

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from _____ to _____

Commission file number 001-35312

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of
Incorporation or Organization)

No. 68-0533453

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

12988 Valley View Road, Eden Prairie, MN 55344

(Address of Principal Executive Offices) (Zip Code)

(952) 345-4200

(Registrant's Telephone Number, Including Area Code)

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

Yes No

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

Yes No

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

Yes No

The number of outstanding shares of the registrant's common stock, \$0.0001 par value, as of May 3, 2016 was 18,389,791.

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(Dollars in thousands, except share amounts)

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
	(unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 16,470	\$ 23,113
Other current assets	547	479
Total current assets	<u>17,017</u>	<u>23,592</u>
Property, plant and equipment, net	462	535
Other assets	299	323
TOTAL ASSETS	<u>\$ 17,778</u>	<u>\$ 24,450</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Current portion of long-term debt	\$ 3,867	\$ 3,798
Accounts payable and accrued expenses	2,410	2,832
Accrued salaries, wages, and other compensation	555	1,368
Total current liabilities	<u>6,832</u>	<u>7,998</u>
Long-term debt, net of discount	2,934	3,881
Other Liabilities	400	400
Total liabilities	<u>10,166</u>	<u>12,279</u>
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of March 31, 2016 and December 31, 2015, \$0.0001 par value per share; authorized 30,000 shares, none outstanding	—	—
Preferred stock as of March 31, 2016 and December 31, 2015, \$0.0001 par value per share; authorized 39,970,000 shares, none outstanding	—	—
Common stock as of March 31, 2016 and December 31, 2015, par value \$0.0001 per share; authorized 100,000,000 shares; issued and outstanding 18,368,849 and 18,344,478 shares, respectively	2	2
Additional paid-in capital	164,336	164,105
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,242	1,246
Accumulated deficit	(157,968)	(153,182)
Total stockholders' equity	<u>7,612</u>	<u>12,171</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 17,778</u>	<u>\$ 24,450</u>

See notes to the condensed consolidated financial statements.

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

	Three months ended March 31,	
	2016	2015
Net sales	\$ —	\$ 59
Operating expenses:		
Selling, general and administrative	1,349	2,186
Research and development	3,206	4,865
Total operating expenses	4,555	7,051
Loss from operations	(4,555)	(6,992)
Interest expense	(229)	(63)
Other income (expense), net	1	(3)
Loss before income taxes	(4,783)	(7,058)
Income tax expense	3	5
Net loss	\$ (4,786)	\$ (7,063)
Basic and diluted loss per share	\$ (0.26)	\$ (0.40)
Weighted average shares outstanding — basic and diluted	18,353	17,509
Other comprehensive income:		
Foreign currency translation adjustments	\$ (4)	\$ 10
Total comprehensive loss	\$ (4,790)	\$ (7,053)

See notes to the condensed consolidated financial statements.

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

	Three months ended March 31,	
	2016	2015
Operating activities:		
Net loss	\$ (4,786)	\$ (7,063)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	81	80
Stock-based compensation expense, net	231	743
Amortization of debt discount and financing fees	84	14
Changes in operating assets and liabilities:		
Other current assets	(67)	(561)
Other assets	2	(135)
Accounts payable and accrued expenses	(1,241)	(162)
Net cash used in operations	(5,696)	(7,084)
Investing activities:		
Purchases of property and equipment	(8)	(72)
Net cash used in investing activities	(8)	(72)
Financing activities:		
Net proceeds from the sale of common stock	—	6,902
Proceeds from (repayments on) borrowings on long-term debt	(940)	6,000
Net cash provided by financing activities	(940)	12,902
Effect of exchange rate changes on cash	1	(12)
Net (decrease) increase in cash and cash equivalents	(6,643)	5,734
Cash and cash equivalents - beginning of period	23,113	31,293
Cash and cash equivalents - end of period	\$ 16,470	\$ 37,027
Supplement schedule of non-cash activities		
Warrants issued in connection with debt financing	\$ —	\$ 266
Supplemental cash flow information		
Interest paid on debt borrowings	\$ 136	\$ 6

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 Sunshine Heart and its subsidiaries 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, 2015.

