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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2016

OR

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

For the transition period from to

Commission file number 001-35312

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**No. 68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

12988 Valley View Road, Eden Prairie, MN 55344
(Address of Principal Executive Offices) (Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

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

Yes x No o

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

Yes x No o

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

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

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

Yes o No x

The number of outstanding shares of the registrant's common stock, $0.0001 par value, as of August 8, 2016 was 20,408,089

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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)

	June 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 12,049	$ 23,113
Other current assets	282	479
Total current assets	12,331	23,592
Property, plant and equipment, net	412	535
Other assets	254	323
TOTAL ASSETS	$ 12,997	$ 24,450
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Current portion of long-term debt	$ 3,938	$ 3,798
Accounts payable and accrued expenses	2,051	2,832
Accrued compensation	954	1,368
Total current liabilities	6,943	7,998
Long-term debt, net of discount and financing fees	1,965	3,881
Other liabilities	400	400
Total liabilities	9,308	12,279
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of June 30, 2016 and December 31, 2015, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Preferred stock as of June 30, 2016 and December 31, 2015, par value $0.0001 per share; authorized 39,970,000 shares, none outstanding	—	—
Common stock as of June 30, 2016 and December 31, 2015, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 18,459,025 and 18,344,478, respectively	2	2
Additional paid-in capital	164,603	164,105
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,240	1,246
Accumulated deficit	(162,156)	(153,182)
Total stockholders' equity	3,689	12,171
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 12,997	$ 24,450

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,	
	2016	2015	2016	2015
Net sales	**$ —**	$ —	$ —	$ 59
Operating expenses:				
Selling, general and administrative	1,412	2,348	2,761	4,534
Research and development	2,570	3,991	5,776	8,856
Total operating expenses	3,982	6,339	8,537	13,390
Loss from operations	(3,982)	(6,339)	(8,537)	(13,331)
Interest expense	207	155	436	218
Other income (expense), net	(1)	4	—	1
Loss before income taxes	(4,190)	(6,490)	(8,973)	(13,548)
Income tax benefit (expense), net	2	132	(1)	127
Net loss	**$ (4,188)**	**$ (6,358)**	**$ (8,974)**	**$ (13,421)**
Basic and diluted loss per share	**$ (0.23)**	**$ (0.35)**	**$ (0.49)**	**$ (0.75)**
Weighted average shares outstanding — basic and diluted	18,403	18,297	18,378	17,903
Other comprehensive income:				
Foreign currency translation adjustments	$ (2)	$ (16)	$ (6)	$ (6)
Total comprehensive loss	**$ (4,190)**	**$ (6,374)**	$ **(8,980)**	$ **(13,427)**

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,	
	2016	2015
Operating Activities:		
Net loss	**$** (8,974)	$ (13,421)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	152	158
Stock-based compensation expense, net	499	1,326
Amortization of debt discount and financing fees	162	51
Changes in operating assets and liabilities:		
Accounts receivable	—	59
Other current assets	197	(407)
Other assets	25	(129)
Accounts payable and accrued expenses	(1,197)	(446)
Net cash used in operations	**(9,136)**	**(12,809)**
Investing Activities:		
Purchases of property and equipment	(29)	(95)
Net cash used in investing activities	**(29)**	**(95)**
Financing Activities:		
Net proceeds from the sale of common stock	—	7,055
Proceeds from (repayments on) borrowings on long-term debt	(1,895)	8,000
Net cash (used in) provided by financing activities	**(1,895)**	**15,055**
Effect of exchange rate changes on cash	(4)	(25)
Net decrease in cash and cash equivalents	(11,064)	2,126
Cash and cash equivalents - beginning of period	23,113	31,293
Cash and cash equivalents - end of period	**$ 12,049**	**$ 33,419**
Supplement schedule of non-cash activities		
Warrants issued in connection with debt financing	$ —	$ 355
Supplemental cash flow information		
Interest paid on debt borrowings	$ 257	$ 113

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, 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 June 30, 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, 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 3,634,645 and 2,863,583 as of June 30, 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. 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 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

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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 $6.1 million as of June 30, 2016, and $8.0 million as of December 31, 2015.

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, the Company began repaying 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. As of June 30, 2016, the Company was in compliance with all covenants under this agreement.

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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. This final payment totals $0.4 million and it has been classified as Other Liabilities on the accompanying balance sheets as of June 30, 2016 and December 31, 2015.

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, 2016 and December 31, 2015, $113,000 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 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. There were no issuances of common stock under this facility in the six months ended June 30, 2016. 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.

As of June 30, 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 periods below:

	Six months ended June 30,	
(in thousands)	2016	2015
Selling, general and administrative expense	$ 315	$ 1,039
Research and development expense	219	518
Total stock-based compensation expense	**$ 534**	**$ 1,557**

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

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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, 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 June 30, 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.

Note 7 — Subsequent Events

On July 11, 2016, the Company announced a change in its clinical and product development strategy that focuses on neuromodulation rather than counterpulsation, the Company's prior therapeutic approach. The Company believes that this new clinical strategy will provide a more cost effective way to develop a fully-implantable system, a faster path to commercialization, and broader access to the NYHA Class III heart failure market.

On July 22, 2016, the Company entered into a securities purchase agreement with an investor for an offering of shares of convertible preferred stock with gross proceeds of approximately $3.5 million in a registered direct offering. The transaction closed on July 26, 2016 and the Company issued 3,468 shares of Series B Convertible Preferred Stock. Concurrently, in a private placement, the investor received warrants to purchase 3,689,361 shares of common stock at an exercise price of $0.94. The warrants are exercisable for 36 months commencing six months from the closing date.

