

**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): **August 9, 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 August 9, 2016, Sunshine Heart, Inc. (the "**Company**") issued a press release reporting its financial results for the second quarter ended June 30, 2016. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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.

Item 9.01 Financial Statements and Exhibits.

The attached exhibit shall be considered filed for purposes of Section 18 of the Exchange Act, and shall be deemed incorporated by reference in the Registration Statements.

(d)

Exhibit No.	Description
99.1	Press Release, dated August 9, 2016, reporting the Company's financial results for the second quarter ended June 30, 2016.

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: August 9, 2016

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated August 9, 2016, reporting the Company's financial results for the second quarter ended June 30, 2016.

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Sunshine Heart Announces Second Quarter 2016 Financial Results and Provides Company Update

Eden Prairie, MN: August 9, 2016: (GLOBE NEWSWIRE) Sunshine Heart, Inc. (NASDAQ: SSH) announced today its financial results for the second quarter ended June 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 clinical and product development strategy and its recent acquisition of the Aquadex FlexFlow® product line.

To access the live webcast, please visit the Investors page of the Sunshine Heart website at 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 59169612. An audio archive of the webcast and a transcript of the call will be available following the call at ir.sunshineheart.com.

Business Highlights

- The company is pursuing an optimal therapeutic strategy focused on neuromodulation, based on insights from counterpulsation.
- New direction provides significant benefits, including: 1) a more cost effective way to develop a fully-implantable system; 2) a faster path to commercialization; and 3) access to a broader segment of the heart failure market and potentially other indications.
- Near term clinical activities include: 1) a first-in-man acute study to demonstrate a hemodynamic response using a proprietary neuromodulation approach, and 2) a chronic study utilizing a proprietary fully implantable system that establishes the effect of the system and safety profile. Patient enrollment for the acute study is expected to begin and end in Q4 2016, and for the chronic study is expected to begin in 2017.
- Recent acquisition of the Aquadex FlexFlow product line from an indirect subsidiary of Baxter International; the transaction is highly strategic and financially compelling, complementing the company's focus on treating heart failure patients; the transaction is expected to be accretive in its first year and to have an annualized revenue run-rate of \$5 million by the end of 2016.
- Meaningful progress on reducing operating expenses in Q2; down 35% from a year ago.
- Completed a registered direct offering of convertible preferred stock and a private placement of warrants for gross proceeds of approximately \$3.5 million in July.
- Ended Q2 with \$12.0 million in cash, \$6.1 million in borrowings. In August, repaid all outstanding borrowings and entered into a new credit facility with Silicon Valley Bank. Management expects to raise additional capital in 2016.

"After completing my first full quarter as CEO, I continue to be excited and optimistic about the significant opportunities ahead of us at Sunshine Heart," said John Erb, Chairman and CEO. "As you can see, we are not sitting still. There are a lot of good things happening at the company and the entire team is focused on executing our strategy. We are excited about the direction we are heading and we are confident that we've identified a better path to deliver a meaningful therapy for heart failure patients."

FINANCIALS

SUNSHINE HEART, INC. AND SUBSIDIARIES

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(In thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Net sales	\$ —	\$ —	\$ —	\$ 59
Operating expenses				
Selling, general and administrative	1,412	2,348	2,761	4,534
Research and development	2,570	3,991	5,776	8,856
Total operating expenses	3,982	6,339	8,537	13,390
Loss from operations	(3,982)	(6,339)	(8,537)	(13,331)
Interest expense	207	155	436	218
Other income (expense), net	(1)	4	—	1
Loss before income taxes	(4,190)	(6,490)	(8,973)	(13,548)
Income tax benefit (expense), net	2	132	(1)	127
Net loss	\$ (4,188)	\$ (6,358)	\$ (8,974)	\$ (13,421)
Basic and diluted loss per share	\$ (0.23)	\$ (0.35)	\$ (0.49)	\$ (0.75)

Weighted average shares outstanding — basic and diluted	18,403	18,297	18,378	17,903
Other comprehensive income:				
Foreign currency translation adjustments	\$ (2)	\$ (16)	\$ (6)	\$ (6)
Total comprehensive loss	\$ (4,190)	\$ (6,374)	\$ (8,980)	\$ (13,427)

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

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

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

	Six months ended June 30,	
	2016	2015
Operating activities:		
Net loss	\$ (8,974)	\$ (13,421)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	152	158
Stock-based compensation expense, net	499	1,326
Amortization of debt discount and financing fees	162	51
Changes in operating assets and liabilities:		
Accounts receivable	—	59
Other current assets	197	(407)
Other assets	25	(129)
Accounts payable and accrued expenses	(1,197)	(446)
Net cash used in operations	(9,136)	(12,809)
Investing activities:		
Purchases of property and equipment	(29)	(95)
Net cash used in investing activities	(29)	(95)
Financing activities:		

Net proceeds from the sale of common stock	—	7,055
Proceeds from (repayments on) borrowings on long-term debt	(1,895)	8,000
Net cash (used in) provided by financing activities	(1,895)	15,055
Effect of exchange rate changes on cash	(4)	(25)
Net (decrease) increase in cash and cash equivalents	(11,064)	2,126
Cash and cash equivalents - beginning of period	23,113	31,293
Cash and cash equivalents - end of period	\$ 12,049	\$ 33,419

USE OF NON-GAAP MEASURES

Management uses non-GAAP measures to establish operational goals and cash flows, and believes that non-GAAP measures may assist investors in analyzing underlying trends in the Company's business over time. Investors should consider these non-GAAP measures in addition to, and not as a substitute for or as superior to, financial reporting measures prepared in accordance with GAAP. In this press release, the Company has reported non-GAAP measures of operating expenses, net loss and loss per share, which exclude equity compensation expenses related to stock options, warrants, restricted stock units and common stock awards, and reconcile to GAAP operating expense, GAAP net loss and GAAP loss per share as follows:

SUNSHINE HEART, INC. AND SUBSIDIARIES
Reconciliation of non-GAAP amounts to GAAP
(Unaudited)
(In thousands, except per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
Operating Expenses				
GAAP operating expenses	\$ 3,982	\$ 6,339	\$ 8,537	\$ 13,390
Equity compensation expense	(286)	(690)	(534)	(1,557)
Non-GAAP operating expenses	\$ 3,696	\$ 5,649	\$ 8,003	\$ 11,833
Net Loss				
GAAP net loss	\$ (4,188)	\$ (6,358)	\$ (8,974)	\$ (13,421)
Equity compensation expense	286	690	534	1,557
Non-GAAP net loss	\$ (3,902)	\$ (5,668)	\$ (8,440)	\$ (11,864)
Loss Per Share				
GAAP basic and diluted loss per share	\$ (0.23)	\$ (0.35)	\$ (0.49)	\$ (0.75)
Non-GAAP basic and diluted loss per share	\$ (0.21)	\$ (0.31)	\$ (0.46)	\$ (0.66)
Weighted average shares outstanding — basic and diluted	18,403	18,297	18,378	17,903

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. Our objective is to improve the quality of life for heart failure patients and halt 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, clinical and pre-clinical study designs and activities, expected timing for initiation, enrollment and completion of clinical trials, research and development activities, ultimate clinical outcomes and benefits of our products to patients, design and development of future studies, site activations, patient enrollment in studies, timing of regulatory filings and approvals, regulatory acceptance of our filings, our expectations with respect to product development and commercialization efforts, 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 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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