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, 2015 and 2014 and through March 31, 2016, 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, 2015, the Company had an accumulated deficit of \$153.2 million and it expects to incur losses for the foreseeable future. To date, the Company has been funded by debt and equity financings. 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 3,644,149 and 2,931,306 for the three months ended March 31, 2016 and 2015, 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 April 2015, the Financial Accounting Standards Board (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. Upon adoption of this standard, the Company reclassified \$105,000 of unamortized debt issuance costs classified as other current assets and as other assets in the accompanying balance sheet to an offset of current and long-term debt as of March 31, 2016. In connection with the adoption of this standard, the Company reclassified \$120,000 of debt issuance costs that were previously reported as current assets and other assets on the December 31, 2015 balance sheet, to an offset to current and long-term debt.

In May 2014, the 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

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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. The standard allows the Company to transition to the new model using either a full or modified retrospective approach, and early adoption is not permitted. 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.

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 November 2015, the FASB issued amended guidance concerning the classification of deferred taxes on the balance sheet to require that deferred tax assets and deferred tax liabilities be presented as noncurrent in a classified balance sheet. The amendment is effective for our annual and interim reporting periods beginning January 1, 2017, with early adoption permitted. The adoption of this standard will not have an impact on the Company's consolidated financial statements as all deferred tax assets are fully reserved.

In February 2016, the FASB issued updated guidance to improve financial reporting about leasing transactions. This guidance will require organizations that lease assets to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. This guidance is effective for the Company's annual reporting period beginning January 1, 2020, and for interim periods beginning January 1, 2021. The Company is evaluating the impact that the adoption of this standard will have, if any, on its financial statements and disclosures.

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 \$7.1 million as of March 31, 2016.

On December 8, 2015, the Company entered into an amendment to the loan and security agreement. The amendment removed the existing requirement to raise a minimum of \$20.0 million in unencumbered net cash proceeds from the issuance and sale of equity securities by March 31, 2016. The Company agreed instead to a liquidity covenant requiring it to maintain cash and cash equivalents in an amount equal to or greater than eight times the Company's monthly cash burn amount. The amendment also increased the prepayment fees required to be paid by the Company in the event that the loan is repaid before its maturity date.

The proceeds from the term loans are used for general corporate and working capital purposes. The Company was 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 a liquidity covenant that requires that the Company maintain cash and cash equivalents in an amount equal or greater than eight times its monthly cash utilization, as well as 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

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business. As of March 31, 2016, the Company was in compliance with all covenants under this agreement.

Upon repayment of the term loans, the Company is required to make a final payment to Silicon Valley Bank equal to 5.0% of the original principal amount of the term loans. This final payment totals \$0.4 million and it has been classified as Other Liabilities on the accompanying balance sheets as of March 31, 2016.

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 March 31, 2016, and December 31, 2015, \$154,000 and \$201,000, respectively, of unamortized debt discount was netted against long-term debt in the accompanying condensed consolidated balance sheets.

Note 3 - Equity

ATM Sales: In March 2014, the Company entered into a sales agreement (the "*Sales Agreement*") with Cowen and Company LLC ("*Cowen*") 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. There were no issuances of common stock under this facility in the three months ended March 31, 2016. During the three months ended March 31, 2015, the Company sold 1,214,395 shares of common stock for net proceeds of \$6.9 million after stock issuance costs of \$0.2 million.

As of March 31, 2016, 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 three months ended March 31, 2016 and 2015:

(in thousands)	Three months ended March 31,	
	2016	2015
Selling, general and administrative expense	\$ 135	\$ 567
Research and development expense	112	300
Total stock-based compensation expense	<u>\$ 247</u>	<u>\$ 867</u>

Note 5 - Fair Value of Financial Instruments

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

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- *Level 1* - Financial instruments with unadjusted quoted prices listed on active market exchanges.
- *Level 2* - Financial instruments lacking unadjusted, quoted prices from active market exchanges, including over the counter traded financial instruments. The prices for the financial instruments are determined using prices for recently traded financial instruments with similar underlying terms as well as directly or indirectly observable inputs, such as interest rates and yield curves that are observable at commonly quoted intervals.
- *Level 3* - Financial instruments that are not actively traded on a market exchange. This category includes situations where there is little, if any, market activity for the financial instrument. The prices are determined using significant unobservable inputs or valuation techniques.