The Series B Preferred Stock is non-voting and convertible into a total of 3,689,361 shares of common stock at the holder's election at any time at a conversion price of $0.94 per share. Subject to limited exceptions, a holder of Series B Convertible Preferred Stock will not have the right to exercise any portion of its shares if the holder, together with its affiliates, would beneficially own over 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise; provided, however, that upon not less than 61 days' prior notice, the holder may increase such percentage, provided that it does not exceed 9.99%. Immediately upon closing of the transaction, 865 shares of the Series B Convertible Preferred Stock were converted into 920,000 shares of common stock.

Under the securities purchase agreement, the Company agreed not issue or announce the issuance or proposed issuance of any common stock or common stock equivalents for 60 days from the date of the agreement and that it will not affect or contract to effect a "Variable Rate Transaction" as defined in the securities purchase agreement so long as the investor holds warrants. The Company granted to the investor, if it issues any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination of units, within twelve (12) months after the closing date, the right to participate in up to 50% of such subsequent financing on the same terms, conditions and price.

In connection with the transaction, the Company paid the placement agent an aggregate cash placement fee equal to 6% of the aggregate gross proceeds raised in the offering and issued warrants to purchase shares of the Company's common stock equal to 6% of the shares of common stock sold to investors in the

offering. The warrant issued to the placement agent was immediately exercisable at an exercise price of $1.35 per share and will be exercisable for five years after the closing of the offering.

Subject to limited exceptions, the warrants issued to the investor and the placement agent will not be exercisable if the holder, together with its affiliates, would beneficially own over 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise; provided, however, that upon not less than 61 days' prior notice, the holder may increase such percentage, provided that it does not exceed 9.99%. The exercise price and number of the shares of common stock issuable upon exercising the warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. In addition, the warrants (but not the warrant issued to the placement agent) is subject to reduction of the exercise price if the Company subsequently issues common stock or equivalents at an effective price less than the current exercise price of such warrants.

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On August 5, 2016, the Company acquired the Aquadex product line from Gambro UF Solutions, Inc., a subsidiary of Baxter International Inc. (the "Seller") a global leader in the hospital products and dialysis markets. Pursuant to an asset purchase agreement (the "Purchase Agreement"), the Company acquired certain assets exclusively related to the production and sale of the Aquadex™ FlexFlow product (the "Business") for consideration consisting of $4.0 million paid in cash, and 1,000,000 shares of the Company's common stock. The Aquadex FlexFlow product is a medical device that can be used to treat heart failure patients as well as other patients with fluid overload who have failed diuretic therapy.

Under the Purchase Agreement, the Company has agreed that: (i) if the Company disposes of any of the Business assets for a price that exceeds $4.0 million within three years of the closing, the Company will pay Seller 40% of the amount of such excess; and (ii) if shares of the Company's common stock cease to be publicly traded on the Nasdaq Capital Market, Seller has the option to require the Company to repurchase, in cash (subject to limited exceptions), all or any part of the common shares held by Seller at a price equal to their fair market value, as determined by a third-party appraiser.

Under the Purchase Agreement, the Company granted to Seller, if the Company proposes to issue or sell new shares of the Company's common stock, any securities convertible into, exchangeable or exercisable for such shares, or options, warrants or other rights to acquire such shares on or prior to July 31, 2017 (the "Subsequent Financing"), the right to purchase all or a part of its pro rata portion of such new securities on terms not less favorable than the most favorable terms received by any other party in such Subsequent Financing.

The Purchase Agreement includes customary representations, warranties, and covenants of the Company and Seller, as well as provisions relating to indemnity, confidentiality, non-competition, non-solicitation, and other matters.

Upon closing of the transactions contemplated by the Purchase Agreement, the Company entered into a patent license agreement and a registration rights agreement, discussed below, as well as a transition services agreement, pursuant to which the Seller shall provide certain services related to the Business to the Company following the closing of the transactions contemplated by the Purchase Agreement, and a commercial manufacturing and supply agreement, pursuant to which the Company will purchase certain products and inventory related to the Business from the Seller for up to eighteen months following the closing of the transactions contemplated by the Purchase Agreement.

On August 5, 2016, upon closing of the transactions contemplated by the Purchase Agreement, the Company entered into a patent license agreement with Seller (the "Patent License Agreement"), pursuant to which it obtained, for no additional consideration, a world-wide license under patents used in the Business to make, have made, use, sell, offer for sale and import, the Aquadex FlexFlow product in the "field of use." The "field of use" is defined as system and apparatus only capable of performing isolated ultrafiltration for treatment of congestive heart failure, and methods to the extent used therein (excluding system, apparatus, or methods performing any kind of renal therapy or dialysis and/or any system capable of providing substitution fluid). The license is exclusive, with respect to some patents, and non-exclusive, with respect to other patents. Under the Patent License Agreement, Seller has agreed to use commercially reasonable efforts to continue maintenance of seven "required maintenance patents," and the Company has agreed to reimburse Seller for all fees, costs, and expenses (internal or external) incurred by Seller in connection with such continued maintenance.

The rights granted to the Company under the Patent License Agreement will automatically revert to Seller in the event the Company ceases operation of the Business or file for, have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. In addition, for two years following the closing, the Patent License Agreement is not assignable by the Compnay (including in connection with a change of control) without Seller's prior written consent.

On August 5, 2016, upon closing of the transactions contemplated by the Purchase Agreement, the Company entered into a registration rights agreement with Seller (the "Registration Rights Agreement"), pursuant to which Seller or its affiliates has the right to request that the Company file a registration statement with the SEC to register all or part of the common shares. Upon receipt of any such request, the Company agreed to use its reasonable best efforts to prepare and file a registration statement as expeditiously as possible but in any event within 30 days of such request, and to cause the registration statement to become effective in accordance with Seller's intended method of distribution. The Company also agreed to pay the expenses incurred in connection with any such registration.

