

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2014

OR

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.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

No. 68-0533453

(I.R.S. Employer
Identification No.)

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 No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The number of outstanding shares of the registrant's common stock, \$0.0001 par value, as of May 2, 2014 was 16,879,823.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	<u>March 31,</u> <u>2014</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2013</u>
Current assets		
Cash and cash equivalents	\$ 47,421	\$ 54,136
Accounts receivable	59	59
Other current assets	824	448
Total current assets	<u>48,304</u>	<u>54,643</u>
Property, plant and equipment, net	572	587
TOTAL ASSETS	<u>\$ 48,876</u>	<u>\$ 55,230</u>
Current liabilities		
Accounts payable	\$ 2,030	\$ 2,188
Accrued salaries, wages, and other compensation	637	1,315
Total current liabilities	<u>2,667</u>	<u>3,503</u>
Total liabilities	2,667	3,503
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of March 31, 2014 and December 31, 2013, par value \$0.0001 per share; authorized 30,000 shares	—	—
Preferred stock as of March 31, 2014 and December 31, 2013, par value \$0.0001 per share; authorized 39,970,000 shares	—	—
Common stock as of March 31, 2014 and December 31, 2013, par value \$0.0001 per share; authorized 100,000,000 shares: issued and outstanding 16,875,116 and 16,825,284 shares, respectively	2	2
Additional paid-in capital	152,363	151,530
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,188	1,207
Accumulated deficit	(107,344)	(101,012)
Total stockholders' equity	<u>46,209</u>	<u>51,727</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 48,876</u>	<u>\$ 55,230</u>

See notes to the condensed consolidated financial statements.

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SUNSHINE HEART, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

Three months ended	
March 31,	
<u>2014</u>	<u>2013</u>

Net sales	\$ 59	\$ —
Operating expenses:		
Selling, general and administrative	2,361	1,976
Research and development	4,063	2,426
Total operating expenses	<u>6,424</u>	<u>4,402</u>
Loss from operations	(6,365)	(4,402)
Other income, net	33	3
Loss before income taxes	(6,332)	(4,399)
Income tax benefit	—	—
Net loss	<u>\$ (6,332)</u>	<u>\$ (4,399)</u>
Basic and diluted loss per share	<u>\$ (0.38)</u>	<u>\$ (0.47)</u>
Weighted average shares outstanding — basic and diluted	<u>16,859</u>	<u>9,417</u>
Other comprehensive income:		
Foreign currency translation adjustments	\$ (19)	\$ (8)
Total comprehensive loss	<u>\$ (6,351)</u>	<u>\$ (4,407)</u>

See notes to the condensed consolidated financial statements.

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

	Three months ended	
	March 31,	
	2014	2013
Net loss	\$ (6,332)	\$ (4,399)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	61	40
Stock-based compensation expense, net	632	367
Amortization of warrants for service agreements	—	120
Changes in assets and liabilities		
Other current assets	(468)	(171)
Accounts payable and accrued expenses	(580)	(71)
Net cash used in operations	<u>(6,687)</u>	<u>(4,114)</u>
Cash flows used in investing activities:		
Purchases of property and equipment	(46)	(9)
Net cash used in investing activities	<u>(46)</u>	<u>(9)</u>
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	16	874
Net cash provided by financing activities	<u>16</u>	<u>874</u>
Effect of exchange rate changes in cash	2	(5)
Net decrease in cash and cash equivalents	(6,715)	(3,254)
Cash and cash equivalents - beginning of period	<u>54,136</u>	<u>14,224</u>
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u>\$ 47,421</u>	<u>\$ 10,970</u>
Supplement schedule of non-cash activities		
Stock options and restricted stock units classified as liabilities, net	\$ (278)	\$ —

See notes to the condensed consolidated financial statements.

