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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2015

OR

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

For the transition period from to

Commission file number 001-35312

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**No. 68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	(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 x No o

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 x No o

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

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

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

The number of outstanding shares of the registrant's common stock, $0.0001 par value, as of November 2, 2015 was 18,339,948.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

SUNSHINE HEART, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets		
Cash and cash equivalents	$ 27,899	$ 31,293
Accounts receivable	—	59
Other current assets	765	360
Total current assets	28,664	31,712
Property, plant and equipment, net	595	661
Other assets	108	—
TOTAL ASSETS	$ **29,367**	$ **32,373**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Current portion of long-term debt	$ 2,867	$ —
Accounts payable and accrued expenses	2,329	2,079
Accrued salaries, wages, and other compensation	856	1,079
Total current liabilities	6,052	3,158
Long-term debt, net of discount	4,880	—
Total liabilities	10,932	3,158
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of September 30, 2015 and December 31, 2014, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Preferred stock as of September 30, 2015 and December 31, 2014, par value $0.0001 per share; authorized 39,970,000 shares, none outstanding	—	—
Common stock as of September 30, 2015 and December 31, 2014, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 18,337,683 and 16,982,642 shares, respectively	2	2
Additional paid-in capital	163,761	154,540
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,250	1,272
Accumulated deficit	(146,578)	(126,599)
Total stockholders' equity	18,435	29,215
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ **29,367**	$ **32,373**

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 September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Net sales	**$ —**	$ 59	$ 59	$ 118
Operating expenses				
Selling, general and administrative	1,725	2,361	6,259	6,965
Research and development	4,548	3,808	13,404	12,284
Total operating expenses	6,273	6,169	19,663	19,249
Loss from operations	(6,273)	(6,110)	(19,604)	(19,131)
Other income (expense), net	(282)	(22)	(499)	22
Loss before income taxes	(6,555)	(6,132)	(20,103)	(19,109)
Income tax (benefit) expense	3	—	(124)	(265)
Net loss	**$ (6,558)**	**$ (6,132)**	**$ (19,979)**	**$ (18,844)**
Basic and diluted loss per share	**$ (0.36)**	**$ (0.36)**	**$ (1.11)**	**$ (1.12)**
Weighted average shares outstanding — basic and diluted	18,330	16,903	18,045	16,881
Other comprehensive income:				
Foreign currency translation adjustments	$ (16)	$ 17	$ (22)	$ (5)
Total comprehensive loss	**$ (6,574)**	**$ (6,115)**	$ (20,001)	**$ (18,849)**

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)

	Nine months ended September 30,	
	2015	2014
Operating Activities:		
Net loss	**$** (19,979)	$ (18,844)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	241	198
Stock-based compensation expense, net	1,811	1,924
Amortization of debt discount	102	—
Changes in operating assets and liabilities		
Accounts receivable	59	—
Other current assets	(406)	(207)
Other assets	(108)	—
Accounts payable and accrued expenses	48	(429)
Net cash used in operations	**(18,232)**	**(17,358)**
Investing Activities:		
Purchases of property and equipment	(175)	(205)
Net cash used in investing activities	**(175)**	**(205)**
Financing Activities:		
Net proceeds from the sale of common stock	7,055	16
Proceeds from borrowings on long-term debt	8,000	—
Net cash provided by financing activities	**15,055**	**16**
Effect of exchange rate changes on cash	(42)	(14)
Net decrease in cash and cash equivalents	(3,394)	(17,561)
Cash and cash equivalents - beginning of period	31,293	54,136
Cash and cash equivalents - end of period	**$ 27,899**	**$ 36,575**
Supplement schedule of non-cash activities		
Stock options and restricted stock units classified as liabilities, net	**$ —**	**$** (337)
Warrants issued in connection with debt financing	**$** 355	**$ —**

See notes to the condensed consolidated financial statements.

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Note 1 - Basis of Presentation

Unless otherwise specified or indicated by the context, **"**Sunshine Heart," "Company," "we," "us" and "our" refer to Sunshine Heart, Inc. and its subsidiaries.