All cash equivalents are considered Level 1 measurements for all periods presented. 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 March 31, 2016 and December 31, 2015.

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 March 31, 2016, 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, 2015.

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, 2015. 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, 2015 and in our subsequent filings with the Securities and Exchange Commission ("SEC").

OVERVIEW

We are a medical device company developing innovative technologies for cardiac and coronary disease. The Company's primary product, the C-Pulse System, is an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure, which can be implanted using a minimally invasive procedure. The C-Pulse System is designed to relieve the symptoms of heart failure through the use of counter-pulsation technology by enabling an increase in cardiac function, an increase in coronary blood flow, and a reduction in the heart's pumping load.

We are in the process of 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 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.

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 initiated OPTIONS HF, a post-market study in Europe to evaluate endpoints similar to those for our U.S. pivotal study.

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 have reduced 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

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study protocol. On May 26, 2015, we announced that the FDA had approved the resumption of patient enrollment in the study and we began the process of reactivating clinical sites and of resuming patient enrollment into the study. We concluded 2015 with 66 enrollments, 35 randomizations, 29 activated centers and 9 additional centers committed to participate.

As we evaluated the pace of enrollment into our pivotal and post market studies, we determined that enrolling these studies would take much longer than anticipated as a result of the invasiveness of the implant procedure and requirements imposed by the trial design. As a result, on March 3, 2016 we announced that we are no longer enrolling patients into the COUNTER HF and OPTIONS HF studies and that we plan to pursue a new strategic direction. We are currently working with our investigators to develop the specifics of our revised clinical and product development strategy. For further information, see Part I, Item 1 “Business-Our Strategy” in our Annual Report on Form 10-K for the year ended December 31, 2015.

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, 2015.

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. 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, 2015.

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, 2015 and 2014, and through March 31, 2016, we incurred losses from operations and net cash outflows from operating activities as disclosed in the consolidated statements of operations and cash flows, respectively.

Our ability to continue as a going concern is dependent on our ability to raise additional capital based on the achievement of existing milestones as and when required. Our directors, after due consideration, believe that we will be able to raise new equity capital as required to fund our business plan. We expect to seek additional financing during 2016. 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 March 31, 2016, we had an accumulated deficit of \$158.0 million and we expect to incur losses for the foreseeable future. To date, we have been funded by private and public equity and debt financings. Although we believe that we will be able to successfully fund our operations, there can be no assurance that we will be able to do so or that we will ever operate profitably.

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Results of Operations

Comparison of Three Months Ended March 31, 2016 to Three Months Ended March 31, 2015

Revenue

Three Months Ended March 31, 2016	Three Months Ended March 31, 2015	Increase (Decrease)	% Change
\$ —	\$ 59,000	\$ (59,000)	N/A

Our revenue has been generated by sales of the C-Pulse System to hospitals and clinics in conjunction with our U.S. clinical study. The C-Pulse System is not approved for commercial sale, however, the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at certain U.S. sites when implanted in connection with our clinical studies. Since certain insurance companies and governmental institutions have a non-coverage policy for experimental or investigational procedures, we have not been successful in achieving reimbursement for some implant procedures. On March 3, 2016, we announced that we are no longer enrolling patients in the COUNTER HF and OPTIONS HF studies, and that we plan to pursue a new strategic direction, as discussed above and under Part I, Item 1 “Business—Our Strategy” in our Form 10-K for the year ended December 31, 2015. Since we have terminated enrollment in our OPTIONS HF and COUNTER HF clinical trials, we do not expect to generate revenue from sales of the C-Pulse System during fiscal 2016. We recognized revenue for one C-Pulse System implant in the three-month period ended March 31, 2015.