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SUNSHINE HEART, INC. AND SUBSIDIARIES
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. (“*Sunshine Heart*,” the “*Company*,” “*we*,” “*us*” and “*our*”) was founded in November 1999 and incorporated in Delaware in August 2002. We are headquartered in Eden Prairie, Minnesota and have a wholly owned subsidiary, Sunshine Heart Company Pty Ltd., located in Clontarf,

New South Wales, Australia and a wholly owned subsidiary, Sunshine Heart Ireland Limited, located in Dublin, Ireland. 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 (the "**C-Pulse System**"), is an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure which can be implanted using a minimally invasive procedure. The C-Pulse System is designed to relieve the symptoms of heart failure through the use of counter-pulsation technology by enabling an increase in coronary blood flow and a reduction in the heart's pumping load. The Company has received approval from the U.S. Food and Drug Administration (the "**FDA**") to conduct a U.S. pivotal clinical study with the C-Pulse System. Commencing February 16, 2012, our shares of common stock began trading on the NASDAQ Capital Market under the symbol "SSH." Chess Depositary Instruments representing beneficial ownership of our common stock previously traded on the Australian Securities Exchange (the "**ASX**") under the symbol "SHC" from September 2004 until our delisting from the ASX, which occurred at the close of trading on May 6, 2013.

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, 2013 and 2012 and through March 31, 2014, 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, 2013, we had an accumulated deficit of \$101,012 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 future capital raising be unsuccessful, 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 subsidiaries, Sunshine Heart Company Pty Ltd. and Sunshine Heart Ireland Limited. All intercompany accounts and transactions between consolidated entities have been eliminated.

Unaudited Interim Condensed Consolidated Financial Information

The interim condensed consolidated balance sheet as of March 31, 2014 and statements of operations and comprehensive loss for the three months ended March 31, 2014 and 2013, as well as the statements of cash flows for the three months ended March 31, 2014 and 2013 and related interim information contained in the notes to the condensed consolidated 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 (the "**Securities Act**"). In the opinion of management, such unaudited interim condensed 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 condensed consolidated information when read in conjunction with the audited consolidated financial statements and notes thereto included in its report on Form 10-K for

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the year ended December 31, 2013. Certain information and disclosures normally included in the consolidated 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, 2014 are not necessarily indicative of the results that may be expected for the year ending December 31, 2014 or any other interim period or for any other future year.

Use of Estimates

The preparation of interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts and disclosures in the interim condensed consolidated financial statements and accompanying notes. Actual results could differ from those 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 U.S. However, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites during our clinical studies. Consequently, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. Our revenue consists solely of sales of the C-Pulse System to hospitals and clinics who participate in our clinical studies per the terms of the clinical study contracts. For clinical study implant revenue, the product title generally transfers on the date the product is implanted. Product costs incurred for our clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred. Upon commercialization, product costs will be capitalized in inventory and recorded to cost of sales as the inventory is sold. We do not charge hospitals and clinics for shipping. We expense shipping costs at the time of shipment.

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, stock options and restricted stock units (“*RSUs*”) totaling 3,512,005 and 2,746,497 for the three months ended March 31, 2014 and 2013, 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.

Accounts Receivable

Accounts receivable are unsecured, are recorded at net realizable value, and do not bear interest. We make judgments as to our ability to collect outstanding receivables based upon significant patterns of uncollectibility, historical experience, and managements’ evaluation of specific accounts and will provide an allowance for credit losses when collection becomes doubtful. The Company performs credit evaluations of its customers’ financial condition on an as-needed basis. Payment is generally due 30 days from the invoice date and accounts past 30 days are individually analyzed for collectability. When all collection efforts have been exhausted, the account is written off against the related allowance. No allowance for doubtful accounts was considered necessary as of March 31, 2014 or December 31, 2013.

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 Financial Accounting Standards Board, Audit Standards Codification Topic 820, Fair Value Measurement, 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:

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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 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.

Note 2—Equity

Stockholder Rights Plan

On June 14, 2013, the Company adopted a stockholder rights plan (the “*Rights Plan*”), which entitles the holders of the rights to purchase from the Company 1/1,000th of a share of Series A Junior Participating Preferred Stock, par value \$0.0001 per share, at a purchase price of \$35.00 per share, as adjusted (a “*Right*”), upon certain trigger events. In connection therewith, on June 14, 2013, the Company’s board of directors authorized 30,000 shares of Series A Junior Participating Preferred Stock and it declared a dividend of one Right per each share of common stock of the Company outstanding as of June 24, 2013. Each 1/1,000th of a share of Series A Junior Participating Preferred Stock has terms that are substantially the economic and voting equivalent of one share of the Company’s common stock. However, until a Right is exercised or exchanged in accordance with the provisions of the Rights Plan, the holder thereof will have no rights as a stockholder of the Company, including, but not limited to, the right to vote for the election of directors or upon any matter submitted to stockholders of the Company. The Rights Plan has a three-year term and the board of directors may terminate the Rights Plan at any time (subject to the redemption of the Rights for a nominal value). The Rights may cause substantial dilution to a person or group (together with all affiliates and associates of such person or group and any person or group of persons acting in concert therewith) that acquires beneficial ownership of 15% or more of the Company’s stock on terms not approved by the board of directors or takes other specified actions.