Principles of Consolidation: The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S.) (U.S. GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information necessary for a fair presentation of results of operations, comprehensive income, financial condition, and cash flows in conformity with U.S. GAAP. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented. Operating results for interim periods are not necessarily indicative of results that may be expected for the year as a whole. The preparation of the financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and the related disclosures at the date of the financial statements and during the reporting period. Actual results could materially differ from these estimates.

For further information, refer to the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

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, 2014 and 2013 and through September 30, 2015, 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, 2014, the Company had an accumulated deficit of $126.6 million and it expects to incur losses for the foreseeable future. To date, the Company has been funded by debt and equity financings, and although the Company believes that it will be able to successfully fund its operations, there can be no assurance that it will be able to do so or that it 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.

Earnings per share: Basic earnings per share is computed based on the weighted average number of common shares outstanding. Diluted earnings per share is computed based on the weighted average number of common shares outstanding, increased by the number of additional shares that would have been outstanding had the potentially dilutive common shares been issued, and reduced by the number of shares the Company could have repurchased from the proceeds from issuance of the potentially dilutive shares. Potentially dilutive shares of common stock include warrants, stock options and other stock-based awards granted under stock-based compensation plans. These potentially dilutive shares totaling 2,481,013 and 3,979,956 as of September 30, 2015 and 2014, 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.

New Accounting Pronouncements: In May 2014, the Financial Accounting Standards Board (FASB) issued amended revenue recognition guidance to clarify the principles for recognizing revenue from contracts with customers. The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. In August 2015, the FASB amended the guidance to defer the effective date by one year, so this guidance will be effective for the Company's interim and annual periods beginning January 1, 2018. The Company is currently evaluating the impact that this standard will have on its business practices, financial condition, results of operations and disclosures.

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In August 2014, the FASB amended guidance relating to the presentation and disclosure of the uncertainties of an entity's ability to continue as a going concern. This guidance explicitly requires management of a company to evaluate whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosure in certain circumstances. This guidance is effective for the Company's interim and annual reporting periods beginning January 1, 2017, with early adoption permitted. The Company is evaluating the impact that the adoption of this standard will have, if any, on its financial statements and disclosures.

In April 2015, the FASB issued amended guidance concerning debt issuance costs in relation to a recognized debt liability to require it be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance is effective for the Company's interim and annual reporting periods beginning January 1, 2016. Early adoption is, however, permitted. The Company is evaluating the timing of adoption and the potential impact on its financial position.

Note 2 - Debt

On February 18, 2015, the Company entered into a loan and security agreement with Silicon Valley Bank for proceeds of up to $10.0 million at an annual interest rate of 7.0%. Under this agreement, a $6.0 million term loan was funded at closing and an additional term loan in the amount of $2.0 million was funded on June 26, 2015. Availability of the second term loan was conditioned on the U.S. Food and Drug Administration (FDA) granting the Company interim analysis of COUNTER HF™, its U.S. pivotal study for the C-Pulse® Heart Assist System. The Company achieved this regulatory milestone in February 2015. The remaining $2.0 million term loan was available until September 30, 2015, provided that the Company had enrolled its one hundredth

patient in the COUNTER HF study on or before that date. The Company did not achieve this milestone and did not secure additional borrowings under this facility. Total borrowings outstanding under the Silicon Valley Bank facility totaled $8.0 million as of September 30, 2015.

The proceeds from the term loans are used for general corporate and working capital purposes. The Company is entitled to make interest only payments until January 1, 2016. Commencing on January 1, 2016, and continuing on the first day of each calendar month thereafter, the Company is required to repay the advances made in twenty-four consecutive equal monthly installments. Principal payments coming due within twelve months have been classified as current in the accompanying balance sheet.

