

**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 June 30, 2015

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-35312

**SUNSHINE HEART, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or Other Jurisdiction of  
Incorporation or Organization)

**No. 68-0533453**

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

**12988 Valley View Road, Eden Prairie, MN 55344**

(Address of Principal Executive Offices) (Zip Code)

**(952) 345-4200**

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes  No

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

Large accelerated filer

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

Accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The number of outstanding shares of the registrant's common stock, \$0.0001 par value, as of August 3, 2015 was 18,333,153.

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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)

	<u>June 30, 2015</u> (unaudited)	<u>December 31, 2014</u>
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 33,419	\$ 31,293
Accounts receivable	—	59
Other current assets	767	360
<b>Total current assets</b>	<u>34,186</u>	<u>31,712</u>
Property, plant and equipment, net	598	661
Other assets	129	—
<b>TOTAL ASSETS</b>	<u>\$ 34,913</u>	<u>\$ 32,373</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Current portion of long-term debt	\$ 1,895	\$ —
Accounts payable	1,458	2,079
Accrued salaries, wages, and other compensation	1,235	1,079
<b>Total current liabilities</b>	<u>4,588</u>	<u>3,158</u>
<b>Long-term debt, net of discount</b>	<u>5,801</u>	<u>—</u>
<b>Total liabilities</b>	<u>10,389</u>	<u>3,158</u>
Commitments and contingencies	—	—
<b>Stockholders' equity</b>		
Series A junior participating preferred stock as of June 30, 2015 and December 31, 2014, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Preferred stock as of June 30, 2015 and December 31, 2014, par value \$0.0001 per share; authorized 39,970,000 shares, none outstanding	—	—

Additional paid-in capital	163,276	154,540
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,266	1,272
Accumulated deficit	(140,020)	(126,599)
<b>Total stockholders' equity</b>	<u>24,524</u>	<u>29,215</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 34,913</u>	<u>\$ 32,373</u>

See notes to the condensed consolidated financial statements.

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

	Three months ended June 30,		Six months ended June 30,	
	2015	2014	2015	2014
<b>Net sales</b>	\$ —	\$ —	\$ 59	\$ 59
Operating expenses				
Selling, general and administrative	2,348	2,243	4,534	4,604
Research and development	3,991	4,413	8,856	8,476
Total operating expenses	6,339	6,656	13,390	13,080
Loss from operations	(6,339)	(6,656)	(13,331)	(13,021)
Other income (expense), net	(151)	11	(217)	44
Loss before income taxes	(6,490)	(6,645)	(13,548)	(12,977)
Income tax benefit	(132)	(265)	(127)	(265)
<b>Net loss</b>	<u>\$ (6,358)</u>	<u>\$ (6,380)</u>	<u>\$ (13,421)</u>	<u>\$ (12,712)</u>
<b>Basic and diluted loss per share</b>	<u>\$ (0.35)</u>	<u>\$ (0.38)</u>	<u>\$ (0.75)</u>	<u>\$ (0.75)</u>
Weighted average shares outstanding — basic and diluted	18,297	16,882	17,903	16,870
<b>Other comprehensive income:</b>				
Foreign currency translation adjustments	\$ (16)	\$ (3)	\$ (6)	\$ (22)
<b>Total comprehensive loss</b>	<u>\$ (6,374)</u>	<u>\$ (6,383)</u>	<u>\$ (13,427)</u>	<u>\$ (12,734)</u>

See notes to the condensed consolidated financial statements.

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

	Six months ended June 30,	
	2015	2014
<b>Operating Activities:</b>		
Net loss	\$ (13,421)	\$ (12,712)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	158	128
Stock-based compensation expense, net	1,326	1,321
Amortization of debt discount	51	—
Changes in assets and liabilities		
Accounts receivable	59	59
Other current assets	(407)	(319)
Other assets	(129)	—
Accounts payable and accrued expenses	(446)	(399)
<b>Net cash used in operations</b>	<u>(12,809)</u>	<u>(11,922)</u>
<b>Investing Activities:</b>		
Purchases of property and equipment	(95)	(113)
<b>Net cash used in investing activities</b>	<u>(95)</u>	<u>(113)</u>

**Financing Activities:**

Net proceeds from the sale of common stock	7,055	16
Proceeds from borrowings on long-term debt	8,000	—
<b>Net cash provided by financing activities</b>	<b>15,055</b>	<b>16</b>
Effect of exchange rate changes on cash	(25)	8
Net increase (decrease) in cash and cash equivalents	2,126	(12,011)
Cash and cash equivalents - beginning of period	31,293	54,136
<b>Cash and cash equivalents - end of period</b>	<b>\$ 33,419</b>	<b>\$ 42,125</b>
<b>Supplement schedule of non-cash activities</b>		
Stock options and restricted stock units classified as liabilities, net	\$ —	\$ (286)
Warrants issued in connection with debt financing	\$ 355	\$ —

See notes to the condensed consolidated financial statements.