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On August 4, 2016, in connection with the Company's acquisition of the Business, the Company repaid all amounts outstanding under its existing debt facility with Silicon Valley Bank (the ***"Bank"***) (the ***"Prior Loan Agreement"***) at which time the Company's obligations under the Prior Loan Agreement immediately terminated, other than those that were specified as surviving termination. The Company paid to the Bank approximately $6.0 million, consisting of the then outstanding principal balance due of approximately $5.5 million, accrued but unpaid interest of approximately $3,200, a final payment of $400,000 and a prepayment premium of approximately $109,000. In connection with the termination, the Bank agreed to release its security interests in all collateral under the Prior Loan Agreement.

On August 5, 2016, the Company entered into a new loan and security agreement with the Bank (the ***"New Loan Agreement"***). Under the New Loan Agreement, the Bank has agreed to provide the Company with up to $5.0 million in debt financing, consisting of (i) a term loan in an aggregate original

principal amount not to exceed $4.0 million (the ***"Term Loan"***) and (ii) a revolving line of credit in an aggregate principal amount not to exceed $1.0 million outstanding at any time (the ***"Revolving Line"***; together with the Term Loan, the ***"Loans"***). The proceeds from the Loans will be used for general corporate and working capital purposes.

Advances under the Term Loan will accrue interest at a floating per annum rate equal to 2.50% above the prime rate as published in the money rates section of The Wall Street Journal, provided that, in the event such prime rate of interest is less than zero, such prime rate shall be deemed to be zero. The Company is entitled to make interest-only payments on advances under the Term Loan through March 31, 2017 (the ***"Amortization Date"***). Commencing on April 1, 2017, and continuing on the first day of each calendar month thereafter, the Company is required to repay advances under the Term Loan in 36 consecutive equal monthly installments of principal plus interest. In the event the Company completes an equity issuance resulting in unrestricted and unencumbered net cash proceeds in an amount of at least $25 million on or before March 31, 2017, the Amortization Date will be extended by six months, and the Company will be required to repay advances under the Term Loan in 30 consecutive equal monthly installments of principal plus interest, commencing on October 1, 2017 and continuing on the first day of each calendar month thereafter. All outstanding principal and accrued interest with respect to advances under the Term Loan are due and payable in full on March 1, 2020. Upon the occurrence and during the continuance of an event of default (as defined in the New Loan Agreement), the obligations to the Bank bear interest at a rate per annum which is 4% above the rate that is otherwise applicable.

Under the Revolving Line, the Company may borrow the lesser of $1.0 million or 80% of the Company's eligible accounts (subject to customary exclusions), minus the outstanding principal balance of any advances under the Revolving Line. Advances under the Revolving Line will accrue interest at a floating per annum rate equal to 1.75% or 1.0% above the prime rate, depending on whether the Company has maintained net liquidity (as defined in the New Loan Agreement) in an amount equal to or greater than six times its monthly cash burn amount (as defined in the New Loan Agreement) for the period specified in the New Loan Agreement. Interest on the principal amount outstanding under the Revolving Line is payable monthly on the last calendar day of the month until March 31, 2020, at which time all outstanding principal and unpaid interest with respect to advances under the Revolving Line are due and payable in full.

The New Loan Agreement requires proceeds of accounts to be deposited into a designated bank account. Amounts received in such account will be applied to reduce the obligations under the Revolving Line, unless net liquidity is in an amount equal to or greater than six times monthly cash burn amount, in which case such amounts will be transferred to the Company's operating account so long as no event of default exists.

Advances under both the Term Loan and the Revolving Line are subject to various conditions precedent, including without limitation the Company's compliance with financial covenants relating to the Company's net liquidity relative to its monthly cash burn amount, which the Company does not currently meet.

The New Loan Agreement contains customary representations, as well as customary affirmative and negative covenants. Among other restrictions, the negative covenants, subject to exceptions, prohibit or limit the Company's ability to do the following: declare dividends or redeem or purchase 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. The New Loan Agreement also requires the Company to maintain at all times upon the earlier to occur of (i) the funding date of the initial advance under the Term Loan or (ii) the funding date

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of the initial advance under the Revolving Line, tested on the last day of each month: (i) net liquidity in an amount equal to or greater than four times the Company's monthly cash burn amount and (ii) unrestricted cash and cash equivalents in accounts with the Bank or its affiliates equal to or greater than 1.25 of the amount of all of the Company's outstanding obligations to the Bank.

The Company's obligations under the New Loan Agreement are secured by a security interest in the Company's assets, excluding intellectual property and certain other exceptions. The Company is subject to a negative pledge covenant with respect to its intellectual property.

The Company's obligations under the New Loan Agreement may be accelerated upon the occurrence of an "event of default," which is defined to include customary events for a financing arrangement of this type, including, without limitation, payment defaults, defaults in the performance of affirmative or negative covenants (including financial ratio maintenance requirements), bankruptcy or related defaults, defaults on certain other indebtedness, the material inaccuracy of representations or warranties, material adverse changes and revocations of government approvals.

