# 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 March 31, 2012

OR

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

For the transition period from

Commission file number 001-35312

to

SUNSHINE HEART, INC.

**Delaware** 

(State or other Jurisdiction of Incorporation or Organization)

**No. 68-0533453** (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 o No x

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 May 4, 2012 was 6,277,538.

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## PART I: FINANCIAL INFORMATION

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## ITEM 1. FINANCIAL STATEMENTS

#### SUNSHINE HEART, INC.

#### Condensed Consolidated Balance Sheets

(Dollars in thousands, except share amounts)

March 21 2012

December 21 2011

	<u>March 31, 2012</u> (unaudited)		Decen	nber 31, 2011
Current assets				
Cash and cash equivalents	\$	3,832	\$	6,563
Other current assets	Φ	645	Ф	346
Total current assets	<u> </u>	4,477		6,909
		521		
Property, plant and equipment, net TOTAL ASSETS	ф.		d.	522
IOTAL ASSETS	\$	4,998	\$	7,431
Current liabilities	ф	4.04	ф	4.055
Accounts payable	\$	1,647	\$	1,857
Accrued salaries, wages, and other compensation		402		978
Total current liabilities		2,049		2,835
Total liabilities		2,049		2,835
Commitments and contingencies		_		
Stockholders' equity				
Preferred Stock as of March 31, 2012 and December 31, 2011, par value \$0.0001 per share; authorized				
40,000,000 shares		_		_
Common stock as of March 31, 2012 and December 31, 2011, par value \$0.0001 per share; authorized				
100,000,000 shares: issued and outstanding 6,276,538 and 6,018,740 shares, respectively		1		1
Additional paid-in capital		71,032		68,652
Accumulated other comprehensive loss:				
Foreign currency translation adjustment		1,186		1,132
Retained earnings		(69,270)		(65,189)
Total stockholders' equity		2,949		4,596
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	4,998	\$	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 March 31,			
	=	2012	2011		
Net sales	\$	_	\$ —		
Cost of goods sold		_	_		
Gross profit	_	_	_		
Operating expenses					

Selling, general and administrative	1,940	642
Research and development	2,166	2,292
Total operating expenses	4,106	2,934
Loss from operations	(4,106)	(2,934)
Interest income	25	117
Loss before income taxes	(4,081)	(2,817)
Income tax benefit	_	_
Net loss	\$ (4,081)	\$ (2,817)
Basic and diluted loss per share	\$ (0.66)	\$ (0.55)
Weighted average shares outstanding — basic and diluted	6,169	5,078
Comprehensive loss	\$ (4,027)	\$ (2,752)

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 three months ended March 31,		
	20	12	20	)11
Net loss	\$	(4,081)	\$	(2,817)
Adjustments to reconcile net loss to cash flows used in operating activities:				
Depreciation and amortization		31		9
Loss on disposal of plant and equipment		63		_
Stock-based compensation expense		318		19
Changes in assets and liabilities				
Accounts receivable		_		242
Other current assets		(299)		(80)
Accounts payable and accrued expenses		(800)		(175)
Net cash used in operations		(4,768)		(2,802)
Cash flows used in investing activities:				
Purchases of property and equipment		(89)		(7)
Net cash used in investing activities		(89)		(7)
Cash flows provided by financing activities:				
Net proceeds from the sale of common stock		2,061		100
Net cash provided by financing activities		2,061		100
Effect of exchange rate changes in cash		65		90
Net decrease in cash and cash equivalents		(2,731)		(2,619)
Cash and cash equivalents - beginning of period		6,563		12,250
CASH AND CASH EQUIVALENTS - END OF PERIOD	\$	3,832	\$	9,631

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 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. 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 Heart 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 March 31, 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 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 March 31, 2012 and statements of operations and cash flows for the three months ended March 31, 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 three months ended March 31, 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.

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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 1,961,633 and 1,188,406 for the three months ended March 31, 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 International Financial Reporting Standards, or 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 guidance on presentation of comprehensive income that requires us to present components of other comprehensive income and of net income in one continuous statement of comprehensive income, or in two separate but consecutive statements. In December 2011, the FASB

issued a deferral of the effective date for presentations of reclassifications of items out of accumulated other comprehensive income (loss). The option to report other comprehensive income within the statement of equity has been removed. This new presentation of comprehensive income 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.

