Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 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 ☐
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 November 10, 2016 was 20,895,278

Table of Contents

TABLE OF CONTENTS

Page Number

PART I—FINANCIAL INFORMATION

Item 1	Financial Statements	3
	Condensed Consolidated Balance Sheets	3
	Condensed Consolidated Statements of Operations and Comprehensive Loss	4
	Condensed Consolidated Statements of Cash Flows	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2	Management's Discussion and Analysis of Financial Condition and Results of Operations	13
Item 3	Quantitative and Qualitative Disclosures About Market Risk	21
Item 4	Controls and Procedures	21

PART II—OTHER INFORMATION

Item 1	Legal Proceedings	22
Item 1A	Risk Factors	22
Item 2	Unregistered Sales of Equity Securities and Use of Proceeds	22
Item 3	Defaults Upon Senior Securities	23
Item 4	Mine Safety Disclosures	23
Item 5	Other Information	23
Item 6	Exhibits	23

Table of Contents

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2016 (unaudited)	December 31, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$ 792	$ 23,113
Accounts receivable	111	—
Inventory	202	—
Other current assets	223	479
Total current assets	1,328	23,592
Property, plant and equipment, net	597	535
Intangible assets, net	4,399	—
Goodwill	268	—
Other assets	29	323
TOTAL ASSETS	$ 6,621	$ 24,450
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Current portion of long-term debt	$ —	$ 3,798
Accounts payable and accrued expenses	2,169	2,832
Accrued compensation	629	1,368
Total current liabilities	2,798	7,998
Long-term debt, net of discount and financing fees	—	3,881
Common stock warrant liability	1,237	—
Other liabilities	126	400
Total liabilities	4,161	12,279
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of September 30, 2016 and December 31, 2015, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Series B convertible preferred stock as of September 30, 2016 and December 31, 2015, par value $0.0001 per share; authorized 3,468 shares, issued and outstanding 2,227 and 0, respectively	—	—
Preferred stock as of September 30, 2016 and December 31, 2015, par value $0.0001 per share; authorized 39,966,532 shares, none outstanding	—	—
Common stock as of September 30, 2016 and December 31, 2015, par value $0.0001 per share; authorized 100,000,000 shares, issued and outstanding 20,866,217 and 18,344,478, respectively	2	2
Additional paid-in capital	167,297	164,105
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,234	1,246
Accumulated deficit	(166,073)	(153,182)
Total stockholders' equity	2,460	12,171

TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 6,621	$ 24,450

See notes to the condensed consolidated financial statements.

Table of Contents

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Net sales	$ 543	$ —	$ 543	$ 59
Costs and Expenses:				
Cost of goods sold	187	—	187	—
Selling, general and administrative	2,683	1,725	5,444	6,259
Research and development	1,735	4,548	7,511	13,404
Total costs and expenses	4,605	6,273	13,142	19,663
Loss from operations	(4,062)	(6,273)	(12,599)	(19,604)
Other income (expense):				
Interest expense	(68)	(280)	(504)	(498)
Loss on early retirement of long-term debt	(500)	—	(500)	—
Other income (expense), net	2	(2)	2	(1)
Change in fair value of warrant liability	646	—	646	—
Total other income (expense)	80	(282)	(356)	(499)
Loss before income taxes	(3,982)	(6,555)	(12,955)	(20,103)
Income tax benefit (expense), net	65	(3)	64	124
Net loss	$ (3,917)	$ (6,558)	$ (12,891)	$ (19,979)
Basic and diluted loss per share	$ (0.27)	$ (0.36)	$ (0.76)	$ (1.11)
Weighted average shares outstanding — basic and diluted	19,974	18,330	18,910	18,045
Other comprehensive income:				
Foreign currency translation adjustments	$ (6)	$ (16)	$ (12)	$ (22)
Total comprehensive loss	$ (3,923)	$ (6,574)	$ (12,903)	$ (20,001)

See notes to the condensed consolidated financial statements.

Table of Contents

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

	Nine months ended September 30,	
	2016	**2015**
Operating Activities:		
Net loss	$ (12,891)	$ (19,979)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization expense	457	241
Stock-based compensation expense, net	764	1,811
Amortization of debt discount and financing fees	187	102
Loss on early retirement of long-term debt	500	
Change in fair value of warrant liability	(646)	—
Changes in operating assets and liabilities:		
Accounts receivable	(111)	59
Inventory	(202)	—
Other current assets	256	(406)
Other assets and liabilities	(471)	(108)
Accounts payable and accrued expenses	(1,406)	48
Net cash used in operations	(13,563)	(18,232)
Investing Activities:		
Purchases of property and equipment	(110)	(175)
Acquisition of Aquadex product line	(4,000)	—

Net cash used in investing activities	(4,110)	(175)
Financing Activities:		
Net proceeds from the sale of preferred stock and common stock	3,362	7,055
Proceeds from (repayments on) borrowings on long-term debt	(8,000)	8,000
Net cash (used in) provided by financing activities	(4,638)	15,055
Effect of exchange rate changes on cash	(10)	(42)
Net decrease in cash and cash equivalents	(22,321)	(3,394)
Cash and cash equivalents - beginning of period	23,113	31,293
Cash and cash equivalents - end of period	$ 792	$ 27,899
Supplement schedule of non-cash activities		
Warrants issued in connection with debt financing	$ —	$ 355
Common stock issued for business acquisition	$ 950	$ —
Supplemental cash flow information		
Cash paid for interest	$ 840	$ 247
Cash paid for income taxes	$ 47	$ —

See notes to the condensed consolidated financial statements.