The agreement is secured by a security interest in assets of the Company and its current and future subsidiaries, including a security interest in intellectual property proceeds, but excluding a current security interest in intellectual property. The agreement contains customary representations (tested on a continual basis) and covenants that, subject to exceptions, restrict the Company's ability to do the following things: declare dividends or redeem or repurchase equity interests; incur additional liens; make loans and investments; incur additional indebtedness; engage in mergers, acquisitions, and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to its existing business. Upon repayment of the term loans, the Company is also required to make a final payment to Silicon Valley Bank equal to 5.0% of the original principal amount of the term loans.

Warrants: In connection with funding of the first term loan for $6.0 million, the Company issued 68,996 warrants at an exercise price of $5.22 per share to Silicon Valley Bank and one of its affiliates. The Company valued these warrants at $3.86 per share utilizing the Black Scholes valuation model and the following assumptions: an expected dividend yield of 0%, an expected stock price volatility of 88.07%, a risk-free interest rate of 1.86%, and an expected life of 6.25 years.

In connection with the funding of the second term loan for $2.0 million, the Company issued 32,609 warrants at an exercise price of $3.68 per share to Silicon Valley Bank and one of its affiliates. The Company valued these warrants at $2.71 per share utilizing the Black Scholes valuation model and the following assumptions: an expected dividend yield of 0%, an expected stock price volatility of 87.04%, a risk-free interest rate of 2.20%, and an expected life of 6.25 years.

All warrants have a life of ten years and were fully vested at the date of grant. The value of these warrants was recorded as debt discount in the accompanying balance sheet and will be amortized to interest expense over the term of the debt agreement using the effective interest rate method. As of September 30, 2015, $253 of unamortized debt discount was netted against long-term debt in the accompanying condensed consolidated balance sheet.

Note 3 - Equity

ATM Sales: In March 2014, the Company entered into a sales agreement with Cowen and Company LLC to sell from time to time, in "at the market" offerings, shares of its common stock having an aggregate offering price of up to $40.0 million. During the nine months ended September 30, 2015, the Company sold 1,256,380 shares of common stock for net proceeds

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of $7.1 million after stock issuance costs of $0.2 million. There were no issuances of common stock under this facility in the nine months ended September 30, 2014.

As of September 30, 2015, the Company had a total of $32.6 million available for future sales under the sales agreement.

Note 4 - Stock-Based Compensation

The Company measures stock-based compensation expense at the grant date based on the fair value of the award and recognizes the compensation expense over the requisite service period, which is generally the vesting period.

The following table presents the classification of stock-based compensation expense recognized for the nine months ended September 30, 2015 and 2014:

	Nine months ended September 30,	
(in thousands)	**2015**	**2014**
Selling, general and administrative expense	$ 1,400	$ 1,631
Research and development expense	694	557
Total stock-based compensation expense	$ 2,094	$ 2,188

Note 5 - Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, and debt. The Company believes 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 FASB Accounting 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:

- *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. The Company does not have any financial instruments classified as Level 2 or Level 3 and there were no movements between these categories during the periods ended September 30, 2015 and December 31, 2014.

Note 6 — Income Taxes

The Company provides for a valuation allowance when it is more likely than not that it will not realize a portion of the deferred tax assets. The Company has established a full valuation allowance for U.S. and foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, the Company has not reflected any benefit of such deferred tax assets in the accompanying financial statements.

As of September 30, 2015, there were no material changes to what the Company disclosed regarding tax uncertainties or penalties in its Annual Report on Form 10-K for the year ended December 31, 2014.

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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 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, 2014. 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, 2014 and in our subsequent filings with the Securities and Exchange Commission (*SEC*).*

Unless otherwise specified or indicated by the context, Sunshine Heart, Company, we, us and our, refer to Sunshine Heart, Inc. and its subsidiaries.

