

**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 September 30, 2013

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.

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 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.

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a smaller reporting company)

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 shares outstanding of the Company's common stock on November 8, 2013 was 16,839,002.

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	<u>September 30,</u> <u>2013</u>	<u>December 31,</u> <u>2012</u>
	<u>(unaudited)</u>	
Current assets		
Cash and cash equivalents	\$ 59,807	\$ 14,224
Accounts receivable	59	—
Other current assets	511	333
Total current assets	<u>60,377</u>	<u>14,557</u>
Property, plant and equipment, net	431	479
TOTAL ASSETS	<u>\$ 60,808</u>	<u>\$ 15,036</u>
Current liabilities		
Accounts payable	\$ 2,042	\$ 1,156
Accrued salaries, wages, and other compensation	910	931
Total current liabilities	<u>2,952</u>	<u>2,087</u>
Total liabilities	2,952	2,087
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of September 30, 2013 and December 31, 2012, par value \$0.0001 per share; authorized 30,000 shares	—	—
Preferred stock as of September 30, 2013 and December 31, 2012, par value \$0.0001 per share; authorized 39,970,000 shares	—	—
Common stock as of September 30, 2013 and December 31, 2012, par value \$0.0001 per share; authorized 100,000,000 shares; issued and outstanding 16,805,411 and 9,282,724 shares, respectively	2	1
Additional paid-in capital	150,667	91,017
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,095	1,185
Accumulated deficit	(93,908)	(79,254)
Total stockholders' equity	<u>57,856</u>	<u>12,949</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 60,808</u>	<u>\$ 15,036</u>

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

Nine months ended

	September 30,		September 30,	
	2013	2012	2013	2012
Net sales	\$ 59	\$ —	\$ 59	\$ —
Operating expenses				
Selling, general and administrative	2,486	1,495	6,612	5,004
Research and development	3,747	1,802	9,323	5,755
Total operating expenses	6,233	3,297	15,935	10,759
Loss from operations	(6,174)	(3,297)	(15,876)	(10,759)
Interest income	3	1	9	30
Loss before income taxes	(6,171)	(3,296)	(15,867)	(10,729)
Income tax benefit	(136)	—	(1,213)	(730)
Net loss	\$ (6,035)	\$ (3,296)	\$ (14,654)	\$ (9,999)
Basic and diluted loss per share	\$ (0.47)	\$ (0.42)	\$ (1.29)	\$ (1.49)
Weighted average shares outstanding — basic and diluted	12,732	7,789	11,354	6,727
Comprehensive loss	\$ (6,200)	\$ (3,308)	\$ (14,744)	\$ (9,948)

See notes to the condensed consolidated financial statements.

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

	For the nine months ended September 30,	
	2013	2012
Net loss	\$ (14,654)	\$ (9,999)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	130	98
Loss on disposal of plant and equipment	—	63
Stock-based compensation expense, net	1,821	907
Amortization of warrants for service agreements	240	160
Changes in assets and liabilities		
Accounts receivable	(59)	—
Other current assets	(179)	(321)
Accounts payable and accrued expenses	946	(574)
Net cash used in operations	(11,755)	(9,666)
Cash flows used in investing activities:		
Purchases of property and equipment	(82)	(132)
Net cash used in investing activities	(82)	(132)
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	57,591	20,620
Net cash provided by financing activities	57,591	20,620
Effect of exchange rate changes on cash	(171)	61
Net increase in cash and cash equivalents	45,583	(10,883)
Cash and cash equivalents - beginning of period	14,224	6,563
CASH AND CASH EQUIVALENTS - END OF PERIOD	\$ 59,807	\$ 17,446

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 Clontarf, 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 counterpulsation technology by enabling an increase in cardiac function, 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. pivotal clinical trial with the C-Pulse Heart System. Our shares of common stock in the form of CHES Depository Interests, or CDIs, were publicly traded in Australia on the Australian Securities Exchange, or ASX, from September 2004 until our delisting from the ASX, effective 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, 2012 and 2011 and through September 30, 2013, 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, 2012, we had an accumulated deficit of \$79,254 and we expect to incur losses for the foreseeable future. To date, the Company has been funded by private and public equity financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

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

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

Unaudited Interim Condensed Consolidated Financial Information: The interim condensed consolidated balance sheet as of September 30, 2013 and statements of operations and comprehensive loss for the three and nine month periods ended September 30, 2013 and 2012, as well as the statements of cash flows for the nine months ended September 30, 2013 and 2012 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. 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 the year ended December 31, 2012. 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 and nine months ended September 30, 2013 are not necessarily indicative of the results that may be expected for the year ending December 31, 2013 or any other interim period or for any other future year.