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**SUNSHINE HEART, INC. AND SUBSIDIARIES**  
**Notes to Condensed Consolidated Financial Statements**  
(Unaudited)

**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 June 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 2,863,583 and 3,643,632 as of June 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. On July 9, 2015, the FASB voted 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 will become available upon the Company enrolling its one hundredth patient in the COUNTER HF study on or before September 30, 2015. Total borrowings outstanding under the Silicon Valley Bank facility totaled \$8.0 million as of June 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.

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 June 30, 2015, \$304,000 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 six months ended June 30, 2015, the Company sold 1,256,380 shares of common stock for net proceeds of \$7.1 million after stock issuance costs of \$0.2 million. There were no issuances of common stock under this facility in the six months ended June 30, 2014.

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

**Note 4 - Stock-Based Compensation**

Under the fair value recognition provisions of U.S. GAAP for accounting for 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 six months ended June 30, 2015 and 2014:

(in thousands)	Six months ended June 30,	
	2015	2014
Selling, general and administrative expense	\$ 1,039	\$ 953
Research and development expense	518	535
Total stock-based compensation expense	\$ 1,557	\$ 1,488

## 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 June 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 June 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.

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.

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. The FDA responded to our pause notification and advised that we submit an investigational device exemption supplement, or IDE, to discuss the reasons for the temporary suspension and a plan for study resumption. We submitted the document to the FDA on March 16, 2015. On April 16, 2015, we announced that the FDA had reviewed our submission and requested minor protocol changes. Following our submission of such changes, on May 26, 2015, we announced that the FDA had approved the resumption of patient enrollment in the study.

## 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.

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, valuation of equity and debt securities, and income tax reserves are updated as appropriate, which in most cases is quarterly.

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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 June 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 June 30, 2015, we had an accumulated deficit of \$140.0 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 June 30, 2015 to Three Months Ended June 30, 2014*

#### *Revenue*

Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Increase (Decrease)	% Change
\$ —	\$ —	\$ —	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 eligible for reimbursement were implanted for which we could recognize revenue in the three-month periods ended June 30, 2015 or 2014. 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 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.

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#### *Selling, General and Administrative Expense*

Three Months Ended June 30, 2015	Three Months Ended June 30, 2014	Increase (Decrease)	% Change
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\$	2,348,000	\$	2,243,000	\$	105,000	4.7%
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Selling, general and administrative expense for the three months ended June 30, 2015 was comparable to the expense reported in same period of 2014. The slight increase in expense is the result of a separation payment paid by the Company, partially offset by efficiencies achieved from the consolidation of certain management positions. 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 June 30, 2015		Three Months Ended June 30, 2014		Increase (Decrease)		% Change
\$	3,991,000	\$	4,413,000	\$	(422,000)		(9.6)%

The decrease in research and development expense for the three months ended June 30, 2015 as compared to the same period of 2014 resulted primarily from the temporary pause of our COUNTER HF study. The study reached a pre-determined pausing point in March 2015, so we temporarily suspended patient enrollments. In May 2015, the FDA granted us approval to resume enrollment and we are currently in the process of re-activating study sites and resuming patient enrollment into the study. We expect our research and development expense will grow in future quarters and will be above prior year levels as patient enrollment grows, and we pursue development efforts related to our fully implantable system.

*Other Income (Expense), net*

	Three Months Ended June 30, 2015		Three Months Ended June 30, 2014		Increase (Decrease)		% Change
\$	(151,000)	\$	11,000	\$	(162,000)		N/M

The change in other income (expense), net for the three months ended June 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. Interest income earned on cash deposits and foreign exchange rate gains and losses are also a component of other income (expense), net, however these amounts were immaterial

*Income Tax Benefit, net*

	Three Months Ended June 30, 2015		Three Months Ended June 30, 2014		Increase (Decrease)		% Change
\$	132,000	\$	265,000	\$	(133,000)		(50.2)%

Our income tax benefit for the three months ended June 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 June 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 June 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.