Table of Contents

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

Note 1 — Nature of Business and Basis of Presentation

Nature of Business: Sunshine Heart, Inc. (the "Company") is an early-stage medical device company focused on developing and commercializing a product portfolio to treat moderate to severe heart failure and related conditions. The Company's commercial product, the Aquadex FlexFlow System (Aquadex) is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with wholly owned subsidiaries in Australia and Ireland. The Company has been listed on the NASDAQ Capital Market since February 2012.

On March 3, 2016, the Company announced that it was no longer enrolling patients in the Company's OPTIONS HF or COUNTER HF clinical studies, which were designed to prove the benefits of counterpulsation for heart failure patients, and that it would pursue a new strategic direction. On July 11, 2016, the Company announced that it was moving forward with a therapeutic strategy focused on neuromodulation rather than counterpulsation. On September 29, 2016, the Company announced a strategic refocus of its near term strategy that includes pausing clinical evaluations of the neuromodulation technology to fully focus the Company's resources on its recently acquired Aquadex system, taking actions to reduce its cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives.

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 September 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 September 30, 2016, the Company had an accumulated deficit of $166.1 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 successfully commercialize its Aquadex products. 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 products, 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.

Revenue Recognition: The Company recognizes revenues from product sales when earned. Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. Revenue is not recognized until title

and risk of loss have transferred to the customer. The shipping terms for the Company's revenue arrangements are FOB shipping point.

Accounts Receivable: The Company's accounts receivable have terms that require payment in 30 days. No allowance for

Table of Contents

doubtful accounts has been established at September 30, 2016 as all amounts were subsequently collected.

Inventories: Inventories represent finished goods purchased from the Company's supplier and are recorded as the lower of cost or market using the first-in-first out method.

Intangible assets: The Company's intangible assets consist of customer relationships, developed technology, and trademarks and tradenames. All intangible assets recognized by the Company result from the acquisition of the Aquadex business. All amounts are provisional until final valuation reports for the acquired intangible assets are received. All intangible assets are estimated to have a useful life of 5-7 years. The Company reviews its definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable through the estimated undiscounted future cash flows derived from such assets. In cases where the carrying value exceeds the undiscounted cash flows, the carrying value is written down to its fair value, using a discounted cash flow analysis. No impairments have been identified or recorded in the periods presented.

Goodwill: Goodwill is the cost of an acquisition in excess of the fair value of acquired assets and liabilities and is recorded as an asset on the balance sheet. Goodwill is not subject to amortization but must be tested for impairment at least annually. This test requires the Company to determine if the implied fair value of the goodwill is less than its carrying amount.

The Company evaluates goodwill for impairment annually on November 1st of each calendar year, or to the extent events or conditions indicate a risk of possible impairment during the interim periods prior to its annual impairment test. Generally, the evaluation of goodwill for impairment involves a two-step test, although under certain circumstance an initial qualitative evaluation may be sufficient to conclude that goodwill is not impaired without conducting the quantitative test.

Step 1 involves comparing the estimated fair value of each respective reporting unit to its carrying value, including goodwill. If the estimated fair value exceeds the carrying value, the reporting unit's goodwill is not considered impaired. If the carrying value exceeds the estimated fair value, step 2 must be performed to determine whether goodwill is impaired and, if so, the amount of the impairment. Step 2 involves calculating an implied fair value of goodwill by performing a hypothetical allocation of the estimated fair value of the reporting unit determined in step 1 to the respective tangible and intangible net assets of the reporting unit. The remaining implied goodwill is then compared to the actual carrying amount of the goodwill for the reporting unit. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. No impairments have been identified or recorded in the periods presented.

Contingent consideration: In connection with the Company's purchase of Aquadex, the Company has an obligation to pay additional consideration that is contingent upon the occurrence of certain future events. Contingent consideration is recognized at the acquisition date at the estimated fair value of the contingent milestone payments. The fair value of the contingent consideration is remeasured to its estimated fair value at the end of each reporting period, with changes recorded to earnings.

Common stock warrant liability: The Company records its common stock warrant liability at fair value at the date of issuance using primarily a Monte Carlo valuation model. The fair value is remeasured to its estimated fair value at the end of each reporting period with changes recorded to earnings.

Earnings per share: Basic earnings per share is computed based on the net loss allocable to common stockholders for each period divided by the weighted average number of common shares outstanding. The net loss allocable to common stockholders for the three and nine month periods ending September 30, 2016 reflects a $1.4 million increase for the deemed dividend to preferred shareholders provided in connection with the third quarter 2016 Series B convertible preferred stock offering (see Note 4). Diluted earnings per share is computed based on the net loss allocable to common stockholders for each period divided by 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 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.

The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share because to do so would be anti-dilutive as of the end of each period presented:

	September 30,	
	2016	2015
Stock options	2,919,245	2,141,536
Restricted stock units	438,953	18,135
Warrants to purchase common stock	4,131,503	321,342
Series B convertible preferred stock	2,369,361	—
Total	9,859,062	2,481,013

Table of Contents

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, August 2015, March 2016, April 2016 and May 2016, the FASB issued amended revenue recognition guidance to clarify the principles for recognizing revenue from contracts with customers. The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The standard allows the Company to transition to the new model using either a full or modified retrospective approach, and early adoption is not permitted. 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 — Aquadex Acquisition

On August 5, 2016, the Company completed the acquisition of certain assets used in the production and sale of the Aquadex product line from an indirect subsidiary of Baxter International Inc. (the "Seller"). The acquisition of these assets meets the criteria for the purchase of a business, and has been accounted for in accordance with Accounting Standards Codification (ASC) 805, *Business Combinations*, with identifiable assets acquired and liabilities assumed recorded at their estimated fair values on the acquisition date. A valuation of the assets and liabilities from the business acquisition was performed utilizing cost, income and market approaches resulting in $5,076 allocated to identifiable net assets.

The Company completed the acquisition in order to strengthen its presence in the heart failure market.