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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 Heart System is not approved for commercial sale. However, the FDA has assigned the C-Pulse System to Category B designation, making it eligible for reimbursement at certain US sites during our clinical trials. 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 Heart System to hospitals and clinics who participate in our clinical trials per the terms of the clinical trial contracts. For clinical trial implant revenue, the product title generally transfers on the date the product is implanted. Product costs incurred for our clinical trials 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 we report the related revenue and record such costs in cost of sales.

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 ("**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 3,325,816 and 2,551,456 for the nine months ended September 30, 2013 and 2012, 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, 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 ("**FASB**"), Audit Standards Codification ("**ASC**") 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:

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 thus, for any period presented, there were no movements between these categories.

Recent Accounting Pronouncements: In February 2013, the FASB issued guidance adding new disclosure requirements for items reclassified out of accumulated other comprehensive income (“*AOCI*”), which became effective for us on January 1, 2013. The guidance is intended to help entities improve the transparency of changes in other comprehensive income (“*OCI*”) and items reclassified out of *AOCI* in financial statements. It does not amend any existing requirements for reporting net income or *OCI* in financial statements. The implementation of the guidance did not have a material impact on our condensed consolidated financial statements.

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,

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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 a two-year period at purchase prices determined in accordance with the Purchase Agreement. Pursuant to the terms of the Purchase Agreement, we have filed and maintain a registration statement on Form S-1 with the SEC under which we have 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 September 30, 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.

Public Offerings

On April 16, 2013 we sold 2,875,000 shares of common stock in a public offering at \$5.25 per share, including 375,000 shares of common stock pursuant to the exercise of the over-allotment option by our underwriters. Proceeds in the public offering and exercise of the over-allotment option, net of transaction costs were \$14,036 in the aggregate.

On September 24, 2013 we sold 4,381,500 shares of common stock in a public offering at \$10.50 per share, including 571,500 shares of common stock pursuant to the exercise of the over-allotment option by our underwriters. Proceeds in the public offering and exercise of the over-allotment option, net of transaction costs were \$42,674 in the aggregate.

Stock-Based Compensation

The Company recognizes all share-based payments, including grants of stock options and compensatory employee stock purchase plans, in the income statement as an operating expense, based on their fair value over the requisite service period. We recorded \$888 and \$328 of related compensation expense to selling, general and administrative expense and research and development expense, respectively, for the three months ended September 30, 2013,

as compared to \$192 and \$23, respectively, of related compensation expense for the three months ended September 30, 2012. We recorded \$1,491 and \$614 of related compensation expense to selling, general and administrative expense and research and development expense, respectively, for the nine months ended September 30, 2013, as compared to \$594 and \$315, respectively, of related compensation expense for the nine months ended September 30, 2012. As of September 30, 2013, a total of \$4,906 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

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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. Stock Awards are valued at the stock price on the date of grant and expensed for the full value on the date of grant. Restricted Stock Unit (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 twelve month period are re-valued using the Black- Scholes method as they vest monthly and expensed to operations and recognizing a corresponding liability.

During the third quarter ended September 30, 2013, the following equity awards were made:

- Common stock grants of 46,509 shares (27,451 net of income tax withholdings) valued at \$507 were awarded to certain executives and included in operating expense. The executives elected to have 19,508 shares withheld to fund income tax withholding payments.
- RSUs were awarded to certain directors for a total of 10,597 shares. These RSU's were fully vested at the date of grant and valued at \$7.50 per share, the closing stock price that day. The total value of \$79 was included in selling, general and administrative expense. These RSU's will be settled for common shares according to the terms of the awards, but no later than the first quarter of Fiscal 2014.
- RSUs totaling 46,509 shares were awarded to certain executives. These RSU's will vest over the next twelve months at a rate of 1/12 per month and were valued at \$10.90 per share, the closing share price on the date of the award. These RSU's will be re-valued every period as they vest and will be expensed accordingly using the liability method of accounting. Vesting on these RSU's commences in October 2013, at which point the corresponding liability and expense will be recorded. The vested RSU's will be settled for common shares beginning in 2014, according to the terms of the awards.