OVERVIEW

We are an early-stage medical device company developing innovative technologies for cardiac and coronary disease. The Company's primary product, the C-Pulse® Heart Assist System (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 pursuing regulatory approvals necessary to commercialize our system in the United States. 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 U.S. Food and Drug Administration (the FDA). In March 2012, the FDA notified us that it had completed its review of the C-Pulse System feasibility study data and concluded we met the applicable agency requirements, and further indicated that we could 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 in our COUNTER HF™ pivotal study in September 2013. The COUNTER HF study is a prospective, randomized, multi-center, controlled study expected to randomize 388 patients in up to 40 clinical sites.

On February 25, 2015, we announced that we had received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF. This interim analysis could reduce the overall duration of the trial.

On March 6, 2015, we announced that COUNTER HF had reached a pre-determined pausing point and we temporarily suspended enrollment in accordance with the study protocol. On May 26, 2015, we announced that the FDA had approved the resumption of patient enrollment in the study. We are once again activating clinical sites and enrolling patients into the study.

On August 31, 2015 we announced that the FDA had approved an amendment to the stopping rule criteria in our COUNTER HF study protocol from "all cause" deaths to "mortality associated with the device, procedure or therapy."

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.

In October 2015, we submitted an application for an NUB to the InEk, the German Institute for Hospital Remuneration System, to obtain reimbursement for this important market. A decision is expected the first week of February 2016.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

We have adopted various accounting policies to prepare the condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States. (U.S. GAAP). Our most significant accounting policies are disclosed in Note 1 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2014.

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The preparation of the condensed consolidated financial statements, in conformity with U.S. GAAP, requires us to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Our estimates and assumptions, including those related to stock-based compensation, and income tax reserves are updated as appropriate, which in most cases is quarterly. We base our estimates on historical experience, valuations, or various assumptions that are believed to be reasonable under the circumstances. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our Annual Report on Form 10-K for the year ended December 31, 2014.

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, 2014 and 2013, and through September 30, 2015, 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 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.

NEW ACCOUNTING PRONOUNCEMENTS

Information regarding new accounting pronouncements is included in Note 1 to the current period's condensed consolidated financial statements.

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 September 30, 2015, we had an accumulated deficit of $147 million and we expect to incur losses for the foreseeable future. To date, we have been funded by debt and 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.

Our C-Pulse System is not approved for commercial sale in the United States, 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. As a result, we are able to invoice hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. As many private insurance companies and certain governmental institutions have a non-coverage policy for experimental or investigational procedures, we have not been successful in achieving reimbursement for some of our implant procedures.

Results of Operations

Comparison of Three Months Ended September 30, 2015 to Three Months Ended September 30, 2014

Revenue

Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	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 US clinical studies have historically generated all of our revenue. No C-Pulse System devices were implanted for which we could recognize revenue in the three-month periods ended September 30, 2015. We received reimbursement for one implant during the same period in 2014. We expect our revenue will be minimal until we begin enrolling patients in our US pivotal clinical

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study at an increased rate and until we 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 September 30, 2015	Three Months Ended September 30, 2014	Increase (Decrease)	% Change
$ 1,725,000	$ 2,361,000	(636,000)	(26.9)%

The decrease in selling, general and administrative expense for the three months ended September 30, 2015 as compared to the same period in 2014 is the result of efficiencies achieved from the consolidation of certain management positions and fluctuations in stock-based compensation. We expect our selling, general and administrative expense will continue to reflect the investment in infrastructure needed to support our anticipated growth as well as the impact of quarterly fluctuations in equity compensation expense.

Research and Development Expense

Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	Increase (Decrease)	% Change
$ 4,548,000	$ 3,808,000	740,000	19.4%

The increase in research and development expense for the three months ended September 30, 2015 as compared to the same period of 2014 resulted primarily from increased infrastructure costs related to our COUNTER HF study. We expect our research and development expense to continue to grow in future quarters and will be above prior year levels as patient enrollment grows, and as we pursue development efforts, including those related to our fully implantable system.

Other Expense

Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	Increase (Decrease)	% Change
$ (282,000)	$ (22,000)	(260,000)	N/M

The change in other expense for the three months ended September 30, 2015 and 2014 as compared to the same period of 2014 is the result of interest charges for borrowings outstanding under our term loan with Silicon Valley Bank. We did not incur interest expense charges in 2014 as we did not have any outstanding debt.