Purchase Consideration: Total purchase consideration for the Aquadex business is as follows:

Table of Contents

(in thousands)		
Cash consideration	$	4,000
Common stock consideration		950
Fair value of contingent consideration		126
Total purchase consideration	$	5,076

- *Common Stock Consideration:* The common stock consideration consisted of 1 million shares of the Company's common stock, worth $0.95 million based on the closing market value of $0.95 per share on August 5, 2016.

- *Contingent Consideration:* In connection with the acquisition of the Aquadex product line, the Company agreed to pay the Seller 40% of any proceeds in excess of $4.0 million related to the sale or disposal of the Aquadex assets within three years of the close of the transaction. The fair value of this contingent consideration was calculated based on the estimated likelihood of occurrence of this event in the timeframe provided by the agreement.

Purchase price consideration does not include expenses of $0.9 million for accounting, audit, legal, and valuation services that were incurred as part of the transaction and were expensed as incurred.

The acquisition was recorded by recognizing the assets acquired at their estimated fair value at the acquisition date. The excess of the cost of the acquisition over the fair value of the assets acquired was recorded as goodwill. The preliminary fair values were based on management's analysis, including work performed by third-party valuation specialists. The initial accounting for the acquisition is not complete because certain information and analysis that may impact the initial valuations are still being obtained or reviewed as a result of the short time period since the closing of the acquisition. The following presents the provisional amounts recognized for the assets acquired on August 5, 2016 (in thousands):

Capital lease asset	$	307
Intangible assets		4,501
Total identifiable assets acquired		4,808
Goodwill		268
Total purchase consideration	$	5,076

Any subsequent changes to the provisional amounts recognized during the measurement period will be recorded in the reporting period in which the adjustment amounts are determined.

The goodwill is primarily attributable to new and/or future customer relationships that were not acquired in the transaction. The fair value of the capital lease asset utilized a combination of the cost and market approaches, depending on the characteristics of the asset classification. Of the $4.5 million of acquired intangible assets, $2.4 million was assigned to customer relationships, $1.8 million was assigned to developed technology, and $0.3 million was assigned to trademarks and tradename. All intangible assets are estimated to have a useful life of 5-7 years.

Pro Forma Condensed Combined Financial Information (Unaudited)

The following unaudited pro forma combined financial information summarizes the results of operations for the periods indicated as if the acquisition of Aquadex had been completed on of January 1, 2015. Pro forma information reflects adjustments that are expected to have a continuing impact on our results of operations and are directly attributable to the acquisition. The unaudited pro forma results include adjustments to reflect, among other things, direct transaction costs relating to the acquisition, the difference in intangible asset amortization to be incurred based on the preliminary values of each identifiable intangible asset, and the difference in depreciation expense to be incurred based on preliminary value of the capital lease asset. The pro forma amounts do not purport to be indicative of the results that would have actually been obtained if the acquisition had occurred as of January 1, 2015 or that may be obtained in the future, and do not reflect future synergies, integration costs, or other such costs or savings.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Pro forma net sales	$ 791	$ 1,188	$ 2,414	$ 3,193
Pro forma net loss from operations	(3,146)	(19,658)	(12,519)	(33,319)
Pro forma basic and diluted net loss per share	$ (0.23)	$ (1.02)	$ (0.72)	$ (1.75)

Table of Contents

Note 3 - Debt

Prior Loan Agreement: On February 18, 2015, the Company entered into a loan and security agreement with Silicon Valley Bank (the 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. The proceeds from the term loans were used for general corporate and working capital purposes. Commencing on January 1, 2016, the Company began repaying the advances made in twenty-four consecutive equal monthly installments.

On August 4, 2016, the Company repaid all amounts outstanding under its existing debt facility of $5.5 million, and incurred a $0.5 million loss on early extinguishment of debt, including the accelerated write-off of unamortized warrants and debt issuance costs. Total borrowings outstanding under this agreement totaled $8.0 million as of 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 the 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 were recorded as debt discount in the accompanying balance sheet and were amortized to interest expense over the term of the debt agreement using the effective interest rate method. As of December 31, 2015, $201,000 of unamortized debt discount was netted against long-term debt in the accompanying condensed consolidated balance sheet. In connection with the repayment of the debt on August 4, 2016, the Company wrote off the remaining unamortized value of the warrants totaling $113,000.

New 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 a term loan in an aggregate original principal amount not to exceed $4.0 million (the “Term Loan”) and 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”). Proceeds from the Loans, if any, will be used for general corporate and working capital purposes. Any advances under the Term Loan accrue interest at a floating annual rate equal to 2.50% above the prime rate. Any advances under the Revolving Line will accrue interest at a floating annual rate equal to 1.75% or 1.0% above the prime rate, depending on liquidity factors. Advances under the Loans are available to the Company until November 30, 2016, subject to compliance with liquidity covenants which the Company does not currently meet. There were no borrowings outstanding under this facility as of September 30, 2016.

Note 4 - 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 nine months ended September 30, 2016. During the nine months ended September 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 September 30, 2016, the Company had a total of $32.6 million available for future sales under the sales agreement.

Series B Convertible Preferred Stock: On July 20, 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. The Series B Convertible 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. Approximately $1.6 million of the proceeds were allocated to the preferred stock, representing the residual proceeds after the warrants (described below) were recorded at fair value. The preferred stock includes a beneficial conversion amount of $1.4 million, representing the intrinsic value of the stock at the time of issuance, which has an effect on earnings per share allocable to common shareholders. As of September 30, 2016, 1,241 shares of the Series B Convertible Preferred Stock

Table of Contents

had been converted into 1,320,000 shares of common stock, and 2,227 shares remained outstanding.

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 the warrants described below.