Under the New Loan Agreement, the Company also agreed to pay the Bank the following fees, in addition to certain expenses incurred by the Bank in connection with the Loans: a commitment fee of $7,500, due and paid by the Company on the effective date of the New Loan Agreement; annual fees of $7,500 due and payable by the Company on the first, second, and third anniversaries of the effective date of the New Loan Agreement, as well as upon the occurrence of other events, such as an event of default or termination of the New Loan Agreement, whichever is earliest to occur; a termination fee in an amount equal to (i) 2.0% of the Revolving Line if terminated on or before the one-year anniversary of the effective date of the New Loan Agreement or (ii) 1.0% of the Revolving Line if terminated after the one-year anniversary of the effective date of the New Loan Agreement; a final payment equal to 2.50% of the original principal amount of advances under the Term Loan or $25,000 in the event there are no advances under the Term Loan; and a prepayment premium in an amount ranging from 1.0% to 3.0% of the outstanding principal amount of advances under the Term Loan.

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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, 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*)*.

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 focused on developing a product portfolio to treat moderate to severe heart failure and related conditions. We are in the process of pursuing regulatory approvals necessary to commercialize our system in Europe and the United States.

The Company's counterpulsation-based product, the C-Pulse System, is an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure. 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.

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.

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. 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.

Recent Developments

On July 11, 2016, we announced that we are moving forward with a therapeutic strategy focused on neuromodulation rather than counterpulsation. In our feasibility trial, our counterpulsation therapy provided greater benefits to patients than would have been expected through the hydraulic action of the aortic cuff alone. We have discovered that the primary mechanism of action providing the clinical benefit was a neuromodulatory effect due to the counterpulsation balloon's placement on the ascending aorta and its activation of the aortic and possibly carotid baroreceptors with each expansion. Compared to our prior clinical strategy, we believe this new focus will provide a more cost effective way to develop a fully-implantable system, a faster path to commercialization, and broader access to the NYHA Class III heart failure market.

On July 22, 2016, we entered into a securities purchase agreement with an investor for an offering of shares of convertible preferred stock with gross proceeds of approximately $3.5 million in a registered direct offering. The transaction closed on July 26, 2016 and we issued 3,468 shares of Series B Convertible Preferred Stock. Concurrently, in a private placement, the investor received warrants to purchase 3,689,361 shares of common stock at an exercise price of $0.94. The warrants are exercisable for 36 months commencing six months from the closing date.

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The Series B Preferred Stock is non-voting and convertible into a total of 3,689,361 shares of common stock at the holder's election at any time at a conversion price of $0.94 per share. Subject to limited exceptions, a holder of Series B Convertible Preferred Stock will not have the right to exercise any portion of its shares if the holder, together with its affiliates, would beneficially own over 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to such exercise; provided, however, that upon not less than 61 days' prior notice, the holder may increase such percentage, provided that it does not exceed 9.99%. Immediately upon closing of the transaction, 865 shares of the Series B Convertible Preferred Stock were converted into 920,000 shares of common stock.

Under the securities purchase agreement, we agreed not issue or announce the issuance or proposed issuance of any common stock or common stock equivalents for 60 days from the date of the agreement and that it will not affect or contract to effect a "Variable Rate Transaction" as defined in the securities purchase agreement so long as the investor holds warrants. We granted to the investor, if it issues any shares of common stock or common stock equivalents for cash consideration, indebtedness or a combination of units, within twelve (12) months after the closing date, the right to participate in up to 50% of such subsequent financing on the same terms, conditions and price.

In connection with the transaction, we paid the placement agent an aggregate cash placement fee equal to 6% of the aggregate gross proceeds raised in the offering and issued warrants to purchase shares of our common stock equal to 6% of the shares of common stock sold to investors in the offering. The warrant issued to the placement agent was immediately exercisable at an exercise price of $1.35 per share and will be exercisable for five years after the closing of the offering.

Subject to limited exceptions, the warrants issued to the investor and the placement agent will not be exercisable if the holder, together with its affiliates, would beneficially own over 4.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise; provided, however, that upon not less than 61 days' prior notice, the holder may increase such percentage, provided that it does not exceed 9.99%. The exercise price and number of the shares of common stock issuable upon exercising the warrants will be subject to adjustment in the event of any stock dividends and splits, reverse stock split, recapitalization, reorganization or similar transaction, as described therein. In addition, the warrants (but not the warrant issued to the placement agent) is subject to reduction of the exercise price if the Company subsequently issues common stock or equivalents at an effective price less than the current exercise price of such warrants.

On August 5, 2016, we acquired the Aquadex product line from Gambro UF Solutions, Inc. a subsidiary of Baxter International Inc., (the "Seller") a global leader in the hospital products and dialysis markets. Pursuant to an asset purchase agreement, (the "Purchase Agreement"), we acquired certain assets exclusively related to the production and sale of the Aquadex™ FlexFlow product (the "Business") for consideration consisting of $4.0 million paid in cash, and 1,000,000 shares of our common stock. The Aquadex FlexFlow product is a medical device that can be used to treat heart failure patients as well as other patients with fluid overload who have failed diuretic therapy.

Under the Purchase Agreement, we agreed that: (i) if the we dispose of any of the Business assets for a price that exceeds $4.0 million within three years of the closing, we will pay Seller 40% of the amount of such excess; and (ii) if shares of the our common stock cease to be publicly traded on the Nasdaq Capital Market, Seller has the option to require us to repurchase, in cash (subject to limited exceptions), all or any part of the common shares held by Seller at a price equal to their fair market value, as determined by a third-party appraiser.

Under the Purchase Agreement, we granted to Seller, if we propose to issue or sell new shares of our common stock, any securities convertible into, exchangeable or exercisable for such shares, or options, warrants or other rights to acquire such shares on or prior to July 31, 2017 (the "Subsequent Financing"), the right to purchase all or a part of its pro rata portion of such new securities on terms not less favorable than the most favorable terms received by any other party in such Subsequent Financing.

