

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 8-K**

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

Date of Report (Date of earliest event reported): **November 8, 2016**

**SUNSHINE HEART, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation)

**001-35312**

(Commission File Number)

**68-0533453**

(IRS Employer  
Identification No.)

**12988 Valley View Road**

**Eden Prairie, Minnesota 55344**

(Address of principal executive offices) (Zip Code)

**(952) 345-4200**

(Registrant's telephone number, including area code)

**Not Applicable**

(Former name or former address, if changed since last report)

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

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

**Item 2.02 Results of Operations and Financial Condition.**

On November 8, 2016, Sunshine Heart, Inc. (the "**Company**") issued a press release reporting its financial results for the third quarter ended September 30, 2016. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.**

In accordance with General Instruction B.2 of Form 8-K, the information included in this Current Report on Form 8-K (including Exhibit 99.1) is furnished pursuant to Items 2.02 and 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Current Report on Form 8-K will not be deemed an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

**(d)**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 8, 2016, reporting the Company's financial results for the third quarter ended September 30, 2016.

**SIGNATURES**

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

Date: November 8, 2016

**SUNSHINE HEART, INC.**

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

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**EXHIBIT INDEX**

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## Sunshine Heart Announces Third Quarter 2016 Financial Results and Provides Company Update

Eden Prairie, MN: November 8, 2016: (GLOBE NEWSWIRE) Sunshine Heart, Inc. (NASDAQ: SSH) announced today its financial results for the third quarter ended September 30, 2016. The Company will host a conference call and webcast at 9:00 AM ET today to discuss its financial results and provide an update on the Company's recently announced strategic realignment, including the acquisition of the Aquadex FlexFlow® business.

To access the live webcast, please visit the Investors page of the Sunshine Heart website at [ir.sunshineheart.com](http://ir.sunshineheart.com). Alternatively, you may access the live conference call by dialing (877) 303-9826 (U.S.) or (224) 357-2194 (international) and using conference ID 4610509. An audio archive of the webcast and a transcript of the call will be available following the call at [ir.sunshineheart.com](http://ir.sunshineheart.com).

### Business Highlights

- As part of strategic realignment, the Company continues to execute near-term strategy to drive growth with the recently acquired Aquadex FlexFlow business.
- Direct field organization providing service to the top 50 hospital accounts that have purchased Aquadex over the past 12 months.
- Pursuing post-market clinical data collection to strengthen evidence for using Aquadex in an outpatient setting.
- In July, completed a registered direct offering of convertible preferred shares and a private placement of stock warrants for total gross proceeds of approximately \$3.5 million. In August, the company repaid all outstanding borrowings to Silicon Valley Bank of \$6.0 million and completed the Aquadex acquisition for \$4.0 million in cash and 1 million shares of common stock.
- In October, completed a registered direct offering and a private placement of convertible preferred shares and stock warrants for total gross proceeds of approximately \$3.6 million.
- Reduced operating expenses in Q3, down over 30% from a year ago; Q4 operating expenses expected to decrease over 50% from a year ago.
- NASDAQ hearing scheduled for mid-November to petition for a further extension of time in order to meet listing requirements.

“It was a challenging quarter and a difficult decision to put our neuromodulation strategy on pause due solely to financial constraints,” said John Erb, Chairman and CEO. “While we continue to believe in the long term potential of the neuromodulation opportunity, focusing all of our efforts on growing our Aquadex business will be critical to bolstering our financial strength and will allow Sunshine Heart to strengthen its presence in the heart failure market.”

## FINANCIALS

### 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
<b>Net sales</b>	\$ 543	\$ —	\$ 543	\$ 59
<b>Costs and Expenses:</b>				
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
<b>Total costs and expenses</b>	<b>4,605</b>	<b>6,273</b>	<b>13,142</b>	<b>19,663</b>
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	—
<b>Total other income (expense)</b>	<b>80</b>	<b>(282)</b>	<b>(356)</b>	<b>(499)</b>
<b>Loss before income taxes</b>	<b>(3,982)</b>	<b>(6,555)</b>	<b>(12,955)</b>	<b>(20,103)</b>

