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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 September 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 November 4, 2012 was 9,278,734.

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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)

	September 30, 2012 (unaudited)	December 31, 2011
Current assets		
Cash and cash equivalents	$ 17,446	$ 6,563
Other current assets	667	346
Total current assets	18,113	6,909
Property, plant and equipment, net	493	522
TOTAL ASSETS	$ 18,606	$ 7,431
Current liabilities		
Accounts payable	$ 1,590	$ 1,857
Accrued salaries, wages, and other compensation	681	978
Total current liabilities	2,271	2,835
Total liabilities	2,271	2,835
Commitments and contingencies	—	—
Stockholders' equity		
Preferred Stock as of September 30, 2012 and December 31, 2011, par value $0.0001 per share; authorized 40,000,000 shares	—	—
Common stock as of September 30, 2012 and December 31, 2011, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 9,247,388 and 6,019,663 shares, respectively	1	1
Additional paid-in capital	90,339	68,652
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	1,183	1,132
Retained earnings	(75,188)	(65,189)
Total stockholders' equity	16,335	4,596
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 18,606	$ 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 September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Net sales	$ —	$ —	$ —	$ —
Cost of goods sold	—	—	—	—
Gross profit	—	—	—	—
Operating expenses				
Selling, general and administrative	1,495	1,430	5,004	3,250
Research and development	1,802	3,273	5,755	7,939
Total operating expenses	3,297	4,703	10,759	11,189
Loss from operations	(3,297)	(4,703)	(10,759)	(11,189)
Interest income	1	31	30	228

Loss before income taxes	(3,296)	(4,672)	(10,729)	(10,961)
Income tax benefit	—	—	(730)	—
Net loss	$ (3,296)	$ (4,672)	$ (9,999)	$ (10,961)
Basic and diluted loss per share	$ (0.42)	$ (0.84)	$ (1.49)	$ (2.09)
Weighted average shares outstanding — basic and diluted	7,789	5,582	6,727	5,249
Comprehensive loss	$ (3,308)	$ (4,812)	$ (9,948)	$ (10,916)

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 nine months ended September 30,	
	2012	**2011**
Cash flows used in operating activities:		
Net loss	$ (9,999)	$ (10,961)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	98	25
Loss on disposal of plant and equipment	63	6
Stock-based compensation expense	907	555
Expense for warrants issued in conjunction with service agreement	160	—
Changes in assets and liabilities		
Accounts receivable	—	259
Other current assets	(321)	(24)
Accounts payable and accrued expenses	(574)	480
Net cash used in operations	(9,666)	(9,660)
Cash flows used in investing activities:		
Purchases of property and equipment	(132)	(34)
Net cash used in investing activities	(132)	(34)
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	20,620	7,650
Net cash provided by financing activities	20,620	7,650
Effect of exchange rate changes in cash	61	38
Net increase (decrease) in cash and cash equivalents	10,883	(2,006)
Cash and cash equivalents - beginning of period	6,563	12,350
CASH AND CASH EQUIVALENTS - END OF PERIOD	$ 17,446	$ 10,344

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, Inc. was founded in November 1999 and incorporated in Delaware in August 2002 and its wholly-owned subsidiary, Sunshine Heart Company Pty Ltd. is located in St Leonards, New South Wales, Australia (together with Sunshine Heart, Inc., "we," "our" or the "Company"). Our headquarters are located in Eden Prairie, MN. 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 Heart 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 Heart 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.

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 investigational device exemption, or IDE, application. In September 2012, we received conditional approval from the FDA for an IDE and expect to initiate our pivotal trial before the end of 2012, once the conditions to the approval have been removed.

We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries that accept the CE Mark 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.

Our shares of common stock have been publicly traded in the U.S. on the NASDAQ since February 2012, and in the form of CHESS Depositary Interests, or CDIs, 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 September 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. All intercompany accounts and transactions between consolidated entities have been eliminated.