*Comparison of Six Months Ended June 30, 2015 to Six Months Ended June 30, 2014*

*Revenue*

	Six Months Ended June 30, 2015		Six Months Ended June 30, 2014		Increase (Decrease)		% Change
\$	59,000	\$	59,000	\$	—		—%

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 C-Pulse System device was implanted for which we recognized revenue in the six-month periods ended June 30, 2015, and June 30, 2014. 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 establish reimbursement in our post-marketing study in select countries in Europe.

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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*

	Six Months Ended June 30, 2015		Six Months Ended June 30, 2014		Increase (Decrease)		% Change
\$	4,534,000	\$	4,604,000	\$	(70,000)		(1.5)%

Selling, general and administrative expense for the six months ended June 30, 2015 was comparable to the expense reported in the same period of 2014. We expect our selling, general and administrative expense will continue to reflect the investment needed in infrastructure to support our anticipated growth, as well as the impact of quarterly fluctuations in equity compensation expense.

*Research and Development Expense*

	Six Months Ended June 30, 2015		Six Months Ended June 30, 2014		Increase (Decrease)		% Change
\$	8,856,000	\$	8,476,000	\$	380,000		4.5%



The increase in research and development expense for the six months ended June 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. The trial reached a pre-determined pausing point in March 2015, so we temporarily suspended patient enrollments. In May 2015, the FDA granted us approval to resume enrollment and we are currently in the process of re-activating study sites and resuming patient enrollment into the study. 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*

	Six Months Ended June 30, 2015		Six Months Ended June 30, 2014		Increase (Decrease)		% Change
\$	(217,000)	\$	44,000	\$	(261,000)		593.2%

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*

	Six Months Ended June 30, 2014		Six Months Ended June 30, 2014		Increase (Decrease)		% Change
\$	127,000	\$	265,000	\$	(138,000)		(52.1)%

Our income tax benefit, net for the six months ended June 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 June 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 June 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.

**Liquidity and Capital Resources**

*Sources of Liquidity*

We have funded our operations primarily through a series of equity and debt issuances. During the six months ended June 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.

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During the period ended June 30, 2014, we received cash proceeds of \$16,000 in connection with the exercise of certain warrants. As of June 30, 2015 and December 31, 2014, cash and cash equivalents were \$33.4 million and \$31.3 million, respectively.

From time to time 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 \$12.8 million and \$11.9 million for the six months ended June 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 \$95,000 and \$113,000 for the six months ended June 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 six months ended June 30, 2015 and 2014, respectively. Net cash provided by financing activities was attributable to debt borrowings and proceeds from sales of our common stock.

*Capital Resource Requirements*

As of June 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.

On June 26, 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.

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, results of clinical studies, timing of regulatory filings and approvals, regulatory acceptance of our filings, research and development activities, ultimate clinical outcomes and benefits of our products to patients, market and physician acceptance of our products, intellectual property protection, and potentially competitive product offerings. The risk factors described in our filings with the SEC could cause actual events to adversely differ from the expectations indicated in these forward-looking statements. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. Sunshine Heart does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Sunshine Heart may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the SEC. We may update our risk factors from time to time.

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## **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 an investment policy that limits our investments to investments in issuers evaluated as creditworthy. 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 June 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 Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of June 30, 2015.

### **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 June 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.

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### ITEM 1A. RISK FACTORS

I You should carefully consider the risks and uncertainties we describe in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, and in other reports filed thereafter with the SEC, before deciding to invest in or retain shares of our common stock. We do not believe there are any material changes to the risk factors discussed in Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014.

### 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: August 5, 2015

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

Date: August 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 June 30, 2015

Exhibit Number	Description
10.1	Second Amendment to Lease, dated April 20, 2015, by and between the Company and Capital Partners Industrial Fund I, LLLP dba Prairie Crossroads Business Center (incorporated by reference herein from Exhibit 10.1 to the Company's Current Report on

10.2*	Separation and Release Agreement, dated June 19, 2015, by and between the Company and Kimberly A. Oleson.
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.

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\*Filed herewith.

\*\*Furnished herewith.