Product costs incurred for our clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred.

Selling, General and Administrative Expense

	Three Months Ended March 31, 2016		Three Months Ended March 31, 2015		Increase (Decrease)		% Change
\$	1,349,000	\$	2,186,000	\$	(837,000)		(38.3)%

The decrease in selling, general and administrative expense for the three months ended March 31, 2016 as compared to 2015 is attributed to the consolidation and streamlining of activities in an effort to increase efficiencies and reduce our cash utilization, and to lower stock compensation costs.

Research and Development Expense

	Three Months Ended March 31, 2016		Three Months Ended March 31, 2015		Increase (Decrease)		% Change
\$	3,206,000	\$	4,865,000	\$	(1,659,000)		(34.1)%

The decrease in research and development expense for the three months ended March 31, 2016 as compared to 2015 resulted primarily from our decision to stop enrollment in the COUNTER HF and OPTIONS HF studies discussed above, which was announced on March 3, 2016. Since we have terminated enrollment in the studies, we expect that our research and development costs will decrease during fiscal 2016, but may increase thereafter as we accelerate funding of our fully implantable system and begin executing on a new clinical strategy.

Interest Expense

	Three Months Ended March 31, 2016		Three Months Ended March 31, 2015		Increase (Decrease)		% Change
\$	229,000	\$	63,000	\$	166,000		263.50%

The increase is primarily due to interest expense related to borrowings outstanding under our term loan with Silicon Valley Bank, which were outstanding only for a portion of the first quarter of 2015. Foreign exchange rate gains and losses are recorded as other expense.

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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 three months ended March 31, 2015, we entered into a loan agreement with SVB for proceeds of up to \$10.0 million, and issued common shares for net cash proceeds of \$6.9 million under our Sales Agreement (ATM) with Cowen. No similar financings were completed during the three months ended March 31, 2016. As of March 31, 2016 and December 31, 2015, cash and cash equivalents were \$16.5 million and \$23.1 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 \$5.7 million and \$7.1 million for the three months ended March 31, 2016 and 2015, 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 financing fees and the effects of changes in operating assets and liabilities.

Cash Flows from Investing Activities

Net cash used in investing activities was \$8,000 and \$72,000 for the three months ended March 31, 2016 and 2015, respectively. The majority of cash used in investing activities during these periods was for the purchase of laboratory and office equipment.

Cash Flows from Financing Activities

Net cash used in financing activities was \$940,000 for the three months ended March 31, 2016 and was attributable to repayments of principal amounts outstanding under our debt facility. Cash provided by financing activities was \$12.9 million for the three months ended March 31, 2015, and was attributable to proceeds from debt borrowings and sales of our common stock.

Capital Resource Requirements

As of March 31, 2016, 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 December 8, 2015, we amended our loan and security agreement with Silicon Valley Bank to remove the requirement that we complete an equity financing of at least \$20.0 million in unencumbered proceeds by March 31, 2016. The amended agreement contains a liquidity covenant that requires that we maintain cash and cash equivalents in an amount equal or greater than eight times our monthly cash utilization. As of March 31, 2016, we were in compliance with all covenants under this facility.

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.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 the U.S. or in international markets. All of our revenue to date has been generated by reimbursement related to our U.S. 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 \$15,000 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 March 31, 2016, 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

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controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”). Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their stated objectives. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of March 31, 2016.

Changes in Internal Controls

There were no changes in the Company’s internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2016 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

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, 2015, and in other reports filed thereafter with the SEC, before deciding to invest in or retain shares of our common stock. Other than as set forth below, 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, 2015.

If the trading price of our common stock fails to comply with the continued listing requirements of NASDAQ, we could face possible delisting. NASDAQ delisting could materially adversely affect the market for our shares.