Common Stock Purchase Agreement

On January 15, 2013, we entered into a Common Stock Purchase Agreement (the “*Purchase Agreement*”) with Aspire Capital Fund, LLC (“*Aspire Capital*”), which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$25.0 million in shares of our common stock (the “*Purchase Shares*”) over an approximate two-year period at purchase prices determined in accordance with the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, we filed a registration statement on Form S-1 with the U.S. Securities and Exchange Commission (the “*SEC*”) under which we registered 3,000,000 shares of our common stock for resale by Aspire Capital.

In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, we issued to Aspire Capital 80,257 shares of our common stock as a commitment fee (the “*Commitment Shares*”). The Purchase Agreement provides that we may not issue and sell more than 1,856,616 shares, or 19.99% of the Company’s outstanding shares as of January 15, 2013.

As of March 31, 2014 and December 31, 2013, we have sold 146,886 shares of common stock to Aspire Capital pursuant to the Purchase Agreement. Including the Commitment Shares, an aggregate of 227,143 shares of common stock have been issued to Aspire Capital pursuant to the Purchase Agreement.

The Purchase Agreement contains customary representations, warranties, covenants, closing conditions and indemnification and termination provisions by, among and for the benefit of the parties. The Purchase Agreement may be terminated by us at any time, at our discretion, without any cost or

penalty to us. Aspire Capital has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short-selling or hedging of our shares. We did not pay Aspire Capital any expense reimbursement in connection with the transaction. There are no limitations on use of proceeds, financial or business covenants, restrictions on future financings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement.

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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 \$468 and \$267 of related compensation expense to selling, general and administrative expense and research and development expense, respectively, for the three months ended March 31, 2014, as compared to \$227 and \$140, respectively, of related compensation expense for the three months ended March 31, 2013. As of March 31, 2014, a total of \$5,568 of unrecognized compensation costs related to non-vested stock option awards was outstanding and is expected to be recognized within the next 4 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 by analyzing their historical forfeiture and termination information and considering how future termination rates are expected to differ from historical rates. Expected dividend yield is based upon the Company's historical and projected dividend activity and the risk-free interest rate is based upon U.S. Treasury rates appropriate for the expected term of the options. The expected term is based on estimates regarding projected employee stock option exercise behavior. Stock options generally vest over four years of service and have contractual lives of 10 years. Fully vested stock awards are valued at the stock price on the date of grant and expensed for the full value on the date of grant. RSU grants are valued at the stock price on the date of grant. Fully vested RSUs are expensed for the full value at the date of grant. RSUs issued that vest over a 12-month period are re-valued using the Black-Scholes method as they vest monthly and expensed to operations and recognizing a corresponding liability.

Options for 55,700 shares were granted during the three months ended March 31, 2014, and the weighted average fair value of these options was \$365, determined using an expected dividend yield of 0%, an expected stock price volatility of 92%, a risk-free interest rate of 2.1% and expected option lives of 6.25 years. Options for 39,700 shares were granted during the three months ended March 31, 2013, and the weighted average fair value of these options was \$185, determined using an expected dividend yield of 0%, an expected stock price volatility of 99%, a risk-free interest rate of 1.3% and expected option lives of 5 years.

For the three months ended March 31, 2014, the Company had 25,604 stock options granted to non-employees with a fair value of \$58. The awards are revalued every period and expensed accordingly using the liability method of accounting.

Warrants

Warrants to purchase 1,613,006 shares of common stock were outstanding at March 31, 2014, as compared to warrants to purchase 1,630,804 shares of common stock outstanding at December 31, 2013.

During the three months ended March 31, 2014, warrants to purchase 2,798 shares of common stock were exercised at a price of AU\$6.40 per share for total cash proceeds of \$16, and warrants to purchase 15,000 shares of common stock were exercised at a price of AU\$6.40 per share in a cashless exercise in which 9,603 shares were surrendered to fund the exercise.