**SEPARATION AND RELEASE AGREEMENT**

THIS SEPARATION AND RELEASE AGREEMENT (this "**Agreement**") is made as of June 19, 2015 by and between **SUNSHINE HEART, INC.**, a Delaware corporation, having a principal place of business at 12988 Valley View Road, Eden Prairie, MN 55344 (the "**Company**") and **KIMBERLY A. OLESON** whose address is 1049 Lois Drive, Shoreview, MN 55126 ("**Employee**").

**BACKGROUND**

Employee has been employed by the Company as its Senior Vice President of Clinical Affairs since April 28, 2014.

The Company and Employee (collectively, the "**Parties**" and each, without distinction, a "**Party**") have mutually agreed to end their existing employment relationship on the terms set forth herein.

NOW, THEREFORE, in consideration of this Agreement and the mutual promises set forth herein, the Parties hereby agree as follows:

**TERMS AND CONDITIONS**

**ARTICLE 1  
EMPLOYMENT SEPARATION, PAYMENTS AND RESIGNATION**

**1.1 SEPARATION OF EMPLOYMENT.** Employee's employment with the Company shall end as of June 19, 2015 (the "**Separation Date**"). Effective as of the Separation Date, Employee resigns from every office of the Company held by Employee. Until the Separation Date, the Company shall continue to pay Employee her salary in accordance with its standard payroll procedures, less deductions required or authorized by law (including any applicable 401(k) deductions). The Company will also pay Employee for 28.0 hours of accrued, unused vacation and paid time off on the first regularly scheduled payroll period following the Separation Date, which resolves the Parties' dispute about the amount of vacation and paid time off owed to her. Employee will receive the foregoing payments regardless of whether she signs this Agreement. The Company will not issue a press release with respect to Employee's separation from the Company. The Company will file a required Form 8-K with the United States Securities and Exchange Commission using the form attached as Exhibit A. In the event the Company communicates Employee's separation from the Company to its employees, the Company will only state that the Employee has resigned her employment effective June 19, 2015.

**1.2 SEPARATION CONSIDERATION.** Provided this Agreement becomes effective in accordance with Section 2.2 hereof, as consideration for Employee's agreements and releases set forth herein, and recognizing that without execution of this Agreement, Employee would not be entitled to any additional compensation beyond wages due, the Company agrees to provide Employee with the following benefits after the Separation Date:

- A.** the Company agrees to pay Employee a one-time, lump sum amount of \$350,000, subject to tax withholding and payable in accordance with the Company's standard payroll practices on the first payroll date after this Agreement becomes effective in accordance with Section 2.2;
- B.** the Company agrees to pay Employee a one-time, lump sum payment in the amount of \$5,936.40 for the payment of the premiums for the continuation of Employee's health insurance coverage under the federal COBRA law, which will be paid on the first payroll date after this Agreement becomes effective in accordance with Section 2.2; and
- C.** the Company will cooperate with Employee with respect to the transfer of Employee's shareholder accounts from American Stock Transfer & Trust Co. LLC to an external provider.

**1.3 EXPENSE REIMBURSEMENT.** Employee will submit her final documented employee expense reimbursement statement reflecting all business expenses incurred by Employee through the Separation Date, if any,

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to the Company within thirty (30) days of the Separation Date. The Company will reimburse Employee for these expenses pursuant to its regular business practice, regardless of whether Employee signs this Agreement.

**1.4 CONFLICT WITH OTHER AGREEMENTS.** In the event of any conflict between this Agreement and that certain offer letter describing Employee's employment terms dated March 27, 2014 between the Company and Employee (the "**Offer Letter**"), this Agreement shall control. In the event of any conflict between this Agreement and that certain Employee Proprietary Information, Inventions Assignment and Non-Competition Agreement dated April 7, 2014 between the Company and Employee (the "**Invention Assignment Agreement**"), the Invention Assignment Agreement shall control. In the event of any conflict between this Agreement and that certain Change in Control Agreement dated April 28, 2014 between the Company and Employee (the "**Change in Control Agreement**"), the Change in Control Agreement shall control.