For the nine months ended September 30, 2013, the Company had 21,803 stock options granted to non-employees with a fair value of \$76. The awards are revalued every period and expensed accordingly using the liability method of accounting.

The Company's stock options generally vest over four years of service and have a contractual life of 10 years. We have 254,768 shares authorized for grant under our Amended and Restated 2011 Equity Incentive Plan, 318,993 shares authorized for grant under our 2013 New Hire Plan and 177,099 shares authorized for grant under our 2013 Non-Executive Directors' Equity Incentive Plan.

Warrants

Warrants to purchase 1,632,257 shares of common stock were outstanding at September 30, 2013, versus 1,633,253 outstanding at December 31, 2012.

During the nine months ended September 30, 2013, warrants to purchase 996 shares of common stock were exercised at a price of AU\$6.40 per share for total proceeds of \$6.

Note 3 - Balance Sheet Information

Property, Plant and Equipment

Property, plant and equipment were as follows:

	<u>September 30, 2013</u>	<u>December 31, 2012</u>
Office Furniture & Fixtures	\$ 110	\$ 102
Leasehold Improvements	145	145
Software	33	12
Production Equipment	486	425
Computer Equipment	110	118
Total	884	802
Accumulated Depreciation	(453)	(323)
	<u>\$ 431</u>	<u>\$ 479</u>

Depreciation expense for the three and nine months ended September 30, 2013 was \$47 and \$130, respectively, versus \$36 and \$98 for the comparable periods in 2012.

Note 4 — Income Taxes

We completed our Minnesota tax return for the twelve month period ended December 31, 2012 and recorded a \$136 research and development tax credit refund during the third quarter of fiscal 2013. For the twelve month period ended December 31, 2011 we received a Minnesota research and development tax credit refund of \$69. The Minnesota research and development tax credit is no longer in effect for tax years beyond 2012. We received a \$1,077 research and development tax credit refund in the quarter ended June 30, 2013, based upon qualified research and development expenditures of our

Australian subsidiary for its tax period ended June 30, 2012. We received a \$730 research and development tax credit refund in the quarter ended June 30, 2012 based upon qualified research and development expenditures of our Australian subsidiary for its tax period ended June 30, 2011. We have not completed the Australian tax return for the period ended June 30, 2013; therefore, we have not reflected a benefit related to the Australian research and development tax credit for that period as we recognize any benefit only upon receipt.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our interim 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, 2012. 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, 2012 and in our subsequent filings with the U.S. Securities and Exchange Commission.

Overview

We are a medical device company developing innovative technologies for cardiac and coronary disease. The Company’s primary product, the C-Pulse® Heart Assist System (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 counterpulsation 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 trial in the first half of 2011. In November 2011, we announced the preliminary results of the six-month follow-up period for the feasibility study and we submitted the clinical data to the FDA. In March 2012, the FDA notified us that it completed its review of the C-Pulse System feasibility trial data, concluded we met the applicable agency requirements, and indicated that we can move forward with an investigational device exemption application. In November 2012, the FDA provided us with unconditional approval to initiate a pivotal trial. We commenced enrollment of our pivotal trial 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 trial in Europe that will evaluate endpoints similar to those for our U.S. pivotal trial and enrollment under this trial 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 Heart System is not approved for commercial sale. However, the FDA has assigned the C-Pulse System to Category B designation, making it eligible for reimbursement at certain US sites during our clinical trials. 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 Heart System to hospitals and clinics who participate in our clinical trials per the terms of the clinical trial contracts. For clinical trial implant revenue, the product title generally transfers on the date the product is implanted. Product costs incurred for our clinical trials 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 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.

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Stock-Based Compensation: We recognize all share-based payments, including grants of stock options 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 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. Restricted Stock Unit (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 twelve month period are re-valued using the Black-Scholes method as they vest monthly and expensed to operations and recognizing a corresponding liability.