There was no other accounting pronouncement adopted during the three-month period ended March 31, 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 March 31, 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 income statement as an operating expense, based on their fair value over the requisite service period. We recorded \$206 and \$112 of related compensation expense to selling, general and administrative expense and research and development expense, respectively, for the three months ended March 31, 2012, as compared to \$13 and \$6, respectively, of related compensation expense for the three months ended March 31, 2011. As of March 31, 2012, a total of \$4,017 of unrecognized compensation costs related to non-vested stock option awards was outstanding and is expected to be recognized within the next 3.75 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 29,375 shares were granted during the three months ended March 31, 2012, and the weighted average fair value of these options was \$173, determined using an expected dividend yield of 0%, an expected stock price volatility of 98.5%, a risk-free interest rate of 1.38% and expected option lives of 6.5 years. There were no options granted in the three months ended March 31, 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 1,581,648 and 1,496,032 shares of common stock were outstanding at March 31, 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.

#### Note 3 - Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	_	March 31, 2012	December 31, 2011	
Library	\$	1	\$	1
Office Furniture & Fixtures		94		177
Leasehold Improvements		145		251
Software		9		37
Production Equipment		373		293
Computer Equipment		114		134
Total		736		893
Accumulated Depreciation		(215)		(371)
	\$	521	\$	522

Depreciation expense for the three months ended March 31, 2012 and 2011 was \$31 and \$9, respectively.

#### 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 U.S. Securities and Exchange Commission.

#### Overview

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse Heart System for treatment of Class III and ambulatory Class IV heart failure. The C-Pulse Heart 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 obtaining regulatory approvals necessary to sell our product. We completed enrollment of the feasibility phase of our clinical trial in the first half of 2011. In November 2011, we obtained the results of the six-month follow-up period for the feasibility phase 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 Heart 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 first half of 2012 for approval to initiate our pivotal trial. We expect to complete our pivotal trial in 2015 and do not anticipate marketing our product in the U.S. before 2016.

We are seeking CE Mark for the C-Pulse Heart System and anticipate that we will obtain approval in the middle of 2012. We have taken initial steps to evaluate the potential market for our product in targeted countries in Europe in anticipation of commencing commercial sales of the C-Pulse Heart System in Europe following CE Mark approval.

#### **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 Heart System is not approved for commercial sale. Our revenue consists solely of sales of the C-Pulse Heart System to hospitals and clinics under contract in conjunction with our clinical trials. For clinical trial implant revenue, the product title generally transfers on the date the product 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.

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

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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 March 31, 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 the future capital raising 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 the product being developed. If we are unable to obtain such funding of an amount and timing 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.

#### **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 guidance on presentation of comprehensive income that requires us to present components of other comprehensive income and of net income in one continuous statement of comprehensive income, or in two separate but consecutive statements. In December 2011, the FASB issued a deferral of the effective date for presentations of reclassifications of items out of accumulated other comprehensive income (loss). The option to report other comprehensive income within the statement of equity has been removed. This new presentation of comprehensive income 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.

#### **Financial Overview**

We are an early-stage medical device company focused on developing, manufacturing and commercializing our C-Pulse Heart 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 March 31, 2012, we had an accumulated deficit of \$69.3 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.

#### **Results of Operations**

Comparison of Three Months Ended March 31, 2012 to Three Months Ended March 31, 2011

Revenue

Three Months Ended	7	Three Months Ended				
 March 31, 2012		March 31, 2011	Inc	rease (Decrease)	% Change	
\$ _	\$	<u> </u>	\$	_		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 sell our C-Pulse Heart System device in the

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three month periods ended March 31, 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, both expected to commence in the second half of 2012.

Research and Development Expense

Three Months Ended March 31, 2012	Three Months Ended March 31, 2011	Increase (Decrease)	% Change	
\$ 2,166,000	\$ 2,292,000	\$ (126,000)		(5.5)%

Our decrease in research and development expense for the first quarter 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 year to year. We expect our research and development expense will increase in the second half of 2012 as we add personnel to support our pivotal clinical trial and pursue our development efforts.

Selling, General and Administrative Expense

	Three Months Ended	Three Months Ended	T (D)	0/ 61	
	March 31, 2012	March 31, 2011	 Increase (Decrease)	% Change	
9	1,940,000	\$ 642,000	\$ 1,298,000		202.2%

Our increase in selling, general and administrative expense for the three months ended March 31, 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 costs as we develop our infrastructure and prepared for our Nasdaq listing completed in February 2012, the change in timing of year end audit fees in conjunction with the change in our fiscal year end from June 30 to December 31 and 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 March 31, 2012	Three Months Ended March 31, 2011	Increase (Decrease)	% Change
\$ 25,000	\$ 117,000	\$ (92,000)	(78.6)%

Our decrease in interest income for the first quarter 2012 compared to the prior year was primarily caused by lower average cash balances during the first quarter of 2012 as compared to 2011.