**1.5 ACKNOWLEDGEMENT.** Except as provided in this Article 1, the Parties acknowledge and agree that Employee is not, and shall not after the Separation Date, be eligible for any additional payment by the Company of any bonus, salary, vacation pay, retirement pension, severance pay, back pay, or other remuneration or compensation of any kind in respect of employment by the Company. Employee hereby confirms to the Company that Exhibit 1 to the Invention Assignment Agreement contains a complete list of all Inventions (as defined in the Invention Assignment Agreement) or improvements to which Employee claims ownership and desires to remove from the operation of the Inventions Assignment Agreement. Employee further agrees that the Invention Assignment Agreement remains in full force and effect and Employee hereby reaffirms her obligations arising under the terms of the Invention Assignment Agreement. Employee agrees to return to the Company all Company Documents and Materials (as defined in the Invention Assignment Agreement and without retaining copies thereof), apparatus, equipment and other physical property in Employee's possession within two (2) days of the Separation Date and in the manner directed by the Chairman of the Company's Board of Directors (the "**Board**").

**1.6 COOPERATION AND ASSISTANCE.** Following the Separation Date, Employee agrees to furnish such information to the Company as may be reasonably required by the Company in connection with any issues or matters of which Employee had knowledge during her employment with the Company; provided that this Section shall only apply with respect to reasonable requests for cooperation that are directed to Employee from the Chief Executive Officer of the Company. In addition, Employee shall make herself reasonably available to assist the Company in matters relating to the transition

of her prior duties to other employees of the Company (including her successor), as may be reasonably requested by the Company through its Chief Executive Officer. For requests for cooperation or assistance made in accordance with the foregoing, the Company shall (A) pay Employee a rate of \$350 per hour for every hour or partial hour of assistance, and (B) reimburse Employee for the reasonable documented out-of-pocket expenses incurred by her in providing such cooperation and assistance; provided that any such expense exceeding Five Hundred Dollars (\$500.00) shall require the advance consent of the Chief Executive Officer. Any services rendered by Employee pursuant to this Section 1.6 shall be governed by the applicable terms and conditions of the Invention Assignment Agreement. Employee shall promptly deliver to Mr. Dave Rosa via email to Dave.Rosa@sunshineheart.com all correspondence and any inquires that Employee receives (including the contents of any telephone calls or emails received by Employee) from any third party concerning the Company; provided that the forwarding of such correspondence and inquiries shall not be subject to the hourly compensation set forth above.

**1.7 CLAIMS AGAINST THE COMPANY.** Subject to the provisions of Section 1.6, above with respect to payment to Employee of \$350 per hour for every hour or partial hour for requests for assistance from the Company's Chief Executive Officer, and with the understanding that Employee's cooperation obligations hereunder are consistent with Employee telling the truth, Employee agrees to cooperate with the Company in any internal investigation, any administrative, regulatory or judicial proceeding or any dispute with a third party. Further, to the fullest extent permitted by law, Employee will not cooperate with or assist any person or entity asserting or investigating a claim against the Company unless required to do so by a lawfully issued subpoena, by court order or as expressly provided by regulation or statute. If Employee is served with a subpoena or is required by court order or otherwise to testify or produce documents in any type of proceeding involving the Company, she shall immediately advise the Company of same and cooperate with the Company in objecting to such request and/or seeking confidentiality protections.

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## ARTICLE 2 RELEASE AND NON-DISPARAGEMENT

**2.1 EMPLOYEE RELEASE OF CLAIMS.** In consideration for the separation consideration set forth in this Agreement, Employee, on behalf of herself, her heirs, executors, legal representatives, spouse and assigns, hereby fully and forever releases the Company and its respective past and present officers, directors, employees, investors, stockholders, administrators, subsidiaries, affiliates, predecessor and successor corporations and assigns, attorneys and insurers (the "**Company's Released Parties**") of and from any claim, duty, obligation or cause of action relating to any matters of any kind, whether presently known or unknown, suspected or unsuspected, that any of them may possess arising from any omissions, acts or facts that have occurred through the date that Employee signs this Agreement, including, without limitation, any and all claims:

**A.** which arise out of, result from, or occurred in connection with Employee's employment by the Company or any of its affiliated entities, the termination of that employment relationship, any events occurring in the course of that employment, or any events occurring prior to the execution of this Agreement;

**B.** for wrongful discharge, discrimination, harassment and/or retaliation; breach of contract, both express and implied; breach of a covenant of good faith and fair dealing, both express and implied; negligent or intentional infliction of emotional distress; negligent or intentional misrepresentation; negligent or intentional interference with contract or prospective economic advantage; slander, libel or invasion of privacy; violation of public policy; fraud, misrepresentation or conspiracy; and false imprisonment;