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

Stock options granted to non-employees are revalued using the Black-Scholes method and are expensed to operations and recognized as a corresponding liability.

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, 2012 and 2011, and through September 30, 2013 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 February 2013, the FASB issued guidance adding new disclosure requirements for items reclassified out of AOCI, which became effective for us on January 1, 2013. The guidance is intended to help entities improve the transparency of changes in OCI and items reclassified out of AOCI in financial statements. It does not amend any existing requirements for reporting net income or OCI in financial statements. The implementation of the guidance did not have a material impact on our condensed consolidated financial statements.

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 September 30, 2013, we had an accumulated deficit of \$93.9 million and we expect to incur losses for the foreseeable future. To date, we have been funded by private and public equity financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

Results of Operations

Comparison of Three Months Ended September, 2013 to Three Months Ended September 30, 2012

Revenue

	Three Months Ended September 30, 2013		Three Months Ended September 30, 2012		Increase (Decrease)	% Change
\$	59,000	\$	—	\$	59,000	N/A%

Sales of the C-Pulse Heart System to hospitals and clinics under contract in conjunction with our North

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American FDA clinical trials historically have generated all of our revenue. Our C-Pulse Heart System is not approved for commercial sale. However, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain US sites during our clinical trials. Consequently, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. We sold one C-Pulse Heart System device in the three month period ended September 30, 2013, as compared to none during the three month period ended September 30, 2012. We expect our revenue will be minimal until we begin enrolling patients in our North American pivotal clinical trial at an increased rate and establish reimbursement in our recently initiated post marketing trial in select countries in Europe. Product costs incurred for our clinical trials are deemed to be development costs and, accordingly, are expensed to research and development as incurred.

Selling, General and Administrative Expense

	Three Months Ended September 30, 2013		Three Months Ended September 30, 2012		Increase (Decrease)	% Change
\$	2,486,000	\$	1,495,000	\$	991,000	66.3%

Our increase in selling, general and administrative expense for the three months ended September 30, 2013 compared to the prior year comparable period is attributed to increased infrastructure expenses, professional fees, and compensation expense to support our anticipated growth. 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 September 30, 2013	Three Months Ended September 30, 2012	Increase (Decrease)	% Change
\$ 3,747,000	\$ 1,802,000	\$ 1,945,000	107.9%

Our increase in research and development expense for the third quarter 2013 compared to the prior year's period resulted primarily from increased personnel and clinical research infrastructure to support our clinical trials in North America and Europe. We expect our research and development expense will continue to be above prior year levels throughout 2013 as we add personnel to support our clinical trials and pursue our development efforts.

Interest Income

Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Increase (Decrease)	% Change
\$ 3,000	\$ 1,000	\$ 2,000	200.0%

Our increase in interest income for the third quarter 2013 compared to the prior year was primarily caused by increased cash balances.

Income Tax Benefit

Three Months Ended September 30, 2013	Three Months Ended September 30, 2012	Increase (Decrease)	% Change
\$ 136,000	\$ —	\$ 136,000	N/A

Historically, our income tax benefits have resulted from research and development tax credit refunds in Australia and the state of Minnesota and are recognized upon receipt of the refund or determination that receipt of the refund is reasonably assured. We completed our Minnesota tax return for the twelve month period ended December 31, 2012 and recognized a \$136,000 research and development tax credit refund during the quarter ended September 30, 2013. Assuming no further changes to the applicable Australian law for research and development tax

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credits, we expect to receive tax refunds in the future in amounts that vary based on research and development expenditures in those jurisdictions. At this time, we are working to complete our analysis of the potential Australian research and development tax credit refund that may be available for the period ended June 30, 2013. The Minnesota research and development tax credit is no longer in effect for tax years beyond 2012.

Comparison of Nine Months Ended September 30, 2013 to Nine Months Ended September 30, 2012

Revenue

Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012	Increase (Decrease)	% Change
\$ 59,000	\$ —	\$ 59,000	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. Our C-Pulse Heart System is not approved for commercial sale. However, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain US sites during our clinical trials. Consequently, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. We sold one C-Pulse Heart System device in the nine month period ended September 30, 2013, as compared to none during the nine month period ended September 30, 2012. We expect our revenue will be minimal until we begin enrolling patients in our North American pivotal clinical trial at an increased rate and establish reimbursement in our recently initiated post marketing trial in select countries in Europe. Product costs incurred for our clinical trials are deemed to be development costs and, accordingly, are expensed to research and development as incurred.