The Purchase Agreement includes customary representations, warranties, and covenants of us and the Seller, as well as provisions relating to indemnity, confidentiality, non-competition, non-solicitation, and other matters.

Upon closing of the transactions contemplated by the Purchase Agreement, we entered into a patent license agreement and a registration rights agreement, described below, as well as a transition services agreement, pursuant to which the Seller shall provide us with certain services related to the Business following the closing of the transactions contemplated by the Purchase Agreement, and a commercial manufacturing and supply agreement, pursuant to which we will purchase certain products and inventory related to the Business from the Seller for up to eighteen months following the closing of the transactions contemplated by the Purchase Agreement.

On August 5, 2016, upon closing of the transactions contemplated by the Purchase Agreement, we entered into a patent license agreement with Seller (the "Patent License Agreement"), pursuant to which we obtained, for no additional consideration, a world-wide license under patents used in the Business to make, have made, use, sell, offer for sale and import, the Aquadex FlexFlow product in the "field of use." The "field of use" is defined as system and apparatus only capable of performing isolated ultrafiltration for treatment of congestive heart failure, and methods to the extent used therein (excluding system, apparatus, or methods performing any kind of renal therapy or dialysis and/or any system capable of providing substitution fluid). The license is exclusive, with respect to some patents, and non-exclusive, with respect to other patents. Under the Patent License Agreement, Seller has agreed to use commercially reasonable efforts to continue maintenance of seven "required maintenance patents," and we have agreed to reimburse Seller for all fees, costs, and expenses (internal or external) incurred by Seller in connection with such continued maintenance.

The rights granted to us under the Patent License Agreement will automatically revert to Seller in the event we cease operation of the Business or file for, have filed against us, or otherwise undertake any bankruptcy, reorganization, insolvency, moratorium, or other similar proceeding. In addition, for two years following the closing, the Patent License Agreement is not assignable by us (including in connection with a change of control) without Seller's prior written consent.

On August 5, 2016, upon closing of the transactions contemplated by the Purchase Agreement, we entered into a registration rights agreement with Seller (the "Registration Rights Agreement"), pursuant to which Seller or its affiliates has the right to request that we file a registration statement with the SEC to register all or part of the common shares. Upon receipt of any such request, we have agreed to use its reasonable best efforts to prepare and file a registration statement as expeditiously as possible but in any event within 30 days of such request, and to cause the registration statement to become effective in accordance with Seller's intended method of distribution. We have also agreed to pay the expenses incurred in connection with any such registration.

On August 4, 2016, in connection with our acquisition of the Business, we repaid all amounts outstanding under our existing debt

facility with Silicon Valley Bank (the "Bank") (the "Prior Loan Agreement") at which time our obligations under the Prior Loan Agreement immediately terminated, other than those that were specified as surviving termination. We paid to the Bank approximately $6.0 million, consisting of the then outstanding principal balance due of approximately $5.5 million, accrued but unpaid interest of approximately $3,200, a final payment of $400,000 and a prepayment premium of approximately $109,000. In connection with the termination, the Bank agreed to release its security interests in all collateral under the Prior Loan Agreement.

On August 5, 2016, we entered into a new loan and security agreement with the Bank (the "New Loan Agreement"). Under the New Loan Agreement, the Bank has agreed to provide us with up to $5.0 million in debt financing, consisting of (i) a term loan in an aggregate original principal amount not to exceed $4.0 million (the "Term Loan") and (ii) a revolving line of credit in an aggregate principal amount not to exceed $1.0 million outstanding at any time (the "Revolving Line"; together with the Term Loan, the "Loans"). The proceeds from the Loans will be used for general corporate and working capital purposes.

Advances under the Term Loan will accrue interest at a floating per annum rate equal to 2.50% above the prime rate as published in the money rates section of The Wall Street Journal, provided that, in the event such prime rate of interest is less than zero, such prime rate shall be deemed to be zero. We are entitled to make interest-only payments on advances under the Term Loan through March 31, 2017 (the "Amortization Date"). Commencing on April 1, 2017, and continuing on the first day of each calendar month thereafter, we are required to repay advances under the Term Loan in 36 consecutive equal monthly installments of principal plus interest. In the event we complete an equity issuance resulting in unrestricted and unencumbered net cash proceeds in an amount of at least $25.0 million on or before March 31, 2017, the Amortization Date will be extended by six months, and we will be required to repay advances under the Term Loan in 30 consecutive equal monthly installments of principal plus interest, commencing on October 1, 2017 and continuing on the first day of each calendar month thereafter. All outstanding principal and accrued interest with respect to advances under the Term Loan are due and payable in full on March 1, 2020.

Upon the occurrence and during the continuance of an event of default (as defined in the New Loan Agreement), the obligations to the Bank bear interest at a rate per annum which is 4% above the rate that is otherwise applicable.

Under the Revolving Line, we may borrow the lesser of $1.0 million or 80% of our eligible accounts (subject to customary exclusions), minus the outstanding principal balance of any advances under the Revolving Line. Advances under the Revolving Line will accrue interest at a floating per annum rate equal to

1.75% or 1.0% above the prime rate, depending on whether we have maintained net liquidity (as defined in the New Loan Agreement) in an amount equal to or greater than six times its monthly cash burn amount (as defined in the New Loan Agreement) for the period specified in the New Loan Agreement. Interest on the principal amount outstanding under the Revolving Line is payable monthly on the last calendar day of the month until March 31, 2020, at which time all outstanding principal and unpaid interest with respect to advances under the Revolving Line are due and payable in full.