**C.** for a violation of any federal, state or municipal statute, regulation or ordinance relating to employment, including, without limitation, (1) Title VII of the Civil Rights Act of 1964, as amended, (2) the Civil Rights Act of 1866, as amended, (3) the Civil Rights Act of 1991, as amended, (4) the Employee Retirement and Income Security Act of 1974, as amended, (5) the Age Discrimination in Employment Act of 1967, as amended (the "**ADEA**"), including without limitation, the Older Workers' Benefit Protection Act, as amended ("**OWBPA**"), (6) the OWBPA, (7) the Americans with Disabilities Act of 1990, as amended, (8) the Minnesota Human Rights Act, as amended (the "**MHRA**"), (9) the Minnesota Equal Pay for Equal Work Law, as amended, (10) the Minnesota healthcare worker whistleblower protection laws, (11) the Minnesota family leave law, (12) the Minnesota personnel record access statutes; (13) the Minnesota Whistleblower Act; and (14) the Sarbanes-Oxley Act;

**D.** for back pay or other unpaid compensation;

**E.** relating to equity of the Company; and/or

**F.** for attorneys' fees and costs.

To the fullest extent permitted by law, Employee will not take any action that is contrary to the promises she has made in this Agreement. Employee represents that she has not filed any lawsuit, arbitration, or other claim against any of the Company's Released Parties, and she agrees not to file or initiate any administrative, regulatory or judicial proceeding against the Company's Released Parties. Employee further agrees she shall not receive any monetary damages, recovery and/or relief of any type related to any released claim(s), whether pursued by Employee or any governmental agency, other person or group. Employee hereby agrees that the release set forth in this Agreement shall be and remain in effect in all respects as a complete general release as to the matters released. Nothing in the foregoing shall prevent Employee from commencing an action or proceeding to enforce Employee's rights arising under this Agreement or a claim for indemnification to which Employee is entitled as a current or former officer of the Company, or inclusion as a beneficiary of any insurance policy related to Employee's service in such capacity.

**2.2 ACKNOWLEDGMENT OF WAIVER OF CLAIMS UNDER ADEA AND MHRA.** Employee acknowledges that she is waiving and releasing any rights she may have under the OWBPA, the ADEA and the MHRA, and that this waiver and release is knowing and voluntary. Employee acknowledges that the consideration given for this waiver and release is in addition to anything of value to which Employee was already entitled. Employee further acknowledges that she has been advised by this writing that: (A) she should consult with an attorney prior to executing this Agreement; (B) she has at least twenty-one (21) days within which to consider this

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Agreement and that if she signed this Agreement before expiration of that twenty-one (21) calendar day period, she did so knowingly and voluntarily and with the intent of waiving her right to utilize the full twenty-one (21) calendar day consideration period; (C) she has the right to revoke her release of claims,

insofar as it extends to potential claims arising under the ADEA, by informing the Company of such revocation within seven (7) calendar days following her execution of this Agreement; and (D) she has the right to rescind her release of claims, insofar as it extends to potential claims arising under the MHRA, by informing the Company of such rescission within fifteen (15) calendar days following Employee's execution of this Agreement. Employee further understands that these revocation and rescission periods shall run concurrently, and that this Agreement is not effective until the fifteen (15) day rescission period (the "**Revocation Period**") has expired. Communication of any such revocation by Employee to the Company shall be provided in writing and mailed by certified or registered mail with return receipt requested and addressed to the Company at its principal corporate offices to the attention of its Chairman of the Board.

**2.3 NO ADMISSION OF LIABILITY.** Neither this Agreement nor any statement contained herein shall be deemed to constitute an admission of liability on the part of the parties herein released. This Agreement's execution and implementation may not be used as evidence, and shall not be admissible in a subsequent proceeding of any kind, except one alleging a breach of this Agreement or the Offer Letter.

**2.4 NON-DISPARAGEMENT.** The Parties agree as follows:

**A.** Employee covenants and agrees that she shall not make or cause to be made any statements, observations, or opinions, or communicate any information (whether in written or oral form), that defame, slander or are likely in any way to harm the reputation of any of the Company's Released Parties or tortiously interfere with any of the Company's Released Parties' respective business relationships; provided that the foregoing obligation does not prohibit Employee from providing truthful testimony in response to a judicial or administrative subpoena or court order or for disclosing information as required by law. Employee understands and agrees that the Company's Released Parties could not be reasonably or adequately compensated in damages in an action at law for breach of Employee's obligations under this Section 2.3. Accordingly, Employee specifically agrees that the Company's Released Parties shall be entitled to temporary and permanent injunctive relief, specific performance, and other equitable relief to enforce the provisions of this Section 2.3. This provision with respect to injunctive relief shall not, however, diminish the right of the Company's Released Parties to claim and recover damages or other remedies in addition to equitable relief.