Selling, General and Administrative Expense

Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012	Increase (Decrease)	% Change
\$ 6,612,000	\$ 5,004,000	\$ 1,608,000	32.1%

Our increase in selling, general and administrative expense for the nine months ended September 30, 2013 compared to the prior year is attributed to increased infrastructure expenses, professional fees, and compensation expense to support our anticipated growth. 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

Nine Months Ended September 30, 2013	Nine Months Ended September 30, 2012	Increase (Decrease)	% Change
\$ 9,323,000	\$ 5,755,000	\$ 3,568,000	62.0%

Our increase in research and development expense for the nine months ended September 30, 2013 compared to the prior year's period resulted primarily from increased personnel and clinical research infrastructure to support our clinical trials in North America and Europe. We expect our revenue will be minimal until we establish reimbursement in our recently initiated post marketing trial in select countries in Europe and begin enrolling patients in our North American pivotal clinical trial, expected to commence in the second half of 2013.

Interest Income

	Nine Months Ended September 30, 2013		Nine Months Ended September 30, 2012		Increase (Decrease)		% Change
\$	9,000	\$	30,000	\$	(21,000)		70.0%

Our decrease in interest income for the first half of 2013 compared to the prior year was primarily caused by decreased cash balances held in Australia during the first nine months of 2013 as compared to 2012.

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Income Tax Benefit

	Nine Months Ended September 30, 2013		Nine Months Ended September 30, 2012		Increase (Decrease)		% Change
\$	(1,213,000)	\$	(730,000)	\$	483,000		66.2%

Our income tax benefit for the nine months ended September 30, 2013 and 2012 resulted from a research and development tax credit in Australia and Minnesota. We completed our Australian tax return for the twelve month period ended June 30, 2012 in the second quarter of 2013 and received a \$1,077,000 research and development tax credit refund during the quarter. We completed our Australian tax return for the twelve month period ended June 30, 2011 in the second quarter of 2012 and received a \$730,000 research and development tax credit refund during the quarter. We completed our Minnesota tax return for the twelve month period ended December 31, 2012 and recognized a \$136,000 research and development tax credit refund during the quarter ended September 30, 2013. Assuming no further changes to the applicable Australian law for research and development tax credits, we expect to receive research and development tax credits refunds in the future in decreased amounts that vary based on reduced research and development expenditures in Australia. At this time, we are working to complete our analysis of the potential research and development tax credit refund that may be available for the period ended June 30, 2013. The Minnesota research and development tax credit is no longer in effect for tax years beyond 2012.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through a series of equity issuances, including the issuance of common shares for net cash proceeds of \$57.6 million and \$20.6 million in the first nine months of 2013 and 2012, respectively. As of September 30, 2013 and December 31, 2012, cash and cash equivalents were \$59.8 million and \$14.2 million, respectively.

We believe, based on our current operating plan, that our cash balances and cash generated from our clinical trials and the net proceeds from the sale of stock to Aspire Capital, if completed in its entirety, will be sufficient to meet our anticipated cash requirements for at least the next twelve months. From time to time we may seek to sell additional equity or convertible debt securities or enter into credit facilities. The sale of additional equity, 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 \$11.8 million and \$9.7 million in the nine months ended September 30, 2013 and 2012, 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.

Cash Flows from Investing Activities

Net cash used in investing activities was \$82,000 and \$132,000 in the nine months ended September 30, 2013 and 2012, respectively. The majority of cash used in investing activities in first nine months of 2012 was for leasehold improvements, furniture and equipment associated with the relocation of our headquarters in January 2012.

Cash Flows from Financing Activities

Net cash provided by financing activities was \$57.6 million and \$20.6 million in the nine months ended September 30, 2013 and 2012, respectively. Net cash provided by financing activities was attributable to net proceeds from sales of our common stock.