Unaudited Interim Consolidated Financial Information: The interim balance sheet as of September 30, 2012 and statements of operations and cash flows for the nine months ended September 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, or Securities Act. 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

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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 nine months ended September 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 U.S. 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 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 2,551,456 and 2,216,615 for the nine months ended September 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 September 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 September 30, 2012

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that are expected to have material impacts on our financial position, operating results or disclosures.

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.

Public Offering

On August 15, 2012 we sold 2,875,000 shares of common stock in a public offering at $7.00 per share and on August 20, 2012, we sold 94,800 shares of common stock upon the exercise of the over-allotment option by our underwriters at $7.00 per share. Proceeds in the public offering and exercise of the over-allotment option, net of transaction costs were $18,552 in the aggregate.

Stock-Based Compensation

The Company recognizes all share-based payments, including grants of stock options and compensatory employee stock purchase plans, in the income statement as an operating expense, based on their fair value over the requisite service period. We recorded $594 and $313 of related compensation expense to selling, general and administrative expense and research and development expense, respectively, for the nine months ended September 30, 2012, as compared to $385 and $170, respectively, of related compensation expense for the nine months ended September 30, 2011. As of September 30, 2012, a total of $3,321 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 nine months ended September 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 nine months ended September 30, 2011.

The Company's stock options generally vest over four years of service and have a contractual life of 10 years. We have 1,032,741 shares authorized for grant under our Amended and Restated 2011 Equity Incentive Plan.

Warrants

Warrants to purchase 1,664,599 and 1,496,032 shares of common stock were outstanding at September 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.

On September 7, 2012, we issued 100,000 non-forfeitable and fully exercisable warrants to purchase common stock at an exercise price of $7.00 per share and a term of 5 years, pursuant to a professional services agreement extending through June 2013. These warrants were determined to have a fair value of $519, of which $160 was charged to expense during the third quarter 2012.

During the nine months ended September 30, 2012, 1,050 warrants were exercised at a price of AU$6.40 per share for total proceeds of AU$7.

Note 3 - Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	September 30, 2012	December 31, 2011
Library	$ 1	$ 1
Office Furniture & Fixtures	98	177
Leasehold Improvements	145	251
Software	9	37
Production Equipment	384	293
Computer Equipment	141	134
Total	778	893
Accumulated Depreciation	(285)	(371)
	$ 493	$ 522

Depreciation expense for the three and nine month periods ended September 30, 2012 and 2011 was $36, $4, $98 and $25, respectively.

Note 4 — Income Taxes

In June 2012, we received a $730 research and development tax credit refund, 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 reflected no net benefit related to the Australian research and development tax credit for that period.

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 filings with the U.S. Securities and Exchange Commission, or SEC, and ASX and in this report.

You should read the matters described in “Risk Factors” and the other cautionary statements made in our annual report on Form 10-K for the year ended December 31, 2011 filed with the SEC and subsequent reports filed with the SEC, including 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.

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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 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 Heart 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 Heart 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.

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 investigational device exemption, or IDE, application. In September 2012, we received conditional approval from the FDA for an IDE and expect to initiate our pivotal trial before the end of 2012, once the conditions to the approval have been removed.

We obtained CE Mark approval for the C-Pulse System in July 2012 and have taken initial steps to evaluate the market potential for our system in targeted countries that accept the CE Mark 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. We currently have no revenue, but we anticipate that any revenue we generate will consist 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 clinical trials. 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 expect to expense shipping costs at the time we report the related revenue and record these 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.

We compute the estimated fair values of stock options using the Black-Scholes option pricing model. No tax

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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 September 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 based on the achievement of existing milestones 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 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 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.

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 September 30, 2012, we had an accumulated deficit of $75.2 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

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successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

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

Revenue

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

Sales of the C-Pulse Heart System to hospitals and clinics under contract in conjunction with our North American FDA clinical trials historically have generated all of our revenue. We did not have any sales of our C-Pulse Heart System device in the three month periods ended September 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 fourth quarter of 2012.