**B.** The Company covenants that it shall not, through its Chief Executive Officer, his direct reports, the members of the Board or any Company-authorized communication, make or cause to be made any statements, observations, or opinions, or communicate any information (whether in written or oral form), that defame, slander or are likely in any way to harm the reputation of Employee or tortiously interfere with any of the Employee's business relationships; provided that the foregoing obligation does not prohibit the Company or the identified individuals from providing truthful testimony in response to a judicial or administrative subpoena or court order or for disclosing information as required by law. The Company understands and agrees that Employee could not be reasonably or adequately compensated in damages in an action at law for breach of the Company's obligations under this Section 2.3. Accordingly, the Company specifically agrees that Employee shall be entitled to temporary and permanent injunctive relief, specific performance, and other equitable relief to enforce the provisions of this Section 2.3. This provision with respect to injunctive relief shall not, however, diminish the right of Employee to claim and recover damages or other remedies in addition to equitable relief.

**C.** The Company will not code or document Employee's termination of employment as an involuntary termination in her personnel file or HRIS systems. All external requests for job references regarding Employee shall be directed to the Company's Director of Human Resources, who will provide the only response on behalf of the Company. The Company's response to such inquiries will be limited to providing Employee's dates of employment and the title of the position she held as of the Separation Date.

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### **ARTICLE 3 REPRESENTATIONS AND WARRANTIES**

**3.1 REPRESENTATIONS AND WARRANTIES OF EMPLOYEE.** Employee warrants and represents to the Company that she:

- A.** has been advised to consult with legal counsel in entering into this Agreement;
- B.** has entirely read this Agreement;
- C.** has voluntarily executed this Agreement without any duress or undue influence and with the full intent of releasing all claims;
- D.** has received no promise, inducement or agreement not herein expressed with respect to this Agreement or the terms of this Agreement;

**E.** is the only person who is or may be entitled to receive or share in any damages or compensation on account of or arising out of her relationship with, or providing services to, the Company or any of its affiliated entities, the termination of that relationship or services, any actions taken in the course of that relationship or services, and any events related to that relationship or services or occurring prior to the execution of this Agreement;

**F.** understands and agrees that in the event any injury, loss, or damage has been sustained by her which is not now known or suspected, or in the event that the losses or damage now known or suspected have present or future consequences not now known or suspected, this Agreement shall nevertheless constitute a full and final release as to the parties herein released, and that this Agreement shall apply to all such unknown or unsuspected injuries, losses, damages or consequences; and

**G.** expressly acknowledges that her entry into this Agreement is in exchange for consideration in addition to anything of value to which she is already entitled.

**3.2 AUTHORITY.** Employee represents and warrants that she has the capacity to act on her own behalf and on behalf of all who might claim through her to bind them to the terms and conditions of this Agreement. Employee warrants and represents that she has not assigned any claim released under this Agreement, and there are no liens or claims of lien or assignments in law or equity or otherwise of or against any of the claims or causes of action released herein.

**3.3 NO OTHER REPRESENTATIONS.** Neither Party has relied upon any representations or statements made by the other Party which are not specifically set forth herein.

**ARTICLE 4  
MISCELLANEOUS**

**4.1 SEVERABILITY.** Should any provision of this Agreement be declared or be determined by any arbitrator or court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term, or provision shall be deemed not to be a part of this Agreement.

**4.2 ENTIRE AGREEMENT.** This Agreement represents the entire agreement and understanding between the Company and Employee concerning Employee's separation from the Company, and supersedes and replaces any and all prior agreements and understandings concerning Employee's relationship with the Company and her compensation by the Company, provided, however, that this Agreement does not supersede or modify the Invention Assignment Agreement, or the Change in Control Agreement which shall remain in full force and effect. This Agreement may only be amended by a writing signed by Employee and the Company.