The New Loan Agreement requires proceeds of accounts to be deposited into a designated bank account. Amounts received in such account will be applied to reduce the obligations under the Revolving Line, unless net liquidity is in an amount equal to or greater than six times monthly cash burn amount, in which case such amounts will be transferred to our operating account so long as no event of default exists.

Advances under both the Term Loan and the Revolving Line are subject to various conditions precedent, including without limitation, our compliance with financial covenants relating to our net liquidity relative to our monthly cash burn amount, which we do not currently meet.

The New Loan Agreement contains customary representations, as well as customary affirmative and negative covenants. Among other restrictions, the negative covenants, subject to exceptions, prohibit or limit our ability to do the following: 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. The New Loan Agreement also requires us to maintain at all times upon the earlier to occur of (i) the funding date of the initial advance under the Term Loan or (ii) the funding date of the initial advance under the Revolving Line, tested on the last day of each month: (i) net liquidity in an amount equal to or greater than four times our monthly cash burn amount and (ii) unrestricted cash and cash equivalents in accounts with the Bank or its affiliates equal

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to or greater than 1.25 of the amount of all of our outstanding obligations to the Bank.

Our obligations under the New Loan Agreement are secured by a security interest in our assets, excluding intellectual property and certain other exceptions. We are subject to a negative pledge covenant with respect to its intellectual property.

Our obligations under the New Loan Agreement may be accelerated upon the occurrence of an “event of default,” which is defined to include customary events for a financing arrangement of this type, including, without limitation, payment defaults, defaults in the performance of affirmative or negative covenants (including financial ratio maintenance requirements), bankruptcy or related defaults, defaults on certain other indebtedness, the material inaccuracy of representations or warranties, material adverse changes and revocations of government approvals.

Under the New Loan Agreement, we also agreed to pay the Bank the following fees, in addition to certain expenses incurred by the Bank in connection with the Loans: a commitment fee of $7,500, due and paid by us on the effective date of the New Loan Agreement; annual fees of $7,500 due and payable by us on the first, second, and third anniversaries of the effective date of the New Loan Agreement, as well as upon the occurrence of other events, such as an event of default or termination of the New Loan Agreement, whichever is earliest to occur; a termination fee in an amount equal to (i) 2.0% of the Revolving Line if terminated on or before the one-year anniversary of the effective date of the New Loan Agreement or (ii) 1.0% of the Revolving Line if terminated after the one-year anniversary of the effective date of the New Loan Agreement; a final payment equal to 2.50% of the original principal amount of advances under the Term Loan or $25,000 in the event there are no advances under the Term Loan; and a prepayment premium in an amount ranging from 1.0% to 3.0% of the outstanding principal amount of advances under the Term Loan.

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 June 30, 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 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

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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 a product portfolio to treat moderate to severe heart failure and related conditions. Our activities since inception have consisted principally of raising capital, performing research and development and conducting preclinical and clinical studies. At June 30, 2016, we had an accumulated deficit of $162.2 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.

Results of Operations

Comparison of Three Months Ended June 30, 2016 to Three Months Ended June 30, 2015

Revenue

Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Change
$ —	$ —	$ —	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 our clinical trials in 2016.

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 June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Change
$ 1,412,000	$ 2,348,000	$ (936,000)	(39.9)%

The decrease in selling, general and administrative expense for the three months ended June 30, 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 June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Change
$ 2,570,000	$ 3,991,000	$ (1,421,000)	(35.6)%

The decrease in research and development expense for the three months ended June 30, 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

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clinical strategy.

Interest Expense

Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Change
$ 207,000	$ 155,000	$ 52,000	33.5%

The increase is primarily due to interest expense related to borrowings outstanding under our term loan with Silicon Valley Bank. Subsequent to quarter end, we repaid all amounts outstanding under this loan facility, as described above in "Overview, Recent Developments."

Income Tax Benefit, net

Three Months Ended June 30, 2016	Three Months Ended June 30, 2015	Increase (Decrease)	% Change
$ 2,000	$ 132,000	$ (130,000)	(98.5)%

Our income tax benefit for the three months ended June 30, 2015 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. We have completed our Australian tax return for the twelve month period ended June 30, 2015 in the second quarter of 2016 but have not yet received a tax credit refund. We expect to receive the refund in the third quarter of 2016. 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, 2016.

Comparison of Six Months Ended June 30, 2016 to Six Months Ended June 30, 2015

Revenue

Six Months Ended June 30, 2016	Six Months Ended June 30, 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. One C-Pulse system was implanted for which we recognized revenue in the six-month period ended June 30, 2015. 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 our clinical trials during fiscal 2016.

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, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Change
$ 2,761,000	$ 4,534,000	$ (1,773,000)	(39.1)%

The decrease in selling, general and administrative expense for the six months ended June 30, 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

Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Change
$ 5,776,000	$ 8,856,000	$ (3,080,000)	(34.8)%

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The decrease in research and development expense for the six months ended June 30, 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

Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Change
$ 436,000	$ 218,000	$ 218,000	100.0%

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 six months ended June 30, 2015. Subsequent to quarter end, we repaid all amounts outstanding under this loan facility, as described above in “Overview, Recent Developments.”

Income Tax (Expense), Benefit, net

Six Months Ended June 30, 2016	Six Months Ended June 30, 2015	Increase (Decrease)	% Change
$ (1,000)	$ 127,000	$ (128,000)	(100.0)%

Our income tax benefit, net for the six months ended June 30, 2015 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. We completed our Australian tax return for the twelve month period ended June 30, 2015 in the second quarter of 2016 but have not yet received a tax credit refund. We expect to receive the refund in the third quarter of 2016. 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, 2016.