Research and Development Expense

Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Increase (Decrease)	% Change

$	1,802,000	$	3,273,000	$	(1,471,000)	(44.9)%

Our decrease in research and development expense for the three months ended September 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 Heart System period to period. We expect our research and development expense will sequentially increase as we add personnel to support our pivotal clinical trial and pursue our development efforts in the fourth quarter of 2012.

Selling, General and Administrative Expense

Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 1,495,000	$ 1,430,000	$ 65,000	4.5%

Our increase in selling, general and administrative expense for the three months ended September 30, 2012 compared to the prior year was primarily caused by increased professional fees and personnel additions in 2011 as we developed our infrastructure, and in preparation for European trials expected to commence in the fourth quarter 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 September 30, 2012	Three Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 1,000	$ 31,000	$ (30,000)	(96.8)%

Our decrease in interest income for the three months ended September 30, 2012 compared to the prior year was primarily caused by the lower interest rates earned on cash balances maintained in the United States, where the majority of our cash was held in the current year period, compared to rates earned on cash balances maintained in Australia, where a large portion of our cash was held during the three months ended September 30, 2011.

Income Tax Benefit

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

Historically, our income tax benefits have resulted from research and development tax credit refunds in Australia

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and the state of Minnesota and are recognized upon receipt of the refund or determination that receipt of the refund is reasonably assured. Assuming no further changes to the applicable Australian or Minnesota 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 those jurisdictions. At this time, we are working to complete our analysis of the potential Australian research and development tax credit refund that may be available for the period ended June 30, 2012.

Comparison of Nine Months Ended September 30, 2012 to Nine Months Ended September 30, 2011

Revenue

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

Sales of the C-Pulse Heart System to hospitals and clinics under contract in conjunction with our North American FDA clinical trials historically have generated all of our revenue. We did not have any sales of our C-Pulse Heart System device in the nine month periods ended September 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.

Research and Development Expense

Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 5,755,000	$ 7,939,000	$ (2,184,000)	(27.5)%

Our decrease in research and development expense for the nine months ended September 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 Heart System period to period.

Selling, General and Administrative Expense

Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 5,004,000	$ 3,250,000	$ 1,754,000	54.0%

Our increase in selling, general and administrative expense for the nine months ended September 30, 2012 compared to the prior year was primarily caused by increased stock-based compensation expense resulting from stock option grants in the second half of the prior year, and increased professional fees and personnel additions in 2011 as we developed our infrastructure and prepared for our Nasdaq listing, which was completed in February 2012, and in preparation for European trials expected to commence in the fourth quarter of 2012.

Interest Income

Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011	Increase (Decrease)	% Change
$ 30,000	$ 228,000	$ (198,000)	(86.8)%

Our decrease in interest income for the nine months ended September 30, 2012 compared to the prior year was primarily caused by lower average cash balances during the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 and the lower interest rates earned on cash balances maintained in the United States, where the majority of our cash was held in the current year period, compared to rates earned on cash balances maintained in Australia, where a large portion of our cash was held during the nine months ended September 30, 2011.

Income Tax Benefit

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

Our income tax benefit for nine months ended September 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

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of 2012 and received a $730,000 research and development tax credit refund during the second quarter of 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 for net proceeds of $20.6 million and $7.7 million in the nine months ended September 30, 2012 and 2011, respectively. As of September 30, 2012 and December 31, 2011, cash and cash equivalents were $17.4 million and $6.6 million, respectively.

We believe, based on our current operating plan, our cash balances and cash generated from our clinical trials will be sufficient to meet our anticipated cash requirements into the second half of 2013, but that we will require additional funding by the end of 2013 to sufficiently fund our operations. 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, debt, or convertible debt securities may result in dilution to our stockholders. If we raise additional funds through the issuance of debt, 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 $9.7 million in each of the nine months ended September 30, 2012 and 2011. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by depreciation, amortization of warrants issued for services, 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 $132,000 and $34,000 in the nine months ended September 30, 2012 and 2011, respectively. The majority of cash used in investing activities in first nine months of 2012 and in 2011 was for leasehold improvements, furniture and equipment associated with the relocation of our headquarters.