Income tax benefit (expense), net	65	(3)	64	124
<b>Net loss</b>	<u>\$ (3,917)</u>	<u>\$ (6,558)</u>	<u>\$ (12,891)</u>	<u>\$ (19,979)</u>
<b>Basic and diluted loss per share</b>	<u>\$ (0.27)</u>	<u>\$ (0.36)</u>	<u>\$ (0.76)</u>	<u>\$ (1.11)</u>
Weighted average shares outstanding – basic and diluted	19,974	18,330	18,910	18,045
<b>Other comprehensive income:</b>				
Foreign currency translation adjustments	\$ (6)	\$ (16)	\$ (12)	\$ (22)
<b>Total comprehensive loss</b>	<u>\$ (3,923)</u>	<u>\$ (6,574)</u>	<u>\$ (12,903)</u>	<u>\$ (20,001)</u>

**SUNSHINE HEART, INC. AND SUBSIDIARIES**

*Condensed Consolidated Balance Sheets*

(In thousands, except share and per share amounts)

	September 30, 2016 <u>(unaudited)</u>	December 31, 2015
<b>ASSETS</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 792	\$ 23,113
Accounts receivable	111	—
Inventory	202	—
Other current assets	223	479
<b>Total current assets</b>	<u>1,328</u>	<u>23,592</u>
Property, plant and equipment, net	597	535
Intangible assets, net	4,399	—
Goodwill	268	—
Other assets	29	323
<b>TOTAL ASSETS</b>	<u>\$ 6,621</u>	<u>\$ 24,450</u>

<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities</b>		
Current portion of long-term debt	\$ —	\$ 3,798
Accounts payable and accrued expenses	2,169	2,832
Accrued compensation	629	1,368
<b>Total current liabilities</b>	<u>2,798</u>	<u>7,998</u>
Long-term debt, net of discount and financing fees	—	3,881
Common stock warrant liability	1,237	—
Other liabilities	126	400
<b>Total liabilities</b>	<u>4,161</u>	<u>12,279</u>
Commitments and contingencies	—	—
<b>Stockholders' equity</b>		
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)
<b>Total stockholders' equity</b>	<u>2,460</u>	<u>12,171</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 6,621</u>	<u>\$ 24,450</u>

**SUNSHINE HEART, INC. AND SUBSIDIARIES**

*Condensed Consolidated Statements of Cash Flows*

**(Unaudited)**

(in thousands)

	Nine months ended September 30,	
	2016	2015
<b>Operating Activities:</b>		
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
<b>Net cash used in operations</b>	<b>(13,563)</b>	<b>(18,232)</b>
<b>Investing Activities:</b>		
Purchases of property and equipment	(110)	(175)
Acquisition of Aquadex product line	(4,000)	—
<b>Net cash used in investing activities</b>	<b>(4,110)</b>	<b>(175)</b>

<b>Financing Activities:</b>		
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
<b>Net cash (used in) provided by financing activities</b>	<b>(4,638)</b>	<b>15,055</b>
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
<b>Cash and cash equivalents - end of period</b>	<b>\$ 792</b>	<b>\$ 27,899</b>

<b>Supplement schedule of non-cash activities</b>			
Warrants issued in connection with debt financing	\$	—	\$ 355
Common stock issued for business acquisition	\$	950	\$ —

<b>Supplemental cash flow information</b>			
Cash paid for interest	\$	840	\$ 247
Cash paid for income taxes	\$	47	\$ —

## About Sunshine Heart

Sunshine Heart, Inc. (Nasdaq:SSH) is an early-stage medical device company focused on developing a product portfolio to treat moderate to severe heart failure and related conditions. The Company's commercial product, the Aquadex system, 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. Our objective is to improve the quality of life for heart failure patients and slow the disease progression. 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.

## Forward-Looking Statements

Certain statements in this release are forward-looking statements that are based on management's beliefs, assumptions, 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 ability to execute on our recently announced strategic realignment, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses. 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 therapy, the possibility we may be unable to raise the funds necessary for the development and commercialization of our therapy and other risks and uncertainties described in our filings with the SEC. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

For further information, please contact:

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Claudia Napal Drayton  
Chief Financial Officer  
Sunshine Heart, Inc.  
T: +1-952-345-4205

Investor Relations  
Sunshine Heart Inc.  
[ir@sunshineheart.com](mailto:ir@sunshineheart.com)

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