Warrants: 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 at no additional cost. The warrants are exercisable for 36 months commencing six months from the closing date. In addition, the Company issued 221,362 warrants to the placement agent to purchase shares of common stock, or 6% of the shares of common stock sold to investors in the offering at no additional cost. These warrants were immediately exercisable at an exercise price of $1.35 per share and will be exercisable for five years after the closing of the offering. The warrants issued to the investor (but not the ones issued to the placement holder) are subject to a 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.

Both the investor and placement agent warrants are accounted for as a liabilities and were recorded at fair value on the date of issuance. Changes in the fair value of these warrants must be measured and recorded for each subsequent reporting period that the warrants remain outstanding, and changes in fair value must be recognized in the statement of operations. These warrants were valued at $1.8 million on the date of issuance and at $1.2 million as of September 30, 2016. The change in fair value of $0.6 million was reflected as an unrealized gain in the accompanying statement of operations.

Transaction Costs: The Company incurred approximately $0.4 million of cash and non-cash transaction costs which were allocated to the preferred stock and investor warrants on a relative fair value basis. The $0.2 million allocated to the preferred stock was recorded as a reduction of additional paid-in-capital, while the $0.2 million allocated to the investor warrants was expensed as incurred.

Note 5 - 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:

	Nine months ended September 30,	
(in thousands)	**2016**	**2015**
Selling, general and administrative expense	$ 506	$ 1,400
Research and development expense	314	694
Total stock-based compensation expense	**$ 820**	**$ 2,094**

Note 6 - Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, warrants, contingent consideration and debt.

Pursuant to the requirements of ASC Topic 820 *"Fair Value Measurement,"* the Company's financial assets and liabilities measured at fair value on a recurring basis are classified and disclosed in one of the following three categories:

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

The fair value of the Company's common stock warrant liability is calculated using a Monte Carlo valuation model and is classified as Level 3 in the fair value hierarchy. The common stock warrants issued July 26, 2016 had a fair value of $1.8

Table of Contents

million on the date of issuance and $1.2 million on September 30, 2016. Fair values were calculated using the following assumptions:

	July 26, 2016	Sept 30, 2016
Risk-free interest rates, adjusted for continuous compounding	0.94%	0.92%
Term (years)	3.5	3.32
Expected volatility	78%	80%

Dates and probability of future equity raises	various	various

During the three months ended September 30, 2016, the Company recognized unrealized gains of $0.6 million in the condensed consolidated statements of operations from changes in fair value of the warrant liability.

The fair value of the Company's contingent consideration, as described in Note 2, was initially measured based on the consideration expected to be transferred (probability-weighted), discounted back to present value, and it is considered a Level 3 instrument. The discount rate used was determined at the time of measurement in accordance with accepted valuation methods. The Company measures the liability on a recurring basis using Level 3 inputs including probabilities of payment and projected payment dates. Changes to any of the inputs may result in significantly higher or lower fair value measurements. There were no changes in the fair value of the contingent consideration subsequent to the initial measurement.

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 any other classified as Level 3 and there were no movements between these categories during the periods ended September 30, 2016 and December 31, 2015.

Note 7 — Income Taxes

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

As of September 30, 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 8—Commitments and Contingencies

Leases: The Company leases office space under a non-cancelable operating lease that expires in March 2019. The lease contains provisions for future annual inflationary adjustments. Rent expense is recognized using the straight-line method over the term of the lease.

Employee Retirement Plan: The Company has a 401(k) profit sharing plan that provides retirement benefit to substantially all full-time U.S. employees. Eligible employees may contribute a percentage of their annual compensation, subject to IRS limitations, with the Company matching a portion of the employee's contributions at the discretion of the Company.

Inventory Purchase Commitments: In connection with the acquisition of the Aquadex product line, the Company entered into a manufacturing and supply agreement with the Seller that will expire within a period not to exceed 18 months from the close of the transaction. Upon termination of this agreement, the Company has an obligation to purchase the remaining Aquadex inventory. We estimate that this amount will not exceed $2.5 million.

Contingent Consideration: As described on Note 2, the Company agreed that if it disposes of any of the Aquadex assets for a price that exceeds $4.0 million within three years of the closing, it will pay the Seller 40% of the amount of such excess. In addition, it also agreed that if shares of its common stock cease to be publicly traded on the Nasdaq Capital Market, the Seller has the option to require the Company 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.

Note 9 — Subsequent Events

On October 30, 2016, the Company entered into an exchange agreement with the holders of its Series B Convertible Preferred Stock and agreed to issue such holders 2,227 shares of the Company's Series B-1 Convertible Preferred Stock in

Table of Contents

exchange for the cancellation of all shares of Series B Convertible Preferred Stock held by such holders. The Series B-1 Convertible Preferred Stock has the same terms as the Series B Convertible Preferred Stock, except that the initial conversion price of the Series B-1 Convertible Preferred Stock is $0.17 per share and the Series B-1 Convertible Preferred Stock is subject to a limitation on conversion so that, if and until the receipt of stockholder approval, the holders cannot convert shares of Series B-1 Convertible Preferred Stock into shares of common stock if such conversion would cause the number of shares of common stock issued upon the conversion of the Series B Convertible Preferred Stock and Series B-1 Convertible Preferred Stock to exceed 19.9% of the number of shares of common stock outstanding on the trading day immediately prior to the date that the securities purchase agreement for the Series B Convertible Preferred Stock was executed.