Income Tax Expense

Three Months Ended September 30, 2015	Three Months Ended September 30, 2014	Increase (Decrease)	% Change
$ (3,000)	$ —	3,000	N/A

Our income tax expense for the three months ended September 30, 2015 resulted from clinical activities in our European subsidiary. There was no tax expense in this subsidiary during the three months ended September 30, 2014.

Comparison of Nine Months Ended September 30, 2015 to Nine Months Ended September 30, 2014

Revenue

Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014	Increase (Decrease)	% Change
$ 59,000	$ 118,000	$ (59,000)	(50)%

Sales of the C-Pulse System to hospitals and clinics under contract in conjunction with our US FDA clinical studies have historically generated all of our revenue. One and two C-Pulse System devices were implanted for which we recognized revenue in the nine-month periods ended September 30, 2015, and September 30, 2014, respectively. We expect our revenue will be minimal until we begin enrolling patients in our US pivotal clinical study at an increased rate and until we

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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

Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014	Increase (Decrease)	% Change
$ 6,259,000	$ 6,965,000	(706,000)	(10.1)%

The decrease in selling, general and administrative expense for the nine months ended September 30, 2015 as compared to the same period in 2014 is the result of efficiencies achieved from the consolidation of certain management positions and fluctuations in stock-based compensation. We expect our selling, general and administrative expense will continue to reflect the investment in infrastructure needed to support our anticipated growth as well as the impact of quarterly fluctuations in equity compensation expense.

Research and Development Expense

Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014	Increase (Decrease)	% Change
$ 13,404,000	$ 12,284,000	1,120,000	9.1%

The increase in research and development expense for the nine months ended September 30, 2015 as compared to the same period of 2014, resulted primarily from increased personnel and clinical research infrastructure to support our clinical studies in the U.S. and Europe and increased development costs associated with our fully implantable system. This increase was partially offset by lower clinical expenditures during our second quarter of the year as a result of the temporary pause in our COUNTER HF trial. We expect our research and development expense will continue to grow and will be above prior year levels throughout 2015 as patient enrollment grows and we pursue development efforts related to our fully implantable system.

Other Income (Expense), net

Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014	Increase (Decrease)	% Change
$ (499,000)	$ 22,000	(521,000)	N/M

The change in other income (expense), net is the result of interest charges related to borrowings outstanding under our term loan with Silicon Valley Bank. We did not incur interest expense charges in 2014 as we did not have any outstanding debt. Interest income earned on cash deposits and foreign currency exchange rate gains and losses are also a component of other income (expense), net, however these amounts were immaterial.

Income Tax Benefit, net

Nine Months Ended September 30, 2015	Nine Months Ended September 30, 2014	Increase (Decrease)	% Change
$ 124,000	$ 265,000	(124,000)	(53.2)%

Our income tax benefit, net, for the nine months ended September 30, 2015 and 2014 resulted from a research and development tax credit in Australia. We completed our Australian tax return for the twelve month period ended September 30, 2014 in the second quarter of 2015 and received a $135,000 research and development tax credit refund during the quarter. We completed our Australian tax return for the twelve month period ended September 30, 2013 in the second quarter of 2014 and received a $265,000 research and development tax credit refund during the quarter. We have substantially reduced research and development expenditures in Australia, so future research and development tax credits refunds, if any, are expected to decrease. 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 twelve month period ended June 30, 2015.