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Capital Resource Requirements

As of September 30, 2013, 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 (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 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 our filings with the SEC. We may update our risk factors from time to time.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective as of September 30, 2013, 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, 2012. Those factors, if they were to occur, could cause our actual results to differ materially from those expressed in our forward-looking statements in this report, and materially adversely affect our financial condition or future results. Although we are not aware of any other factors that we currently anticipate will cause our forward-looking statements to differ materially from our future actual results, or materially affect the Company's financial condition or future results, additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results.

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

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 September 30, 2013:

<u>Date Issued</u>	<u>Shares of Common Stock Issued</u>	<u>Exercise Price (Australian Dollars)</u>
July 2, 2013	23	\$ 6.40
September 27, 2013	973	\$ 6.40

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 of 1933, as amended (the "Securities Act") relative to transactions by an issuer not involving a public offering. In connection with the exercise of the warrants:

- each of 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;

- each of 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.

Date: November 12, 2013

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
 (Principal financial officer and principal accounting officer)

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**Exhibit Index
 Sunshine Heart, Inc.
 Form 10-Q for Quarter Ended September 30, 2013**

Exhibit Number	Description
10.1*	First Amendment to the Sunshine Heart, Inc. New-Hire Equity Incentive Plan.
10.2*	Form of Stock Option Grant Notice and Option Agreement for the Sunshine Heart, Inc. New-Hire Equity Incentive Plan.
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.

**FIRST AMENDMENT
TO THE
SUNSHINE HEART, INC.
NEW-HIRE EQUITY INCENTIVE PLAN**

The Sunshine Heart, Inc. New-Hire Equity Incentive Plan (the "**Plan**") is hereby amended in the following respects, effective October 21, 2013, in accordance with Sections 2(b)(vi) and 2(c)(i) of the Plan.

The first sentence of Section 3(a) of the Plan is deleted in its entirety and replaced with the following sentence:

"Subject to the provisions of Section 9 relating to adjustments upon changes in stock, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards after the Effective Date shall not exceed, in the aggregate, 600,000 shares (the "**Share Reserve**")."

**SUNSHINE HEART, INC.
STOCK OPTION GRANT NOTICE
UNDER THE NEW-HIRE EQUITY INCENTIVE PLAN**

Sunshine Heart, Inc. (the “*Company*”), pursuant to its New-Hire Equity Incentive Plan (the “*Plan*”), hereby grants to Participant an Option to purchase the number of shares of the Company’s Common Stock set forth below as an inducement material to the Participant entering into an employment relationship with the Company. This Option is not intended to qualify as an incentive stock option within the meaning of Section 422 of the Code and shall therefore be treated a non-qualified option. This Option is subject to all of the terms and conditions as set forth in this notice, in the Option Agreement, the Plan and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement. If there is any conflict between the terms in this notice and the Plan, the terms of the Plan will control.

Participant:

Date of Grant:

Vesting Commencement Date:

Number of Shares Subject to Option:

Exercise Price (Per Share):

Expiration Date:

Vesting Schedule: 1/48th of the shares will vest on the twelfth day of each month commencing the Vesting Commencement Date.

Payment: By one or a combination of the following items (described in the Option Agreement):

- o By cash, check, bank draft or money order payable to the Company;
- o By delivery of already-owned shares if the shares are publicly traded;
- o By a “net exercise” arrangement (as described in your Option Agreement); or
- o Pursuant to a broker assisted cashless exercise.

Additional Terms/Acknowledgements: Participant acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Participant acknowledges and agrees that this Stock Option Grant Notice and the Option Agreement may not

be modified, amended or revised except as provided in the Plan. Participant further acknowledges and agrees that this Option was granted to Participant as an inducement material the Participant entering into an employment relationship with the Company. Participant further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Participant and the Company regarding this Option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) Options previously granted and delivered to Participant, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written service severance arrangement that would provide for vesting acceleration of this Option upon the terms and conditions set forth therein.

By accepting this Option, Participant consents to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

SUNSHINE HEART, INC.