On March 23, 2016, we received notice from the NASDAQ Capital Market that we did not meet the continued listing requirements for listing our common stock on the NASDAQ Capital Market because for 30 consecutive business days the bid price of our common stock had closed below \$1.00 per share. To regain compliance, the closing bid price of our common stock must be at least \$1.00 per share for a minimum of ten consecutive business days (or such longer period of time as the NASDAQ staff may require in some circumstances, but generally not more than 20 consecutive business days) before September 19, 2016. If we are not able to achieve compliance by September 19, 2016, we will need to cure the deficiency by effecting a reverse stock split. However, if it appears to the NASDAQ staff that we will not be able to cure the deficiency, or if we do not meet the other listing standards, NASDAQ could provide notice that our common stock will become subject to delisting. We cannot guarantee that our stock price will meet the listing requirements and therefore our common stock may be subject to delisting. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

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

Not applicable

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

[Table of Contents](#)**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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Sunshine Heart, Inc.

Date: May 5, 2016

By: /s/ John L. Erb
 John L. Erb
 Chief Executive Officer and Chairman of the Board
 (principal executive officer)

Date: May 5, 2016

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 March 31, 2016

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
10.1	Executive Employment Agreement between Sunshine Heart, Inc. and John L. Erb, dated March 1, 2016†	8-K	001-35312	March 2, 2016	10.1		
10.2	Separation and Release Agreement by and between Sunshine Heart, Inc. and Brian J. Brown, dated February 3, 2016					X	
10.3	Separation and Release Agreement by and between Sunshine Heart, Inc. and Debra Kridner, dated January 24, 2016					X	
10.	Third Amendment to the Sunshine Heart, Inc. New-Hire Equity Incentive Plan †	S-8	333-210215	March 15, 2016	99.13		
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X	
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X	
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002						X
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002						X
101.INS	XBRL Instance Document					X	
101.SCH	XBRL Taxonomy Extension Schema Document					X	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X	

† Indicates management compensatory plan, contract or arrangement.

SEPARATION AND RELEASE AGREEMENT

THIS SEPARATION AND RELEASE AGREEMENT (this “**Agreement**”) is made 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 **BRIAN J. BROWN** (“**Employee**”). NOW, THEREFORE, in consideration of this Agreement and the mutual promises set forth herein, the Parties hereby agree as follows:

**ARTICLE 1
EMPLOYMENT TERMINATION AND PAYMENTS**

1.1 TERMINATION OF EMPLOYMENT. Employee’s employment with the Company terminated as of January 6, 2016 (the “**Termination Date**”). The Company will pay Employee his accrued but unpaid compensation through the Termination Date, a payment of \$17,641.81 to account for his accrued but unused paid time off as of the Termination Date, and his expenses through the Termination Date that are properly reimbursable under the Company’s policies, all of which will be paid in accordance with its standard payroll procedures, less deductions required or authorized by law. Employee will receive the foregoing payments regardless of whether he signs this Agreement.

1.2 SEPARATION CONSIDERATION. Provided this Agreement becomes effective in accordance with Section 2.2, the Company will pay Employee (1) severance in the amount of \$35,271.64 and (2) a bonus amount of \$45,853.13, in each case less deductions required or authorized by law. The Company will pay these amounts in a lump sum on or before the first payroll date after this Agreement becomes effective in accordance with Section 2.2. In addition, provided that Employee timely elects continued health insurance coverage under the federal COBRA law, the Company will pay Employee a lump sum payment of \$3,407.58 (less deductions required or authorized by law), which amount equals one hundred percent of the cost of the premiums for such health insurance continuation coverage for the two month period following the end of his coverage as a result of his termination.

1.3 CONFLICT WITH OTHER AGREEMENTS. In the event of any conflict between this Agreement and that certain offer letter describing Employee’s employment terms dated May 28, 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 June 2, 2014 between the Company and Employee (the “**Invention Assignment Agreement**”), the Invention Assignment Agreement shall control.

1.4 ACKNOWLEDGEMENT. Except as provided in this Article 1, the Parties acknowledge and agree that Employee is not, and shall not after the Termination Date, be eligible for any additional payment by the Company of any bonus, salary, retirement pension, severance pay, back pay, or other remuneration or compensation of any kind in respect of employment by the Company, provided that nothing in this Agreement alters Employee’s rights with respect to any existing stock options, which will continued to be governed by the applicable plan and any agreement specifically related thereto. 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 his 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 7 days of the Termination Date.