Also, on October 30, 2016, the Company entered into securities purchase agreements with an institutional investor for shares of convertible preferred stock and warrants with an aggregate purchase price of $3.8 million in a registered direct offering and simultaneous private placement. The first closing of the transaction occurred on November 3, 2016, whereby the Company received $3.6 million in gross proceeds and issued and sold and issued 2,900 shares of Series C Convertible Preferred Stock, 700 shares of Series D Convertible Preferred Stock, both at $0.17 per share, and warrants to purchase an aggregate of 21,176,471 shares of its common stock at an exercise price equal to $0.18 per share. At the second closing, which is subject to the Company receiving shareholder approval of the transactions, the Company expects to issue and sell 200 shares of Series D Convertible Preferred Stock and warrants to purchase an aggregate of 1,176,471 shares of common stock for a gross purchase price of $0.2 million.

In connection with the registered direct offering and the private placement, 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 1,270,588 warrants to purchase its common stock at an exercise price of $0.21 per share.

The Company is required under the securities purchase agreement to file a proxy statement with the SEC for the purposes of holding a special meeting of its stockholders to vote on a proposal to approve the issuance of the shares of common stock underlying the Series C Convertible Preferred Stock, Series D Convertible Preferred Stock and warrants issued in connection with the offering and private placement. No shares of common stock are issuable upon

conversion of the Series C Convertible Preferred Stock or Series D Convertible Preferred Stock or upon exercise of the warrants issued to the investors and to the placement agent until shareholder approval has been received.

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 and commercializing a product portfolio to treat moderate to severe heart failure and related conditions. Our commercial product, the Aquadex FlexFlow System (Aquadex) is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. We are a Delaware corporation headquartered in Minneapolis with wholly owned subsidiaries in Australia and Ireland. We have been listed on the NASDAQ Capital Market since February 2012.

On March 3, 2016, we announced that we were no longer enrolling patients in the Company's OPTIONS HF or COUNTER HF clinical studies, which were designed to prove the benefits of counterpulsation for heart failure patients, and that we would pursue a new strategic direction. On July 11, 2016, we announced that we were moving forward with a therapeutic strategy focused on neuromodulation rather than counterpulsation, after we discovered that the primary mechanism of

Table of Contents

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.

Recent Developments

On September 29, 2016, we announced a strategic refocus of our near term strategy that includes pausing clinical evaluations of the neuromodulation technology to fully focus the Company's resources on our recently acquired Aquadex system, taking actions to reduce our cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives.

On October 30, 2016, we entered into an exchange agreement with the holders of its Series B Convertible Preferred Stock and agreed to issue such holders 2,227 shares of the Company's Series B-1 Convertible Preferred Stock in exchange for the cancellation of all shares of Series B Convertible Preferred Stock held by such holders. The Series B-1 Convertible Preferred Stock has the same terms as the Series B Convertible Preferred Stock, except that the initial conversion price of the Series B-1 Convertible Preferred Stock is $0.17 per share and the Series B-1 Convertible Preferred Stock is subject to a limitation on conversion so that, if and until the receipt of stockholder approval, the holders cannot convert shares of Series B-1 Convertible Preferred Stock into shares of common stock if such conversion would cause the number of shares of common stock issued upon the conversion of the Series B Convertible Preferred Stock and Series B-1 Convertible Preferred Stock to exceed 19.9% of the number of shares of common stock outstanding on the trading day immediately prior to the date that the securities purchase agreement for the Series B Convertible Preferred Stock was executed.

Also, on October 30, 2016, we entered into securities purchase agreements with an institutional investor for shares of convertible preferred stock and warrants with an aggregate purchase price of $3.8 million in a registered direct offering and simultaneous private placement. The first closing of the transaction occurred on November 3, 2016, and we received $3.6 million in gross proceeds and issued and sold and issued 2,900 shares of Series C Convertible Preferred Stock, 700 shares of Series D Convertible Preferred Stock, both at $0.17 per share, and warrants to purchase an aggregate of 21,176,471 shares of our common stock at an exercise price equal to $0.18 per share. At the second closing, which is subject to the Company receiving shareholder approval of the transactions, we expect to issue and sell 200 shares of Series D Convertible Preferred Stock and warrants to purchase an aggregate of 1,176,471 shares of common stock for a gross purchase price of $0.2 million.

In connection with the registered direct offering and the private placement, we paid the placement agent an aggregate cash placement fee equal to 6% of the aggregate gross proceeds raised in the offering and issued 1,270,588 warrants to purchase its common stock at an exercise price of $0.21 per share.

We are required under the securities purchase agreement to file a proxy statement with the SEC for the purposes of holding a special meeting of its stockholders to vote on a proposal to approve the issuance of the shares of common stock underlying the Series C Convertible Preferred Stock, Series D Convertible Preferred Stock and warrants issued in connection with the offering and private placement. No shares of common stock are issuable upon conversion of the Series C Convertible Preferred Stock or Series D Convertible Preferred Stock or upon exercise of the warrants issued to the investors and to the placement agent until shareholder approval has been received.

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. Other than new estimates made in connection with the valuation of our warrant liability, contingent consideration, and valuation of intangible assets related to the Aquadex acquisition, 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.

Revenue Recognition: We recognize revenue from product sales when earned. Specifically, revenue is recognized when

Table of Contents

persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, and collectability is reasonably assured. Revenue is not recognized until title and risk of loss have transferred to the customer. The shipping terms for our revenue arrangements are FOB shipping point.

Accounts Receivable: Our accounts receivable have terms that require payment in 30 days. We did not establish an allowance for doubtful accounts at September 30, 2016 as all amounts were subsequently collected.

Inventories: Inventories represent finished goods purchased from our supplier and are recorded as the lower of cost or market using the first-in-first out method.

Intangible assets: Our intangible assets consist of $2.4 million for customer relationships, $1.8 million for developed technology, and $0.3 million for trademarks and tradenames. All intangible assets are estimated to have a useful life of 5-7 years. We review our definite-lived intangible assets for impairment when impairment indicators exist. When impairment indicators exist, we determine if the carrying value of the intangible assets exceeds the related undiscounted cash flows. In cases where the carrying value exceeds the undiscounted cash flows, the carrying value is written down to its fair value, generally using a discounted cash flow analysis. No impairments have been identified or recorded in the periods presented.