#### **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 \$2.1 million and \$100,000 in the first quarters of 2012 and 2011, respectively. As of March 31, 2012 and December 31, 2011, cash and cash equivalents were \$3.8 million and \$6.6 million, respectively.

We believe that our cash on hand will be sufficient to fund our operations through substantially all of the first half of 2012 as we prepare for the pivotal clinical trial, but that we will require additional financing within the next three months to sufficiently fund our operations. We expect to obtain additional financing as needed through sales of our common stock or other securities or debt facilities. Although we have successfully financed our operations through the issuance of common stock to date, we cannot be assured that we will be able to continue to be successful in financing our operations in the future.

Cash Flows from Operating Activities

Net cash used in operating activities was \$4.8 million and \$2.8 million in the first quarter 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, non-cash, stock-based compensation and the effects of changes in operating assets and liabilities.

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Cash Flows from Investing Activities

Net cash used in investing activities was \$89,000 and \$7,000 in the first quarter 2012 and 2011, respectively. The majority of cash used in investing activities in first quarter 2012 was for leasehold improvements, furniture and equipment associated with the relocation of our headquarters in January 2012. Cash used in investing activities in the first quarter 2011 related to purchases of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$2.1 million and \$100,000 in the first quarter 2012 and 2011, respectively. Net cash provided by financing activities was attributable to proceeds from sales of our common stock.

Capital Resource Requirements

As of March 31, 2012, we did not have any material commitments for capital expenditures.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements.

#### Forward-Looking Statements and Risk Factors

Certain statements in this report are forward-looking statements that are based on management's beliefs, assumptions and expectations and information currently available to management. All statements that address future operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation, our expectations with respect to product development and commercialization efforts, results of clinical trials, timing of regulatory filings and approvals, regulatory acceptance of our filings, research and development activities, ultimate clinical outcomes and benefits of our products to patients, market and physician acceptance of the products, intellectual property protection, and potentially competitive product offerings. The risk factors described in our filings with the U.S. Securities and Exchange Commission (SEC) and ASX could cause actual events to adversely differ from the expectations indicated in these forward-looking statements. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. Sunshine Heart does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Sunshine Heart may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of the C-Pulse Heart System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in

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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 March 31, 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. 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 February 8, 2012 we conducted a private placement of 256,875 shares of common stock, par value \$0.0001 per share (in the form of CDIs), for a purchase price of AU\$8.00 per share, for proceeds, net of transaction costs of \$2.1 million. Australian institutional investors and U.S. accredited investors were purchasers in the private placement. As part of this placement, 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. Proceeds for the offering will be used to fund our operations, and research and clinical development activities. This sale of securities was made in reliance upon the exemption from registration requirements of the Securities Act of 1933, as amended, or Securities Act, available under Section 4(2) of the Securities Act and Rule 506 of Regulation D. The purchasers of the securities in this transaction made in reliance upon Section 4(2) of the Securities Act and Rule 506 of Regulation D represented that they were sophisticated persons and that they intended to acquire the securities for investment only and not with a view to, or for sale in connection with, any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in such sale. We believe that these purchasers either received adequate information about us or had adequate access, through their relationships with us, to such information.

#### 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: May 14, 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 March 31, 2012

Exhibit Number	Description
10.1	Form of Securities Purchase Agreement, dated February 6, 2012 (incorporated by reference to Exhibit 10.19 to the Company's
	Amendment No. 4 to Registration Statement on Form 10, filed with the SEC on February 8, 2012).
10.2	Form of Warrant to Purchase Common Stock issued to investors pursuant to Securities Purchase Agreement dated February 6, 2012
	(incorporated by reference to Exhibit 10.20 to the Company's Amendment No. 4 to Registration Statement on Form 10, filed with the
	SEC on February 8, 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.

<sup>\*</sup>Filed herewith.

#### 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: May 14, 2012

By: /s/ David A. Rosa

David A. Rosa

Chief Executive Officer

#### 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: May 14, 2012

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

# 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 March 31, 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: May 14, 2012

By: /s/ David A. Rosa

David A. Rosa Chief Executive Officer

# 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 March 31, 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: May 14, 2012

By: /s/Jeffrey S. Mathiesen

Jeffrey S. Mathiesen Chief Financial Officer

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