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**4.3 ASSIGNMENT.** This Agreement may not be assigned by Employee without the prior written consent of the Company. The Company may assign this Agreement without Employee's consent in connection with a merger or sale of its assets and/or to a corporation controlling, controlled by or under common control with the Company. This Agreement shall inure to the benefit of, and be binding upon, each Party's respective heirs, legal representatives, successors and assigns.

**4.4 GOVERNING LAW; CONSENT TO JURISDICTION, WAIVER OF JURY TRIAL.** This Agreement shall be governed by and construed in accordance with the laws of the State of Minnesota, without regard to its principles of conflicts of laws. Each of the Parties hereto irrevocably submits to the exclusive jurisdiction of the state and federal courts of the State of Minnesota for the purpose of any suit, action, proceeding or judgment relating to or arising out of this Agreement, and consents to the laying of venue in such courts. **EACH OF THE PARTIES KNOWINGLY AND VOLUNTARILY WAIVES ANY RIGHT TO REQUEST A TRIAL BY JURY IN ANY LITIGATION WITH RESPECT TO THIS AGREEMENT AND REPRESENTS THAT COUNSEL HAS BEEN CONSULTED SPECIFICALLY AS TO THIS WAIVER.** In addition, should it become necessary for either Party to seek to enforce any of the covenants contained in this Agreement through any legal, administrative or alternative dispute resolution proceeding, the non-prevailing party shall be required to pay the prevailing party's reasonable expenses (legal costs, attorneys' fee and otherwise) related thereto.

**4.5 COUNTERPARTS/ FACSIMILE SIGNATURE.** This Agreement may be executed in one or more counterparts and by facsimile, each of which shall constitute an original and all of which together shall constitute one and the same instrument. Signatures of the Parties transmitted by facsimile or via .pdf format shall be deemed to be their original signatures for all purposes.

**SIGNATURES ON THE FOLLOWING PAGE**

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The Parties have executed this Separation and Release Agreement as of the date set forth below.

**SUNSHINE HEART, INC.**

By: /s/ Dave Rosa  
Name: Dave Rosa  
Title: CEO

/s/ Kimberly A. Oleson  
**KIMBERLY A. OLESON**

Date: June 19, 2015

**ELECTION TO EXECUTE PRIOR TO EXPIRATION OF  
TWENTY-ONE DAY CONSIDERATION PERIOD  
(To be signed only if Separation and Release Agreement is signed  
prior to expiration of 21 days after it is presented to Employee)**

I understand that I have up to twenty-one (21) days within which to consider and execute the foregoing Separation and Release Agreement. However, after having had sufficient time to consider the matter and to consult with counsel, I have freely and voluntarily elected to execute the Separation and Release Agreement before the twenty-one (21) day period has expired.

/s/ Kimberly A. Oleson  
**KIMBERLY A. OLESON**

Date: June 19, 2015

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 8-K**

**Current Report Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **June 19, 2015**

**SUNSHINE HEART, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other  
jurisdiction of  
incorporation)

**001-35312**  
(Commission File Number)

**68-0533453**  
(IRS Employer  
Identification No.)

**12988 Valley View Road**  
**Eden Prairie, Minnesota 55344**  
(Address of principal executive offices) (Zip Code)

**(952) 345-4200**  
(Registrant's telephone number, including area code)

**Not Applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

In a separation and release agreement dated June 19, 2015, Sunshine Heart, Inc. (the "**Company**") and Kimberly A. Oleson, the Company's Senior Vice President of Clinical Affairs, agreed upon terms relating to Ms. Oleson's separation from the Company, which was effective June 19, 2015. Ms. Oleson agreed to a full release of claims and other terms. In exchange, the Company agreed, among other things, to pay Ms. Oleson a one-time, lump sum amount of \$350,000, as well as \$5,936.40 for Ms. Oleson's COBRA continuation coverage.

**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 hereunto duly authorized.

Date: June [ ], 2015

**SUNSHINE HEART, INC.**

By: /S/ CLAUDIA DRAYTON  
Name: Claudia Drayton  
Title: Chief Financial Officer

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## 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 June 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: August 5, 2015

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

## 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 June 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: August 5, 2015

/s/ Claudia Drayton  
\_\_\_\_\_  
Claudia Drayton  
Chief Financial Officer

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

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

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

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

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

/s/ Claudia Drayton  
\_\_\_\_\_  
Claudia Drayton  
Chief Financial Officer