Goodwill: Goodwill is the cost of an acquisition in excess of the fair value of acquired assets and liabilities and is recorded as an asset on our balance sheet. Goodwill is not subject to amortization but must be tested for impairment at least annually. This test requires us to assign goodwill to an appropriate reporting unit and to determine if the implied fair value of the reporting unit's goodwill is less than its carrying amount.

We evaluate goodwill for impairment annually on November 1st of each calendar year, or to the extent events or conditions indicate a risk of possible impairment during the interim periods prior to our annual impairment test. Generally, the evaluation of goodwill for impairment involves a two-step test, although under certain circumstance an initial qualitative evaluation may be sufficient to conclude that goodwill is not impaired without conducting the quantitative test.

Step 1 involves comparing the estimated fair value of each respective reporting unit to its carrying value, including goodwill. If the estimated fair value exceeds the carrying value, the reporting unit's goodwill is not considered impaired. If the carrying value exceeds the estimated fair value, step 2 must be performed to determine whether goodwill is impaired and, if so, the amount of the impairment. Step 2 involves calculating an implied fair value of goodwill by performing a hypothetical allocation of the estimated fair value of the reporting unit determined in step 1 to the respective tangible and intangible net assets of the reporting unit. The remaining implied goodwill is then compared to the actual carrying amount of the goodwill for the reporting unit. To the extent the carrying amount of goodwill exceeds the implied goodwill, the difference is the amount of the goodwill impairment. No impairments have been identified or recorded in the periods presented.

Contingent consideration: In connection with the Company's purchase of Aquadex, the Company has an obligation to pay additional consideration that is contingent upon the occurrence of certain future events. Contingent consideration is recognized at the acquisition date at the estimated fair value of the contingent milestone payments. The fair value of the contingent consideration is remeasured to its estimated fair value at the end of each reporting period, with changes recorded to earnings.

Common stock warrant liability: The Company records its common stock warrant liability at fair value at the date of issuance using primarily a Monte Carlo valuation model. The fair value is remeasured to its estimated fair value at the end of each reporting period with changes recorded to earnings.

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 September 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 2017. Should future capital raising be unsuccessful, we may not be able to continue as a going concern. Furthermore, our ability to continue as a going concern is subject to our ability to develop and successfully commercialize the product being developed. If we are unable to obtain such funding of an amount and timing necessary to meet our future operational plans, or to successfully commercialize our intellectual property, we may be unable to continue as a going concern. No adjustments have been made relating to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we not continue as a going concern.

Table of Contents

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 and commercializing 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 September 30, 2016, we had an accumulated deficit of $166.1 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 September 30, 2016 to Three Months Ended September 30, 2015

Revenue

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 543,000	$ —	$ 543,000	N/M

On August 5, 2016, we completed the acquisition of the Aquadex product line from a subsidiary of Baxter International Inc. The Aquadex product line generated revenues of $484,000 from the date of acquisition through September 30, 2016. Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with our Aquadex consoles. We estimate that there are over 500 installed Aquadex consoles around the United States. We had no commercial sales prior to the acquisition of the Aquadex product line.

On March 3, 2016, we announced that we were no longer enrolling patients in the Company's OPTIONS HF or COUNTER HF clinical studies. Prior to this announcement, all of our revenue was generated by sales of the C-Pulse System to hospitals and clinics in conjunction with our U.S. clinical study. The C-Pulse System was not approved for commercial sale, however, the FDA had 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. During the quarter ended September 30, 2016, we received reimbursement and recognized $59,000 in revenue for one implant that was performed before the announcement that we were no longer enrolling patients in the study. Since we terminated enrollment in our OPTIONS HF and COUNTER HF clinical trials, we do not expect to generate revenue from our clinical trials in the foreseeable future.

On September 29, 2016, we announced a strategic refocus of our near term strategy to fully focus the Company's resources on our recently acquired Aquadex system. As such, we expect our Aquadex revenue to grow significantly in the upcoming quarters as we drive increased utilization of disposable sales within our installed base.

Cost of Sales

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 187,000	$ —	$ 187,000	N/M

In connection with the acquisition of the Aquadex product line, we entered into a manufacturing and supply agreement with the Seller. Cost of sales reflects the agreed-upon price paid to Seller for the manufacturing of the disposables and consoles. This acquisition closed on August 5, 2016. Prior to that date, we did not have commercial sales or related product costs.

Selling, General and Administrative Expense

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 2,683,000	$ 1,725,000	$ 958,000	55.5%

Table of Contents

The increase in selling, general and administrative expense relate primarily to $0.9 million transaction fees (accounting, audit, valuation and legal fees) incurred in connection with the acquisition of the Aquadex product line. In addition, subsequent to the date of the Aquadex acquisition, we incurred commercial expenses in connection with the marketing and sale of the Aquadex product line. These increases were partially offset by efficiencies achieved as a result of consolidation and streamlining activities in our administrative functions, and to lower stock compensation costs. As we continue to ramp up our sales organization we expect that our selling expenses will continue to increase in future quarters, and that general and administrative expenses will continue to decrease.

Research and Development Expense

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 1,735,000	$ 4,548,000	$ (2,813,000)	(61.9)%

The decrease in research and development expense for the three months ended September 30, 2016 as compared to 2015 resulted primarily from our decision to stop enrollment in the COUNTER HF and OPTIONS HF studies, which was announced on March 3, 2016. Further, on September 29, 2016, we announced a strategic refocus of our near term strategy that includes pausing clinical evaluations of the neuromodulation technology to fully focus the Company's resources on our recently acquired Aquadex system. As a result, we expect that our research and development expenditures will continue to decrease in future quarters.