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Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through a series of equity and debt issuances. During the nine months ended September 30, 2015, we entered into a loan agreement with Silicon Valley Bank for proceeds of up to $10.0 million, and issued common shares for net cash proceeds of $7.1 million under our sales agreement with Cowen and Company LLC. Under our loan agreement, a $6.0 million term loan was funded at closing and an additional term loan in the amount of $2.0 million was funded on June 26, 2015. The remaining $2.0 million term loan was available until September 30, 2015, provided that we had enrolled our one hundredth patient in the COUNTER HF study on or before that date. We did not achieve this milestone and did not secure additional borrowings under this facility. Total borrowings outstanding under the Silicon Valley Bank facility totaled $8.0 million as of September 30, 2015. During the period ended September 30, 2014, we received cash proceeds of $16,000 in connection with the exercise of certain warrants. As of September 30, 2015 and December 31, 2014, cash and cash equivalents were approximately $27.9 million and $31.3 million, respectively.

Under the terms of our loan with Silicon Valley Bank, we are required to complete an equity financing resulting in unencumbered net cash proceeds in an amount of at least $20.0 million no later than March 31, 2016. We are currently in discussions with Silicon Valley Bank to explore alternative structures with a goal of achieving increased financing flexibility. We are unable to comment on the specifics of these alternatives or assess the likelihood of success as these discussions are ongoing. Even if we are successful in achieving greater flexibility under our loan, our cash on hand may not be sufficient to fund our operations, including scheduled repayments of principal under our loan, for the next twelve months, and we may need to raise additional capital to continue to fund the development of the C-Pulse System and our operations.

We may seek to sell additional equity or 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, debt, 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 $18.2 million and $17.4 million for the nine months ended September 30, 2015 and 2014, 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 debt discount, and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was $175,000 and $205,000 for the nine months ended September 30, 2015 and 2014, respectively. The majority of cash used in investing activities was for the purchase of laboratory and office equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $15.1 million and $16,000 for the nine months ended September 30, 2015 and 2014, respectively. Net cash provided by financing activities was attributable to debt borrowings and net proceeds from sales of our common stock.

Capital Resource Requirements

As of September 30, 2015, we did not have any material commitments for capital expenditures.

Off-Balance Sheet Arrangements

In April 2015, we amended our lease agreement for our office space leased in Eden Prairie, Minnesota, to extend it for an additional thirty-six months beyond its original expiration date. This amended lease agreement expires March 31, 2019.

In June 2015, we closed on a second term loan with Silicon Valley Bank which requires that we complete an equity financing resulting in unencumbered net cash proceeds in an amount of at least $20.0 million by March 31, 2016. We are currently in discussions with Silicon Valley Bank to explore alternative structures with a goal of increased financing flexibility, although there can be no assurance that we will be successful in doing so.

Except as disclosed above, we have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources

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, clinical and pre-clinical studies activities and results, design and development of future studies, site activations, patient enrollment in studies, timing of regulatory filings and approvals, our ability to renegotiate the terms of our outstanding debt, regulatory acceptance of our filings, research and development

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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

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents. We maintain our accounts for cash and cash equivalents principally at one major bank in the United States and one major bank in the United Kingdom. We have not experienced any losses on our deposits of our cash and cash equivalents.

We do not currently sell our products in US or in international markets. All of our revenue to date has been generated by reimbursement related to our US clinical studies.

We do not believe our operations are currently subject to significant market risks for interest rates, foreign currency exchange rates, commodity prices or other relevant market price risks of a material nature. Under our current policies, we do not use foreign currency derivative instruments to manage exposure to fluctuations in foreign exchange rates.

We are exposed to declines in the interest rates paid on deposited funds. A hypothetical 100 basis point decline in the current market interest rates paid on deposits would result in interest earnings being reduced by approximately $30,000 on an annual basis.

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 September 30, 2015, 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 Certifying Officers concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2015.

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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 September 30, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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 in this report, you should carefully consider the factors discussed in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2014, which could materially affect our business, financial condition, or results of operations. The risks described in our Annual Report on Form 10-K are not the only risks that we face. In addition, risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, and/or results of operations. Other than the addition of the following risk factors, there have been no material changes in or additions to the risk factors included in our Annual Report on Form 10-K for the year ended December 31, 2014.

We need to modify the terms of our outstanding debt, and we may not be able to do so on terms that are favorable to us, if at all.