**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 himself, his 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, and (12) the Minnesota personnel record access statutes;

- D. for back pay or other unpaid compensation; and/or
- E. for attorneys' fees and costs.

To the fullest extent permitted by law, Employee will not take any action that is contrary to the promises he has made in this Agreement. Employee represents that he has not filed any lawsuit, arbitration, or other claim against any of the Company's Released Parties. Employee states that he knows of no violation of state, federal, or municipal law or regulation by any of the Company's Released Parties, and knows of no ongoing or pending investigation, charge, or complaint by any agency charged with enforcement of state, federal, or municipal law or regulation. Employee further agrees he 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.

2.2 ACKNOWLEDGMENT OF WAIVER OF CLAIMS UNDER ADEA AND MHRA. Employee acknowledges that he is waiving and releasing any rights he 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 he has been advised by this writing that: (a) he should consult with an attorney prior to executing this Agreement; (b) he has at least 45 days within which to consider this Agreement and the information disclosed on Exhibit A, and that if he signed this Agreement before expiration of that 45 calendar day period, he did so knowingly and voluntarily and with the intent of waiving his right to utilize the full 45-day consideration period; (c) he has the right to revoke his 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 his execution of this Agreement; and (d) he has the right to rescind his 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 Vice President of Human Resources.

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.

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2.4 NON-DISPARAGEMENT. Employee covenants and agrees that he 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. 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. 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. 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.

2.5 REFERENCES. All external requests for job references regarding Employee shall be directed to the Company's Vice President 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 he held.

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) 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 his 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; (E) understands and agrees that in the event any injury, loss, or damage has been sustained by him 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 (F) expressly acknowledges that his entry into this Agreement is in exchange for consideration in addition to anything of value to which he is already entitled.

3.2 AUTHORITY. Employee represents and warrants that he has the capacity to act on his own behalf and on behalf of all who might claim through him to bind them to the terms and conditions of this Agreement. Employee warrants and represents that he 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.

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ARTICLE 4 MISCELLANEOUS

4.1 SEVERABILITY. This Agreement shall be enforceable to the fullest extent permitted by law. If any provision is held to be unenforceable, then such provision will be construed or revised in a manner so as to permit its enforceability to the fullest extent permitted by applicable law. If such provision cannot be reformed in that manner, such provision will be deemed to be severed from this Agreement, but every other provision of this Agreement will remain in full force and effect.

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 his compensation by the Company, provided, however, that this Agreement does not supersede or modify the Invention Assignment Agreement, which shall remain in full force and effect. This Agreement may only be amended by a writing signed by Employee and the Company.

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 the Company to seek to enforce any of the covenants contained in this Agreement through any legal, administrative or alternative dispute resolution proceeding, Employee shall reimburse the Company for its reasonable fees and expenses (legal costs, attorney's fees 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.

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

SUNSHINE HEART, INC.

By: /s/ Sandra Eayrs
Name: Sandra Eayrs
Title: VP of HR

/s/ Brian J. Brown
BRIAN J. BROWN
Date: 3 Feb 2016

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SEPARATION AND RELEASE AGREEMENT

THIS SEPARATION AND RELEASE AGREEMENT (this “**Agreement**”) is made 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 **DEBRA KRIDNER** (“**Employee**”). NOW, THEREFORE, in consideration of this Agreement and the mutual promises set forth herein, the Parties hereby agree as follows:

**ARTICLE 1
EMPLOYMENT TERMINATION AND PAYMENTS**

1.1 TERMINATION OF EMPLOYMENT. Employee’s employment with the Company terminated as of January 6, 2016 (the “**Termination Date**”). The Company will pay Employee her accrued but unpaid compensation through the Termination Date, a payment of \$24,715.44 to account for her accrued but unused paid time off as of the Termination Date, and her expenses through the Termination Date that are properly reimbursable under the Company’s policies, all of which will be paid in accordance with its standard payroll procedures, less deductions required or authorized by law. Employee will receive the foregoing payments regardless of whether she signs this Agreement.