Interest Expense

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 68,000	$ 280,000	$ (212,000)	(75.7)%

The decrease in interest expense is related to the repayment of borrowings outstanding under our prior term loan with Silicon Valley Bank. Beginning January 1, 2016, we began repaying the principal due on this loan, and on August 4, 2016, we repaid all amounts outstanding under this loan facility, totaling $5.5 million.

Loss on Early Retirement of Long-Term Debt

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 500,000	$ —	$ 500,000	N/M

On August 4, 2016, we repaid all amounts outstanding under our prior term loan with Silicon Valley Bank, totaling $5.5 million. In connection with the repayment of this debt, we incurred a $0.5 million loss, including the accelerated write-off of unamortized warrants and debt issuance costs.

Change in Fair Value of Warrant Liability

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 646,000	$ —	$ 646,000	N/M

The value of the common stock warrant liability decreased by $646,000 since they were issued on July 20, 2016. There were no warrants outstanding that required to be measured at fair value in any periods prior to the third quarter of 2016.

Income Tax Benefit (Expense), net

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 65,000	$ (3,000)	$ 68,000	N/M

Our income tax benefit for the three months ended September 30, 2016 resulted primarily from a research and development tax credit in Australia. We have substantially reduced research and development expenditures in Australia, so future research and development tax credits refunds, if any, are expected to decrease.

Table of Contents

We generate minimal amounts of income tax expense in connection with activities incurred by our Irish subsidiary.

Comparison of Nine Months Ended September 30, 2016 to Nine Months Ended September 30, 2015

Revenue

Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 543,000	$ 59,000	$ 484,000	820%

On August 5, 2016, we completed the acquisition of the Aquadex product line from a subsidiary of Baxter International Inc. The Aquadex product line generated revenues of $484,000 from the date of acquisition through September 30, 2016. Revenue is generated mainly from the sale of disposable blood filters and catheters used in conjunction with our Aquadex consoles. We estimate that there are over 500 installed Aquadex consoles around the United States. We had no commercial sales prior to the acquisition of the Aquadex product line.

On March 3, 2016, we announced that we were no longer enrolling patients in the Company's OPTIONS HF or COUNTER HF clinical studies. Prior to this announcement, all of our revenue was generated by sales of the C-Pulse System to hospitals and clinics in conjunction with our U.S. clinical study. The C-Pulse System was not approved for commercial sale, however, the FDA had 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. One C-Pulse system was implanted for which we recognized $59,000 in revenue in each of the nine-month periods ended September 30, 2016 and 2015. Since we terminated enrollment in our OPTIONS HF and COUNTER HF clinical trials, we do not expect to generate revenue from our clinical trials in the foreseeable future.

On September 29, 2016, we announced a strategic refocus of our near term strategy to fully focus the Company's resources on our recently acquired Aquadex system. As such, we expect our Aquadex revenue to grow significantly in the upcoming quarters as we drive increased utilization of disposable sales within our installed base.

Cost of Sales

Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 187,000	$ —	$ 187,000	N/M

In connection with the acquisition of the Aquadex product line, we entered into a manufacturing and supply agreement with the Seller. Cost of sales reflects the agreed-upon price paid to Seller for the manufacturing of the disposables and consoles. This acquisition closed on August 5, 2016. Prior to that date, we did not have commercial sales or related product costs.

Selling, General and Administrative Expense

Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 5,444,000	$ 6,259,000	$ (815,000)	(13.0)%

The decrease in selling, general and administrative expense relates primarily to efficiencies achieved as a result of consolidation and streamlining activities in our administrative functions, and to lower stock compensation costs. These efficiencies were partially offset by $0.9 million of transaction fees (accounting, audit, valuation and legal fees) incurred in connection with the acquisition of the Aquadex product line. In addition, subsequent to the date of the Aquadex acquisition, we incurred commercial expenses in connection with the marketing and sale of the Aquadex product line. As we continue to ramp up our sales organization we expect that our selling expenses will continue to increase in future quarters and that general and administrative expenses will continue to decrease.

Research and Development Expense

Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 7,511,000	$ 13,404,000	$ (5,893,000)	(44.0)%

The decrease in research and development expense for the nine months ended September 30, 2016 as compared to 2015

Table of Contents

resulted primarily from our decision to stop enrollment in the COUNTER HF and OPTIONS HF studies, which was announced on March 3, 2016. Further, on September 29, 2016, we announced a strategic refocus of our near term strategy that includes pausing clinical evaluations of the neuromodulation technology to fully focus the Company's resources on our recently acquired Aquadex system. As a result, we expect that our research and development expenditures will continue to decrease in future quarters.

Interest Expense

Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 504,000	$ 498,000	$ 6,000	1.2%

We incurred interest expense in connection with our prior debt facility with Silicon Valley Bank. On August 4, 2016, we repaid all amounts outstanding under this loan facility, totaling $5.5 million.

Loss on Early Retirement of Long-Term Debt

Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 500,000	$ —	$ 500,000	N/M

On August 4, 2016, we repaid all amounts outstanding under our prior term loan with Silicon Valley Bank, totaling $5.5 million. In connection with the repayment of this debt, we incurred a $0.5 million loss, including the accelerated write-off of unamortized warrants and debt issuance costs.

Change in Fair Value of Warrant Liability

Three Months Ended September 30, 2016	Three Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 646,000	$ —	$ 646,000	N/M

The value of the common stock warrant liability decreased by $646,000 since they were issued on July 20, 2016. There were no warrants outstanding that required to be measured at fair value during the three months ended September 30, 2015.