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. Subsequent to the end of the second quarter of 2016, on July 26, 2016, we completed an equity financing of Series B Convertible Preferred Stock for gross cash proceeds of approximately $3.5 million. As of June 30, 2016 and December 31, 2015, cash and cash equivalents were $12.0 million and $23.1 million, respectively.

We expect to seek additional financing during 2016 and, 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 $9.1 million and $12.8 million for the six months ended June 30, 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 $29,000 and $95,000 for the six months ended June 30, 2016 and 2015, respectively. The majority of cash used in investing activities was for the purchase of laboratory and office equipment.

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Cash Flows from Financing Activities

Net cash (used in)/provided by financing activities was $(1.9) million and $15.1 million for the six months ended June 30, 2016 and 2015, respectively. Net cash used in financing activities was attributable to repayments of the principal amounts outstanding on our debt facility with Silicon Valley Bank. Net cash provided by financing activities was attributable to debt borrowings and proceeds from sales of our common stock.

Subsequent to quarter end, we repaid all amounts outstanding under our loan facility with Silicon Valley Bank, as described above in “Overview, Recent Developments.”

Capital Resource Requirements

As of June 30, 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 June 30, 2016, we were in compliance with all covenants under this facility.

Under the terms of a license, supply and manufacturing agreement with a major supplier involved in the development and manufacture of our C-Pulse system, we are committed to minimum annual expenditures as follows: $250,000 in each 2016, 2017, and 2018.

On August 5, 2016, we entered into an asset purchase agreement with Gambro UF Solutions, Inc., a subsidiary of Baxter International Inc., (the “Seller”) whereby we agreed that if the we dispose of any of the acquired assets for a price that exceeds $4.0 million within three years of the closing, we will pay the Seller 40% of the amount of such excess; and if shares of our common stock cease to be publicly traded on the Nasdaq Capital Market, the Seller has the option to require us to repurchase, in cash, all or any part of the common shares held by the Seller at a price equal to their fair market value, as determined by a third-party appraiser.

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 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, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired business, 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 our products,

the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the SEC. We may update our risk factors from time to time.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

As of June 30, 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 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, 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 June 30, 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, as updated in Item 1A. "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2016.

Failure to integrate our recently-acquired business into our operations successfully could adversely affect our business.

As discussed above under Part I, Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations—Overview", we recently closed the acquisition from Gambro UF Solutions, Inc. of certain assets exclusively related to the production and sale of the Aquadex™ FlexFlow product (the ***"Acquired Business"***). Our integration of the operations of the Acquired Business requires significant efforts and we may need to allocate more resources to integration and product development activities than originally anticipated. These efforts will result in additional expenses and involve significant amounts of management's time that cannot then be dedicated to other projects. Our failure to manage and coordinate the growth of the combined company successfully could also have an adverse impact on our business. Investments in medical technology are inherently risky, and we cannot guarantee that the Acquired Business will be profitable or successful or will not have a material unfavorable impact on us. Acquisitions can cause decrease in customer loyalty and product orders in connection with the change of ownership and management. Customers may be unwilling to continue doing business with us after our acquisition of the Acquired Business from the sellers and some customers may not consent to the assignment of their contracts with the sellers or agree to enter into a new contract with us. Inconsistencies in standards, controls, procedures and policies may adversely affect our ability to achieve the anticipated benefits of the acquisition. We also could experience negative effects on our results of operations, cash flows, and financial condition from

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acquisition-related charges, amortization of intangible assets and asset impairment charges. These effects, individually or in the aggregate, could harm our business.

We compete against many companies, some of which have longer operating histories, more established products and greater resources than we do, which may prevent us from achieving further market penetration or improving operating results.

Competition from medical device companies and medical device divisions of health care companies, as well as pharmaceutical companies and gene- and cell-based therapies is intense and is expected to increase. Our system will compete against therapies, including pharmacological therapies, as well as other medical device competitors that treat or may treat in the future Class III or ambulatory Class IV heart failure patients, including Baxter International, Inc. Berlin HeartGmbH, Boston Scientific, Inc., Davita Healthcare Partners, Fresenious SE & Co., Jarvik Heart, Inc., Medtronic Plc, NxStage, ReliantHeart, Inc., and St. Jude Medical Corporation, as well as a range of other specialized medical device companies with devices at varying stages of development. Some of these competitors have significantly greater financial and human resources than we do and have established reputations, as well as worldwide distribution channels and sales and marketing capabilities that are significantly larger and more established than ours. Additional competitors may enter the market, and we are likely to compete with new companies in the future. We also face competition from other medical therapies which may focus on our target market as well as competition from manufacturers of pharmaceutical and other devices that have not yet been developed. Competition from these companies could harm our business. In addition, because our system has been implanted in a limited number of patients to date, all of the material risks and potential competitive disadvantages of our system are not necessarily known at this time.

Our ability to compete effectively depends upon our ability to distinguish our Company and our system from our competitors and their products. Factors affecting our competitive position include:

- financial resources;
- product performance and design;
- product safety;
- acceptance of our system in the marketplace;
- sales, marketing and distribution capabilities;
- manufacturing and assembly costs;
- pricing of our system and of our competitors' products;
- the availability of reimbursement from government and private health insurers;
- success and timing of new product development and introductions;
- regulatory approvals in the United States; and
- intellectual property protection.

We have limited commercial manufacturing experience and could experience difficulty in producing the Aquadex FlexFlow product or may need to depend on third parties to manufacture the products.