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Note 3—Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	March 31, 2014	December 31, 2013
Office Furniture & Fixtures	\$ 111	111
Leasehold Improvements	145	145
Software	63	61
Production Equipment	585	574
Computer Equipment	237	204
Total	1,141	1,095
Accumulated Depreciation	(569)	(508)
	<u>\$ 572</u>	<u>\$ 587</u>

Depreciation expense for the three months ended March 31, 2014 and 2013 was \$61 and \$40, respectively.

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The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our interim condensed consolidated financial statements and related notes included in Part I, Item 1 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, 2013. 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, 2013 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 System, is an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure, which can be implanted using a minimally invasive procedure. The C-Pulse System is designed to relieve the symptoms of heart failure through the use of counter-pulsation technology by enabling an increase in cardiac function, an increase in coronary blood flow, and a reduction in the heart's pumping load.

We are in the process of obtaining regulatory approvals necessary to sell our system in the United States while also gathering additional clinical data in Europe. We completed enrollment of our North American feasibility clinical study in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility study data, concluded we met the applicable agency requirements, and indicated that we can move forward with an investigational device exemption application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal study. We commenced enrollment of our pivotal study in the third quarter of 2013.

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 have initiated a post-market study in Europe that will evaluate endpoints similar to those for our U.S. pivotal study and enrollment under this study commenced in the second quarter of 2013.

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 U.S. However, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites during our clinical studies. Consequently, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. Our revenue consists solely of sales of the C-Pulse System to hospitals and clinics who participate in our clinical studies per the terms of the clinical study contracts. For clinical study implant revenue, the product title generally transfers on the date the product is implanted. Product costs incurred for our clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred. Upon commercialization, product costs will be capitalized in inventory and recorded to cost of sales as the inventory is sold. We do not charge hospitals and clinics for shipping. We expense shipping costs at the time of shipment.

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. We have concluded that the functional currency of our U.S.-based parent company is the U.S. Dollar, the functional currency of the Australian subsidiary is the Australian Dollar and the functional currency of the Ireland subsidiary is the European Euro. Translation adjustments result from translating the subsidiaries' 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

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accumulated in a separate component of equity.

Comprehensive Loss

The components of comprehensive loss include net loss and the effects of foreign currency translation adjustments.

Stock-Based Compensation

We recognize all share-based payments, including grants of stock options, RSUs, warrants and common stock awards in the Condensed Consolidated Statements of Operations and Comprehensive Loss as an operating expense based on their fair value over the requisite service period.

We compute the estimated fair values of stock options and warrants using the Black-Scholes option pricing model. Market price at the date of grant is used to calculate the fair value of RSUs and common stock awards. No tax benefit has been recorded due to the full valuation allowance on all deferred tax assets that we have recorded.

Stock-based compensation expense is based on awards ultimately expected to vest including estimates for 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, in most cases, recorded based upon liability measurement at each reporting period for awards to consultants.

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, 2013 and 2012, and through March 31, 2014, 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 future capital raising be unsuccessful, 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.

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 studies. At March 31, 2014, we had an accumulated deficit of \$107.3 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.

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Results of Operations

Comparison of Three Months Ended March 31, 2014 to Three Months Ended March 31, 2013

Revenue

Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	Increase (Decrease)	% Change
\$ 59,000	\$ —	\$ 59,000	N/A

Sales of the C-Pulse System to hospitals and clinics under contract in conjunction with our North American FDA clinical studies historically have generated all of our revenue. Our C-Pulse System is not approved for commercial sale in the U.S. However, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites during our clinical studies. Consequently, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. One C-Pulse System device was implanted for which we recognized revenue in the three-month period ended March 31, 2014, as compared to none during the three-month period ended March 31, 2013. We expect our revenue will be minimal until we begin enrolling patients in our North American pivotal clinical study at an increased rate and establish reimbursement in our post-marketing study in select countries in Europe. Product costs incurred for our clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred.

Selling, General and Administrative Expense

Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	Increase (Decrease)	% Change
\$ 2,361,000	\$ 1,976,000	\$ 385,000	19.5%

Our increase in selling, general and administrative expense for the three months ended March 31, 2014 as compared to 2013 is attributed to increased infrastructure expenses to support our anticipated growth and increased equity compensation costs. 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.