Income Tax Benefit, net

Nine Months Ended September 30, 2016	Nine Months Ended September 30, 2015	Increase (Decrease)	% Change
$ 64,000	$ 124,000	$ (60,000)	(48.4)%

Our income tax benefit for the nine months ended September 30, 2016 and 2015 resulted mainly from research and development tax credits in Australia. We have substantially reduced research and development expenditures in Australia, so future research and development tax credits refunds, if any, are expected to decrease.

We generate minimal amounts of income tax expense in connection with activities incurred by our Irish subsidiary.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations primarily through a series of equity and debt issuances. On July 26, 2016, we completed an equity financing of Series B Convertible Preferred Stock and warrants for gross cash proceeds of approximately $3.5 million. On August 4, 2016, we entered into a new loan agreement with Silicon Valley Bank for proceeds of up to $5.0 million, advances under which loan agreement are available to us until November 30, 2016, subject to various conditions precedent, including compliance with liquidity covenants that we do not currently meet. On November 3, 2016, we completed an equity financing with an institutional investor of shares of convertible preferred stock and warrants for gross proceeds of $3.6 million. See "—Recent Developments" above for a discussion of this equity financing. During the nine months ended September 30, 2015, we entered into a loan agreement with Silicon Valley Bank for proceeds of up to $10.0 million, and issued common shares for net cash proceeds of $7.1 million under our sales agreement with Cowen and Company LLC. As of September 30, 2016 and December 31, 2015, cash and cash equivalents were $0.8 million and $23.1 million, respectively.

We expect to seek additional financing during 2017 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 $13.6 million and $18.2 million for the nine months ended September 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 $4.1 million and $0.2 million for the nine months ended September 30, 2016 and 2015, respectively. In 2016, we paid $4.0 million for the acquisition of the Aquadex product line. Other uses of cash relate to the purchase of laboratory and office equipment.

Cash Flows from Financing Activities

Net cash (used in)/provided by financing activities was $(4.6) million and $15.1 million for the nine months ended September 30, 2016 and 2015, respectively. Net cash used during the nine month period ended September 30, 2016 is attributable to repayments of the principal amounts outstanding on our debt facility with Silicon Valley Bank, offset by net proceeds from the issuance of preferred stock in July 2016. Net cash provided by financing activities in the nine month period ended September 30, 2015 was attributable to debt borrowings and proceeds from sales of our common stock.

Capital Resource Requirements

As of September 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.

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 for the Aquadex product line with 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.

In connection with the acquisition of the Aquadex product line, the Company entered into a manufacturing and supply agreement with the Seller that will expire within a period not to exceed 18 months from the close of the transaction. Upon termination of this agreement, the Company has an obligation to purchase the remaining Aquadex inventory. We estimate that this amount will not exceed $2.5 million.

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 businesses, 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.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

As of September 30, 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 September 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 September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. On August 5, 2016, the Company completed the acquisition of certain assets used in the production and sale of the Aquadex product line from an indirect subsidiary of Baxter International Inc. We are in the process of integrating Aquadex's operations into the Company. We are in the process of implementing our internal control structure over the acquired operations, and we expect to complete this effort during fiscal 2017.

Table of Contents

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 Reports on Form 10-Q for the quarters ended March 31, 2016 and June 30, 2016.

Nasdaq may delist our common stock from its exchange which could limit your ability to make transactions in our securities and subject us to additional trading restrictions.

On September 21, 2016, we received notice from the Listing Qualifications Staff (the "Staff") of The NASDAQ Stock Market LLC ("Nasdaq") indicating that the Staff had determined to delist our securities from The Nasdaq Capital Market due to our then continued non-compliance with the minimum bid price requirement. We timely requested a hearing before the Nasdaq Hearings Panel (the "Panel") which is currently expected to take place in November of 2016.

At the hearing, the Company will present its plan to evidence compliance with all applicable criteria for continued listing on The Nasdaq Capital Market, including the Company's plan to effect a reverse stock split for purposes of complying with the minimum bid price requirements, and request an extension within which to do so. There can be no assurance that the Panel will determine to continue the Company's listing or that the Company will be able to evidence compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

In order to continue listing our securities on Nasdaq, we must maintain certain financial, distribution and stock price levels, including a minimum amount in shareholders' equity (generally $2,500,000). We cannot assure you that we will be able to meet these listing requirements.

If Nasdaq delists our common stock from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- reduced liquidity with respect to our securities;

- a determination that our shares are a “penny stock,” which will require brokers trading in our securities to adhere to more
- stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for our Company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

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

We expect to seek additional financing during 2017. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate and could adversely affect our ability to raise additional capital. Additional financing may not be available when we need it or may not be available on terms that are favorable to us. If adequate funds are not available to us on a timely basis or at all, we would likely be required to significantly reduce our operations.

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

Not applicable.

Table of Contents

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.

Table of Contents

SIGNATURES

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

Sunshine Heart, Inc.

Date: November 14, 2016

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

Date: November 14, 2016

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

Table of Contents

Exhibit Index
Sunshine Heart, Inc.
Form 10-Q for the Quarterly Period Ended September 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		
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.1		
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.2		
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock.	8-K	001-35312	November 3, 2016	3.3		
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		

Table of Contents

Exhibit Number	Exhibit Description	Incorporated By Reference			Exhibit Number	Filed Herewith	Furnished Herewith
		Form	File Number	Date of First Filing			
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	10.2		
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X	
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X	
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002						X

32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		X
101.INS	XBRL Instance Document	X	
101.SCH	XBRL Taxonomy Extension Schema Document	X	
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X	
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	X	
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X	
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X	

*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 September 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: November 14, 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 September 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: November 14, 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 September 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: November 14, 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 September 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: November 14, 2016

/s/ Claudia Drayton
Claudia Drayton
Chief Financial Officer