Cash Flows from Financing Activities

Net cash provided by financing activities was $20.6 million and $7.7 million in the nine months ended September 30, 2012 and 2011, respectively. Net cash provided by financing activities was attributable to proceeds from sales of our common stock and warrants.

Capital Resource Requirements

As of September 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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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 September 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 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.

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PART II: OTHER INFORMATION

ITEM 1A. RISK FACTORS

In addition to the other information set forth elsewhere in this report, you should carefully consider the factors discussed in Part I, Item 1A Risk Factors of the Company's Annual Report on Form 10-K for the year ended December 31, 2011 and in Risk Factors of the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2012 filed on July 30, 2012. Those factors, if they were to occur, could cause our actual results to differ materially from those expressed in our forward-looking statements in this report, and materially adversely affect our financial condition or future results. Although we are not aware of any other factors 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 materially adversely affect our actual business, financial condition and/or operating results.

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

On August 15, 2012 we completed the initial public offering of our common stock pursuant to our Registration Statement on Form S-1 (File No. 333-182727), which was declared effective by the SEC on August 9, 2012. The underwriters for the offering were Canaccord Genuity Inc., Lazard Capital Markets LLC, Cowen and Company, Craig-Hallum Capital Group LLC, and Northland Securities, Inc.

We issued and sold a total of 2,969,800 shares of common stock at a public offering price of $7.00 per share, including 94,800 shares sold pursuant to the partial exercise of the underwriters' over-allotment option. The aggregate sale price for all of the shares sold by us was $20,788,600, resulting in net proceeds to us of approximately $18,552,000 after payment of underwriting discounts and commissions and legal, accounting and other fees incurred in connection with the offering.

The net proceeds were deposited into our checking and money market bank accounts. We have used and expect to use the net proceeds to fund our pivotal clinical trial, to satisfy the Company's payables and for general corporate purposes, which will include providing working capital and funding capital expenditures and research and development. The amounts we actually spend for these purposes may vary significantly and will depend on a number of factors. Accordingly, our management will retain broad discretion in the allocation of the net proceeds.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

ITEM 5. OTHER INFORMATION

We currently intend to hold our annual meeting of stockholders in May 2013 rather than August. Because we intend to hold our 2013 annual meeting of stockholders on a date that is more than 30 days from the date of our 2012 annual meeting of stockholders, the deadline for a stockholder proposal to be considered for inclusion in our proxy statement for our 2013 annual meeting of stockholders will be a reasonable time before we begin to print and send our proxy statement for the 2013 annual meeting. We currently anticipate holding the 2013 annual meeting of stockholders on or about May 14, 2013 and printing proxy statements for the meeting on or about April 1, 2013; therefore, we request that all stockholder proposals be submitted by December 1, 2012. Any proposal should be addressed to Sunshine Heart, Inc., Attention: Chief Financial Officer, 12988 Valley View Road, Eden Prairie, Minnesota 55344. The proposal must comply with SEC regulations regarding the inclusion of stockholder proposals in company-sponsored proxy materials.

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: November 9, 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 September 30, 2012

Exhibit Number	Description
3.1	Certificate of Incorporation, as amended (incorporated by reference to our Form 10 filed with the Securities and Exchange Commission on February 1, 2012).
3.2	Amended and Restated Bylaws (incorporated by reference to our Form 10 filed with the Securities and Exchange Commission on September 30, 2011).
10.1†	Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan (incorporated by reference to Appendix A to our Definitive Proxy Statement filed with the Securities and Exchange Commission on July 27, 2012).
10.2†	Form of Stock Option Grant Notice and Form of Option Agreement (Director) (incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the Securities and Exchange Commission on September 18, 2012).
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.
† Executive compensation agreement.

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: November 9, 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: November 9, 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 September 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: November 9, 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 September 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: November 9, 2012

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