We have limited experience in commercial manufacturing and no experience in commercially manufacturing the Aquadex FlexFlow product. As a result, we may not be able to develop and implement efficient, low-cost manufacturing capabilities and processes that will enable us to manufacture the Aquadex FlexFlow product or future products in significant volumes, while meeting the legal, regulatory, quality, price, durability, engineering, design and production standards required to market our products successfully. In addition, we depend upon third parties to manufacture and supply components for the Aquadex FlexFlow product.

We depend upon third-party suppliers, including single source suppliers to us and our customers, making us vulnerable to supply problems and price fluctuations.

We will rely on third-party suppliers, including single source suppliers, to provide us with certain components of the Aquadex FlexFlow product and to provide key components or supplies for use with our products. We depend on our suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. The forecasts of demand we use to determine order quantities and lead times for components purchased from outside suppliers may be incorrect. Our failure to obtain required components or subassemblies when needed and at a reasonable cost would adversely affect our business. These suppliers may encounter problems during manufacturing for a variety of reasons, any of which could delay or impede their ability to meet our demand. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business.

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Product defects, including lawsuits for product liability, could harm our business, results of operations and financial condition.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, unanticipated use of a product or inadequate disclosure of risks relating to the use of the product can lead to injury or other adverse events. These events could lead to recalls or safety alerts relating to a product (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. Any recall of our Aquadex FlexFlow product or our system could result in significant costs, as well as negative publicity and damage to our reputation that could reduce demand for our products. Personal injuries relating to the use of our products could also result in product liability claims being brought against us. In some circumstances, such adverse events could also cause delays in new product approvals.

As discussed under Part I, Item 1 "Business—Our Strategy" in our Annual Report on Form 10-K for the year ended December 31, 2015, we are currently in the process of reviewing and making further improvements to our system in response to feedback received from patients and physicians. We may be unable to improve the system in ways that improve patient acceptance, including by Class III heart failure patients in particular. We are also working on improving the design of and further developing our fully-implantable system. Any one of these factors related to the current or future design of the system could substantially harm our business, results of operations and financial condition.

The design, manufacture and marketing of medical devices carries a significant risk of product liability claims. Our products treats Class III and ambulatory Class IV heart failure for patients who typically have serious medical issues. As a result, our exposure to product liability claims may be heightened because the people who use our products have a high risk of suffering adverse outcomes, regardless of the safety or efficacy of our system. Because our system has been implanted in a limited number of patients to date, we cannot assure you that we are currently aware of all material risks related to use of our system or that could lead to product liability claims against us.

We may be held liable if any product we develop or commercialize causes injury or is found otherwise unsuitable during product testing, manufacturing, marketing, sale or consumer use. The safety studies we must perform and the regulatory approvals required to commercialize our products will not protect us from any such liability. We carry product liability insurance with a $10 million aggregate limit. However, if there are product liability claims against us, our insurance may be insufficient to cover the expense of defending against such claims, or may be insufficient to pay or settle such claims. Furthermore, we may be unable to obtain adequate product liability insurance coverage for commercial sales of any approved product. If such insurance is insufficient to protect us, our business, results of operations and financial condition will be harmed. If any product liability claim is made against us, our reputation and future sales will be damaged, even if we have adequate insurance coverage. Even if a product liability claim against us is without merit or if we are not found liable for any damages, a product liability claim could result in decreased interest in our clinical studies, decreased demand for our system, if approved for commercialization, injury to our reputation, diversion of management's attention from operating our business, withdrawal of clinical study participants, significant costs of related litigation, loss of revenue or the inability to commercialize our products.

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.

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 11, 2016

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

Date: August 11, 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 June 30, 2016

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
2.1	Asset Purchase Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016.	8-K	001-35312	August 8, 2016	2.1		
3.1	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock.	8-K	001-35312	July 25, 2016	3.1		

4.1	Form of Series B Convertible Preferred Stock Certificate.	8-K	001-35312	July 22, 2016	4.1		
4.2	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement, dated July 20, 2016, among the Company and the purchasers signatory thereto.	8-K	001-35312	July 22, 2016	4.3		
4.3	Form of Common Stock Purchase Warrant issued to Northland Securities, Inc.	8-K	001-35312	July 22, 2016	4.3		
4.4	Registration Rights Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016	8-K	001-35312	August 8, 2016	4.1		
10.1	Securities Purchase Agreement, dated July 20, 2016 among the Company and the purchasers signatory thereto.	8-K	001-35312	July 22, 2016	10.1		
10.2	Patent License Agreement between Sunshine Heart, Inc. and Gambro UF Solutions, Inc. dated August 5, 2016.	8-K	001-35312	August 8, 2016	10.1		
10.3	Loan and Security Agreement between Sunshine Heart, Inc. and Silicon Valley Bank dated August 5, 2016.	8-K	001-35312	August 8, 2016	10.2s		
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	

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Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
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	

*Filed herewith.
**Furnished herewith.

Exhibit 31.1

CHIEF EXECUTIVE OFFICER'S 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 June 30, 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(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 11, 2016

/s/ John L. Erb
John L. Erb
Chief Executive Officer

Exhibit 31.2

CHIEF FINANCIAL OFFICER'S 302 CERTIFICATION

I, Claudia Drayton, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sunshine Heart, Inc. for the quarterly period ended June 30, 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(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 11, 2016

/s/ Claudia Drayton
Claudia Drayton
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report of Sunshine Heart, Inc. (the ***"Company"***) on Form 10-Q for the quarterly period ended June 30, 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: August 11, 2016

/s/ John L. Erb
John L. Erb
Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report of Sunshine Heart, Inc. (the ***"Company"***) on Form 10-Q for the quarterly period ended June 30, 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: August 11, 2016

/s/ Claudia Drayton
Claudia Drayton
Chief Financial Officer