OPTIONHOLDER:

By: _____
Signature

Signature

Title: _____

Date: _____

Date: _____

ATTACHMENTS: Option Agreement, New-Hire Equity Incentive Plan and Notice of Exercise

ATTACHMENT II

NEW-HIRE EQUITY INCENTIVE PLAN

ATTACHMENT III

NOTICE OF EXERCISE

SUNSHINE HEART, INC.
NEW-HIRE EQUITY INCENTIVE PLAN

OPTION AGREEMENT FOR EMPLOYEES (NEW HIRES ONLY)
(NONSTATUTORY STOCK OPTION)

Pursuant to your Stock Option Grant Notice ("**Grant Notice**") and this Option Agreement, Sunshine Heart, Inc. (the "**Company**") has granted you an Option ("**Option**") under its New-Hire Equity Incentive Plan (the "**Plan**") to purchase the number of shares of the Company's Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. Defined terms not explicitly defined in this Option Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your Option are as follows:

1. VESTING. Subject to the provisions contained herein, your Option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service.

2. NUMBER OF SHARES AND EXERCISE PRICE. The number of shares of Common Stock subject to your Option and your exercise price per share referenced in your Grant Notice may be adjusted from time to time for Capitalization Adjustments.

3. EXERCISE.

(a) You may exercise the vested portion of your Option during its term by (i) delivering the Notice of Exercise, attached hereto as Exhibit A and by completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate. You may exercise your Option only for whole shares of Common Stock; the Company shall not be required to issue any fractional shares of Common Stock under any circumstances.

(b) By exercising your Option you agree that, as a condition to any exercise of your Option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of your Option.

(c) The exercise of your Option must comply with all applicable laws and regulations governing your Option, and you may not exercise your Option if the Company determines that such exercise would not be in material compliance with such laws and regulations. Notwithstanding anything to the contrary contained herein, the Committee may suspend your right to exercise the Option for any period of up to 180 days in any 365-day period for which the Committee determines, in good faith, that such suspension would be necessary or advisable in order to comply with the requirements of (i) any applicable federal securities law or rule or regulation thereunder; (ii) any rule of a national securities exchange, national securities association, or other self-regulatory organization; or (iii) any other federal or state law or regulation (each an "**Option Exercise Suspension**"). Notwithstanding the foregoing, no Option

Exercise Suspension shall extend the term of the Option in a manner that would result in the Option becoming nonqualified deferred compensation subject to Section 409A of the Code.

4. METHOD OF PAYMENT. Payment of the exercise price is due in full upon exercise of all or any part of your Option. You may elect to make payment of the exercise price in cash or by check or in any one or more of the following manners unless otherwise provided in your Grant Notice:

(a) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.

(b) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your Option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company.

Notwithstanding the foregoing, you may not exercise your Option by delivery to the Company of Common Stock if doing so would violate the provisions of the Listing Rules, any law, regulation or agreement restricting the redemption of the Company's stock.

(c) Subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your Option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your Option and will not be exercisable thereafter if those shares are (i) used to pay the exercise price pursuant to the "net exercise," (ii) delivered to you as a result of such exercise, and (iii) withheld to satisfy tax withholding obligations.

5. METHOD OF PAYMENT. Payment of the exercise price is due in full upon exercise of all or any part of your Option. You may elect to make payment of the exercise price in cash or by check or in any one or more of the following manners unless otherwise provided in your Grant Notice:

(a) Provided that at the time of exercise the Common Stock is publicly traded, pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check)

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by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds.

(b) Provided that at the time of exercise the Common Stock is publicly traded, by delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. "Delivery" for these purposes, in the sole discretion of the Company at the time you exercise your Option, will include delivery to the Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. Notwithstanding the foregoing, you may not exercise your Option by delivery to the Company of Common Stock if doing so would violate the provisions of the Listing Rules, any law, regulation or agreement restricting the redemption of the Company's stock.

(c) Subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your Option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your Option and will not be exercisable thereafter if those shares are (i) used to pay the exercise price pursuant to the "net exercise," (ii) delivered to you as a result of such exercise, and (iii) withheld to satisfy tax withholding obligations.

6. TERM. You may not exercise your Option before the Date of Grant or after its Expiration Date. Subject to Section 6, below, the term of your Option commences on the Date of Grant and expires upon the earliest of the following:

- (a) three (3) months after the termination of your Continuous Service for any reason other than your death or Disability;
- (b) twelve (12) months after the termination of your Continuous Service due to your death or Disability;
- (c) the Expiration Date indicated in your Grant Notice; or
- (d) the day before the tenth (10th) anniversary of the Date of Grant.