1.2 SEPARATION CONSIDERATION. Provided this Agreement becomes effective in accordance with Section 2.2, the Company will pay Employee (1) severance in the amount of \$74,144.31 and (2) a bonus amount of \$48,193.80, in each case less deductions required or authorized by law. The Company will pay these amounts in a lump sum on or before the first payroll date after this Agreement becomes effective in accordance with Section 2.2. In addition, provided that Employee timely elects continued health insurance coverage under the federal COBRA law, the Company will pay Employee a lump sum payment of \$4,735.32 (less deductions required or authorized by law), which amount equals one hundred percent of the cost of the premiums for such health insurance continuation coverage for the six month period following the end of her coverage as a result of her termination.

1.3 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 14, 2010 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 March 20, 2010 between the Company and Employee (the “**Invention Assignment Agreement**”), the Invention Assignment Agreement shall control.

1.4 ACKNOWLEDGEMENT. Except as provided in this Article 1, the Parties acknowledge and agree that Employee is not, and shall not after the Termination Date, be eligible for any additional payment by the Company of any bonus, salary, retirement pension, severance pay, back pay, or other remuneration or compensation of any kind in respect of employment by the Company, provided that nothing in this Agreement alters Employee’s rights with respect to any existing stock options, which will continued to be governed by the applicable plan and any agreement specifically related thereto. 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 Invention 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. The parties further agree, with respect to Section 6 of the Invention Assignment Agreement, that the phrase “a product competitive with a product of the Company which Employee was involved with at the time of Employee’s employment by the Company” is limited to balloon counterpulsation technologies for Class 3 Heart Failure and does not include the Barostim Neo product developed by CVRx, Inc. 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 7 days of the Termination Date.

**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, and (12) the Minnesota personnel record access statutes;

D. for back pay or other unpaid compensation; and/or

E. 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. Employee states that she knows of no violation of state, federal, or municipal law or regulation by any of the Company's Released Parties, and knows of no ongoing or pending investigation, charge, or complaint by any agency charged with enforcement of state, federal, or municipal law or regulation. 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.

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 45 days within which to consider this Agreement and the information disclosed on Exhibit A, and that if she signed this Agreement before expiration of that 45 calendar day period, she did so knowingly and voluntarily and with the intent of waiving her right to utilize the full 45-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 Vice President of Human Resources.

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

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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. 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. 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. 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. 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.

2.5 REFERENCES. 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; 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. All external requests for job references regarding Employee shall be directed to the Company's Vice President 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.

2.6 COMPANY RELEASE OF CLAIMS. In consideration for the obligations of Employee set forth in this Agreement and Employee's release of claims, the Company, on behalf of itself and the Company's Released Parties, hereby fully and forever releases Employee of and from any claim or cause of action relating to Employee's employment with the Company, whether presently known or unknown, suspected or unsuspected, that any of them may possess arising from any omissions, acts or facts that have occurred up until and including the Termination Date, provided, however, that the released claims does not include claims relating to fraud, theft, breach of confidentiality or unlawful conduct. The Company agrees that this release shall be and remain in effect in all respects as a complete general release as to the matters released.

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

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this Agreement without any duress or undue influence and with the full intent of releasing all claims; (D) 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

SARBANES-OXLEY SECTION 302 CERTIFICATION

I, John L. Erb, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sunshine Heart, Inc. for the quarterly period ended March 31, 2016;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2016

/s/ John L. Erb

John L. Erb
Chief Executive Officer

2SARBANES-OXLEY SECTION 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 March 31, 2016;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2016

/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 March 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "**Report**"), I, John L. Erb, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: May 5, 2016

/s/ John L. Erb

John L. Erb
Chief Executive Officer

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

In connection with the Quarterly Report of Sunshine Heart, Inc. (the "**Company**") on Form 10-Q for the quarterly period ended March 31, 2016, 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: May 5, 2016

/s/ Claudia Drayton

Claudia Drayton
Chief Financial Officer