As a result of the funding on June 26, 2015 of the additional term loan under our agreement with Silicon Valley Bank, we are required to complete an equity financing resulting in unencumbered net cash proceeds of at least $20.0 million no later than March 31, 2016 to avoid an event of default under the agreement. Upon an event of default, Silicon Valley Bank has a number of rights, including the ability to declare all outstanding amounts immediately due and payable. As of September 30, 2015, we had $8.0 million outstanding under our agreement with Silicon Valley Bank.

Our ability to avoid an event of default under our loan agreement depends on our ability to complete an equity financing or renegotiate the terms of our outstanding debt. We are currently in discussions with Silicon Valley Bank to explore alternative structures with a goal of achieving increased financing flexibility. We are unable to comment on the specifics of these alternatives or assess the likelihood of success as these discussions are ongoing. There is no guarantee that our lender would agree to a modification of the terms of our agreement on terms that are acceptable to us or at all. If our efforts to modify the terms of our agreement are unsuccessful, our lender could cause the loan amount to be immediately due and payable. In addition, our loan is secured by a security interest in our assets, including a security interest in intellectual property proceeds but excluding a current security interest in intellectual property, and our lender could decide to foreclose against the assets securing its loan. We could, at a minimum, be forced to delay, scale back or eliminate some or all of our operations, including our employee base, and we could be forced into bankruptcy or liquidation.

We will need to raise additional capital in the near future. If additional capital is not available, we will have to delay, reduce or cease operations.

We have been making interest only payments on our loan with Silicon Valley Bank and will continue to do so until January 1, 2016. Commencing on January 1, 2016, we are required to repay the principal and interest under our loan in 24 consecutive equal monthly installments. As discussed above, under the terms of our loan agreement, we are required to complete an equity financing resulting in unencumbered net cash proceeds of at least $20.0 million no later than March 31, 2016, and we are currently in discussions with Silicon Valley Bank to explore alternative structures with a goal of achieving increased financing flexibility. Even if we are successful in achieving greater flexibility under our loan, our cash on hand may not be sufficient to fund our operations, including scheduled repayments of principal under the loan, for the next 12 months, and we may need to raise additional capital to continue to fund the development of the C-Pulse System and our operations. Furthermore, changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital (for example, as occurred following the temporary suspension of enrollment of our COUNTER HF study in the spring of this year). Additional financing may not be available when we need it or may not be available on terms that are favorable to us. If adequate funds are not available to us on a timely basis or at all, we may be required to significantly reduce our operations and may not be able to continue the development of the C-Pulse System.

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

None

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

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SIGNATURES

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

Sunshine Heart, Inc.

Date: November 5, 2015

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

Date: November 5, 2015

By: /s/ Claudia Drayton
Claudia Drayton
Chief Financial Officer
(principal financial officer)

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Exhibit Index
Sunshine Heart, Inc.
Form 10-Q for the Quarterly Period Ended September 30, 2015

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.

Exhibit 31.1

CHIEF EXECUTIVE OFFICER'S 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 September 30, 2015;

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(s) 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(s) 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 5, 2015

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

Exhibit 31.2

CHIEF FINANCIAL OFFICER'S 302 CERTIFICATION

I, Claudia Drayton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sunshine Heart, Inc. for the quarterly period ended September 30, 2015;

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(s) 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(s) 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 5, 2015

/s/ Claudia Drayton
Claudia Drayton
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report of Sunshine Heart, Inc. (the ***"Company"***) on Form 10-Q for the quarterly period ended September 30, 2015, 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: November 5, 2015

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

Exhibit 32.2

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

In connection with the Quarterly Report of Sunshine Heart, Inc. (the ***"Company"***) on Form 10-Q for the quarterly period ended September 30, 2015, as filed with the Securities and Exchange Commission on the date hereof (the ***"Report"***), I, Claudia Drayton, 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 5, 2015

/s/ Claudia Drayton
Claudia Drayton
Chief Financial Officer