Research and Development Expense

Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	Increase (Decrease)	% Change
\$ 4,063,000	\$ 2,426,000	\$ 1,637,000	67.5%

Our increase in research and development expense for the three months ended March 31, 2014 as compared to 2013 resulted primarily from increased personnel and clinical research infrastructure to support our clinical studies in North America and Europe. We expect our research and development expense will continue to be above prior year levels throughout 2014 as we add personnel to support our clinical studies and pursue our development efforts.

Other Income, Net

Three Months Ended March 31, 2014	Three Months Ended March 31, 2013	Increase (Decrease)	% Change
\$ 33,000	\$ 3,000	\$ 30,000	1000.0%

Foreign currency exchange gains, primarily on intercompany liabilities due from our Australian subsidiary, resulted in the increase for the three months ended March 31, 2014 as compared to 2013.

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 cash proceeds of \$16,000 and \$0.9 million in the first three months of 2014 and 2013, respectively. As of March 31, 2014 and December 31, 2013, cash and cash equivalents were \$47.4 million and \$54.1 million, respectively.

From time to time we may seek to sell additional equity or convertible debt securities or enter into credit facilities.

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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 \$6.7 million and \$4.1 million for the three months ended March 31, 2014 and 2013, respectively. The net cash used in each of these periods primarily reflects the net loss for those periods, offset in part by stock-based compensation, depreciation, amortization of warrants issued for services and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was \$46,000 and \$9,000 for the three months ended March 31, 2014 and 2013, respectively. The majority of cash used in investing activities in the three months ended March 31, 2014 was for laboratory and office equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$16,000 and \$0.9 million for the three months ended March 31, 2014 and 2013, respectively. Net cash provided by financing activities was attributable to proceeds from sales of our common stock.

Capital Resource Requirements

As of March 31, 2014, 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 studies, 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 our products, intellectual property protection, and potentially competitive product offerings. The risk factors described in our filings with the SEC 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 System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the SEC. We may update our risk factors from time to time.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer (together, the “*Certifying Officers*”), as appropriate, to allow for timely decisions regarding required disclosure.

In designing and evaluating disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired objectives. Also, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. The design of any system of controls is based, in part, upon certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As of March 31, 2014, the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of management, including the Certifying Officers, of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”). Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of March 31, 2014.

Changes in Internal Controls

There were 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 three months ended March 31, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently subject to any material legal proceedings.

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, 2013. 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

The following sets forth the information required by Item 701 of Regulation S-K with respect to the unregistered sales of equity securities by the Company completed during the three-month period ended March 31, 2014:

Date Issued	Shares of Common Stock Issued	Exercise Price (Australian Dollars)
January 17, 2014	2,798	\$ 6.40
March 11, 2014	5,397	\$ 6.40*

* Paid by means of cashless exercise in which 9,603 shares were surrendered to the Company to fund the exercise.

The issuances referenced above relate to the issuance of our shares of common stock issued in connection with the exercise of certain warrants. The issuance of these shares was exempt from registration pursuant to Section 4(2) of the Securities Act relative to transactions by an issuer not involving a public offering. In connection with the exercise of the warrants:

- the purchasers represented to us that they were accredited investors and were acquiring the shares for investment purposes only and not with a view to, or for sale in connection with, any distribution thereof and that they could bear the risks of the investment and could hold the securities for an indefinite period of time;
- the purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration;
- all certificates representing the securities sold included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities; and
- there were no underwriters employed in connection with the above mentioned sales.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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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.

Sunshine Heart, Inc.

Date: May 13, 2014

By: /s/ David A. Rosa
 David A. Rosa
 Chief Executive Officer and President
 (principal executive officer)

Date: May 13, 2014

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

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Exhibit Index
Sunshine Heart, Inc.
Form 10-Q for the Quarterly Period Ended March 31, 2014

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

*Filed herewith.

**Furnished herewith.

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SARBANES-OXLEY SECTION 302 CERTIFICATION

I, David A. Rosa, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sunshine Heart, Inc. for the quarterly period ended March 31, 2014;
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 13, 2014

/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 Quarterly Report on Form 10-Q of Sunshine Heart, Inc. for the quarterly period ended March 31, 2014;
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 13, 2014

/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 quarterly period ended March 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (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 13, 2014

/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 quarterly period ended March 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (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 13, 2014

/s/ Jeffrey S. Mathiesen

Jeffrey S. Mathiesen

Chief Financial Officer