7. CORPORATE TRANSACTION; CHANGE IN CONTROL. In the event of a Corporate Transaction or Change in Control, your Option shall be subject to the provisions of Sections 9(c) and (d) of the Plan, including any forfeiture provisions described therein.

8. TRANSFERABILITY. Your Option is not transferable, except (i) by will or by the laws of descent and distribution, (ii) pursuant to a domestic relations order and (iii) with the prior written approval of the Company, by instrument to an inter vivos or testamentary trust, in a form

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accepted by the Company, in which the Option is to be passed to beneficiaries upon the death of the trust or (settlor).

9. WITHHOLDING OBLIGATIONS.

(a) At the time you exercise your Option, in whole or in part, or at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for, any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with your Option.

(b) Upon your request and subject to approval by the Company, in its sole discretion, and in compliance with any applicable conditions or restrictions of law, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your Option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your Option as a liability for financial accounting purposes). Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your Option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your Option when desired even though your Option is vested, and the Company shall have no obligation to issue a certificate for such shares of Common Stock unless such obligations are satisfied.

10. TAX CONSEQUENCES. You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your Option or your other compensation. In particular, you acknowledge that this Option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the “fair market value” per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the Option.

11. NOTICES. Any notices provided for in your Option or the Plan shall be given in writing and shall be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

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12. GOVERNING PLAN DOCUMENT. Your Option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your Option and those of the Plan, the provisions of the Plan will control. In addition, your Option (and any compensation paid, shares issued under your Option, or proceeds received upon the sale of such shares) is subject to recoupment in accordance with The Dodd—Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback or compensation recovery policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

13. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS. The value of this Option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company’s or any Affiliate’s employee benefit plans.

14. VOTING RIGHTS. You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

15. SEVERABILITY. If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

16. CONSENT TO TRANSFER OF PERSONAL DATA. In administering the Plan, or to comply with applicable legal, regulatory, tax, or accounting requirements, it may be necessary for the Company to transfer certain Participant data to an affiliate or to its outside service providers or governmental agencies. By accepting the Option, you consent, to the fullest extent permitted by law, to the use and transfer, electronically or otherwise, of your personal data to such entities for such purposes.

17. MISCELLANEOUS.

(a) The rights and obligations of the Company under your Option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company’s successors and assigns.

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(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Option.

(c) You acknowledge and agree that you have reviewed your Option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Option, and fully understand all provisions of your Option.

(d) This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(e) All obligations of the Company under the Plan and this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

* * *

This Option Agreement will be deemed to be signed by you upon the signing by you of the Stock Option Grant Notice to which it is attached.

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SUNSHINE HEART, INC.
12988 Valley View Road
Eden Prairie, MN 55344

Date of Exercise: _____

This constitutes notice to Sunshine Heart, Inc. (the "*Company*") under my Option that I elect to purchase the below number of shares of Common Stock of the Company (the "*Shares*") for the price set forth below.

Type of Option (check one): Nonstatutory

Stock Option dated:

Number of Shares as to which Option is exercised:

Certificates to be issued in name of:

Total exercise price: \$

Cash payment delivered herewith: \$

[Value of Shares delivered herewith(1): \$]

[Value of Shares pursuant to net exercise(2): \$]

[[Regulation T Program (cashless exercise(3)): \$]

-
- (1) Shares must meet the public trading requirements set forth in the Option. Shares must be valued in accordance with the terms of the Option being exercised, and must be owned free and clear of any liens, claims, encumbrances or security interests. Certificates must be endorsed or accompanied by an executed assignment separate from certificate.
 - (2) Sunshine Heart, Inc. must have established net exercise procedures at the time of exercise, in order to utilize this payment method.
 - (3) Shares must meet the public trading requirements set forth in the option.

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, and (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this Option.

Very truly yours,

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.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2013

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 quarterly 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 the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2013

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 September 30, 2013 as filed with the Securities and Exchange Commission (the "*Report*"), I, David A. Rosa, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2013

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 September 30, 2013 as filed with the Securities and Exchange Commission (the "*Report*"), I, Jeffrey S. Mathiesen, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2013

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