we are required to comply with the internal control evaluation and certification requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" as defined in the JOBS Act or a "smaller reporting company" as defined by applicable SEC rules.

We continue to evaluate our existing internal controls over financial reporting against the standards adopted by the Public Company Accounting Oversight Board. During the course of our ongoing evaluation of the internal controls, we may identify areas requiring improvement, and may have to design enhanced processes and controls to address issues identified through this review. Remediating any deficiencies, significant deficiencies or material weaknesses that we or our independent registered public accounting firm may identify may require us to incur significant costs and expend significant time and management resources. We cannot assure you that any of the measures we implement to remedy any such deficiencies will effectively mitigate or remedy such deficiencies. The existence of one or more material weaknesses could affect the accuracy and timing of our financial reporting. Investors could lose confidence in our financial reports, and the value of our common stock and CDIs may be harmed, if our internal controls over financial reporting are found not to be effective by management or by an independent registered public accounting firm or if we make disclosure of existing or potential significant deficiencies or material weaknesses in those controls.

Failure to maintain effective disclosure controls and procedures could result in the loss of investor confidence and an adverse impact on the price of our common stock.

In connection with preparing our registration statement on Form S-1 filed with the SEC on July 17, 2012, we discovered that compensation expenses arising from certain stock option grants were inadvertently omitted from the summary compensation table in amendment no. 1 to our Form 10-K for the fiscal year ended December 31, 2011, which we previously filed with the SEC. We corrected this omission promptly after discovering it by filing a second amendment to our Form 10-K. If we do not, or if investors perceive that we do not, establish and maintain adequate disclosure controls and procedures, investors could lose confidence in our reports filed with the SEC, which would harm the trading price of our common stock.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with the Company.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, or (iv) any other action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions described above. This forum selection provision may limit our stockholders' ability to obtain a judicial forum that they find favorable for disputes with us or our directors, officers or other employees or stockholders.

Our certificate of incorporation, bylaws and the Delaware General Corporation Law may delay or deter a change of control transaction.

Certain provisions of our certificate of incorporation and bylaws may have the effect of deterring takeovers, such as

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those provisions authorizing our board of directors to issue, from time to time, any series of preferred stock and fix the designation, powers, preferences and rights of the shares of such series of preferred stock; prohibiting stockholders from acting by written consent in lieu of a meeting; requiring advance notice of stockholder intention to put forth director nominees or bring up other business at a stockholders' meeting; prohibiting stockholders from calling a special meeting of stockholders; requiring a $66^2/3\%$ majority stockholder approval in order for stockholders to amend certain provisions of our certificate of incorporation or bylaws or adopt new bylaws; providing that, subject to the rights of preferred shares, the directors will be divided into three classes and the number of directors is to be fixed exclusively by our board of directors; and providing that none of our directors may be removed without cause. Section 203 of the Delaware General Corporation Law, from which we did not elect to opt out, provides that if a holder acquires 15% or more of our stock without prior approval of our board of directors, that holder will be subject to certain restrictions on its ability to acquire us within three years. These provisions may delay or deter a change of control of us, and could limit the price that investors might be willing to pay in the future for shares of our common stock.

It may be difficult to effect service of U.S. process and enforce U.S. legal process against our directors.

Five of our eight directors reside outside of the United States, principally in Australia. A substantial portion of the assets of our directors also are located outside of the United States. Therefore, it may not be possible to effect service of process within the United States upon these persons in order to enforce judgments of U.S. courts against these persons based on the civil liability provisions of the U.S. federal securities laws. In addition, there is doubt as to the enforceability in Australia, in original actions or in actions to enforce judgments of U.S. courts, of claims predicated solely upon U.S. federal securities laws. This could make it more difficult or impossible for investors to litigate or recover damages from our directors in securities litigation or other claims.

If we are not able to maintain sufficient cash funds, we may cease trading on the ASX.

If we are not able to maintain sufficient funds to fund our activities or if ASX considers that our financial position is not adequate to warrant the continued quotation of our CDIs on ASX, ASX may suspend our CDIs from quotation. This would limit our liquidity and, in particular, could harm the ability of CDI holders to liquidate their position in our company. In addition, the value of our company could decline if we are not able to maintain our listing on ASX.

We are an "emerging growth company," under federal securities laws and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. The JOBS Act also permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to U.S. public companies. We could be an emerging growth company for up to five years, although we could lose that status sooner if our revenues exceed $1 billion, if we issue more than $1 billion in non-convertible debt in a three-year period, or if the market value of our common stock held by non-affiliates exceeds $700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and CDIs and our stock price may decline or be more volatile.

In addition, Section 102(b)(1) of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. An "emerging growth company" can delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period, and as a result of this election, our financial statements may not be comparable to those of companies that comply with public company effective dates for new or revised accounting standards for U.S. public companies.

Our CDIs are traded on the ASX and we are subject to the Listing Rules of the ASX, which increase our operating costs and subject us to regulations not applicable to most other companies listed on the Nasdaq Capital Market.

Since 2004, CDIs representing beneficial ownership of our common stock have been traded on the ASX. We therefore are subject to the Listing Rules of the ASX, which regulate certain actions we can take, such as limiting the circumstances under which we may issue shares of our common stock or CDIs without stockholder approval and require us to disregard votes cast by certain stockholders potentially interested in matters to be voted on at annual or special meetings of stockholders when such stockholders are permitted to vote at the meeting in accordance with the General Corporation Law of Delaware and Nasdaq Listing Rules. Most other companies listed on the Nasdaq Capital Market are not subject to the additional regulatory requirements imposed by the ASX Listing Rules, which increase our operating costs relative to other Nasdaq-listed companies, may make it more difficult to effect certain corporate actions, and might make an investment in our common stock less attractive to potential purchasers.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits filed as part of this Quarterly Report on Form 10-Q are listed in the Exhibit Index immediately following the signature page of this report.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: July 30, 2012 **SUNSHINE HEART, INC.**

By: /s/ David A. Rosa
David A. Rosa
Chief Executive Officer
(Principal executive officer)

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer and Secretary
(Principal financial officer and principal accounting officer)

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Exhibit Index
Sunshine Heart, Inc.
Form 10-Q for Quarter Ended June 30, 2012

Exhibit Number	Description
31.1*	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

*Filed herewith.

Exhibit 31.1

SARBANES-OXLEY SECTION 302 CERTIFICATION

I, David A. Rosa, certify that:

1. I have reviewed this report on Form 10-Q of Sunshine Heart, 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 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 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.

Date: July 30, 2012

By: /s/ David A. Rosa
David A. Rosa
Chief Executive Officer

Exhibit 31.2

SARBANES-OXLEY SECTION 302 CERTIFICATION

I, Jeffrey S. Mathiesen, certify that:

1. I have reviewed this report on Form 10-Q of Sunshine Heart, Inc., 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 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.

Date: July 30, 2012

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Sunshine Heart, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2012 as filed with the Securities and Exchange Commission (the "Report"), I, David A. Rosa, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 30, 2012

By: /s/ David A. Rosa
David A. Rosa
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Sunshine Heart, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2012 as filed with the Securities and Exchange Commission (the "Report"), I, Jeffrey S. Mathiesen, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: July 30, 2012

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer