

**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): **May 3, 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 May 3, 2016, Sunshine Heart, Inc. (the "**Company**") issued a press release reporting its financial results for the first quarter ended March 31, 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 May 3, 2016, reporting the Company's financial results for the first quarter ended March 31, 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: May 3, 2016

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

3

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 3, 2016, reporting the Company's financial results for the first quarter ended March 31, 2016.

4



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

Eden Prairie, MN: May 3, 2016: (GLOBE NEWSWIRE) Sunshine Heart, Inc. (NASDAQ: SSH) announced today its financial results and provided a company update for the first quarter ended March 31, 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 business strategy.

To access the live webcast, please visit the Investors page of the Sunshine Heart website at <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 99913745. An audio archive of the webcast and a transcript of the call will be available following the call at <http://ir.sunshineheart.com>.

Business Update:

- Company is making solid progress on pursuing a more optimal clinical strategy to expedite the approval of C-Pulse therapy in the U.S.
- Advancing the development of a fully implantable system by conducting an acute first-in-man study in 2016 that measures neuromodulation effects
- Expect to submit clinical protocol for a short-term study of CP-1 to the FDA by the end of Q3; estimate protocol approval and commencement of patient enrollment in the U.S. by early 2017
- Data from OPTIONS-HF study showing improvements in cardiac remodeling, functional capacity, and quality of life, to be presented at the European society of Cardiology Heart Failure conference May 21st, 2016 in Florence, Italy.
- Meaningful progress on reducing operating cash-burn in in Q1; down 35% from Q1 a year ago.
- Ended Q1 with \$16.5 million in cash, \$7.1 million in borrowings; management continues to expect to raise capital in 2016

“After my first two months as CEO, I continue to be excited by the significant opportunity in front us at Sunshine Heart,” said John Erb, Chairman and CEO. “The entire organization is focused on pursuing a business and clinical strategy that will allow us to realize the full potential of C-Pulse therapy in helping heart failure patients. We have learned a great deal about the treatment of heart failure patients and we are leveraging that knowledge. In that regard, I am pleased with the clinical progress we are making. We intend to submit our protocol for a short-term clinical study to the FDA by the end of the third quarter. This will allow us to collect additional clinical evidence to support the development of our fully implantable system.”

FINANCIALS

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

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

SUNSHINE HEART, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Dollars in thousands, except share amounts)

	March 31, 2016 (unaudited)	December 31, 2015
ASSETS		

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

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

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

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	
	March 31,	
	2016	2015
Operating Expenses		
GAAP operating expenses	\$ 4,555	\$ 7,051
Equity compensation costs	(247)	(867)
Non-GAAP operating expenses	\$ 4,308	\$ 6,184
Net Loss		
GAAP net loss	\$ (4,786)	\$ (7,063)
Equity compensation costs	247	867
Non-GAAP net loss	\$ (4,539)	\$ (6,196)
Loss Per Share		
GAAP basic and diluted loss per share	\$ (0.26)	\$ (0.40)
Non-GAAP basic and diluted loss per share	\$ (0.25)	\$ (0.35)
Weighted average shares outstanding — basic and diluted	18,353	17,509

About the C-Pulse® Heart Assist System

The C-Pulse Heart Assist System, or C-Pulse System, an investigational device in the United States, Canada and countries that do not recognize the CE mark approval, utilizes the scientific principles of intra-aortic balloon counterpulsation applied in an extra-aortic approach to assist the left ventricle by reducing the workload required to pump blood throughout the body, while increasing blood flow to the coronary arteries. Combined, these potential benefits may help sustain the patient's current condition or, in some cases, reverse the heart failure process, thereby potentially preventing the need for later-stage heart failure devices, such as left ventricular assist devices (LVADs), artificial hearts or transplants. It may also provide relief from the symptoms of Class III and ambulatory Class IV heart failure and improve quality of life and cardiac function. Based on the results from our feasibility study, we also believe that some patients treated with our C-Pulse System may be able to stop using the device due to sustained improvement in their conditions as a result of the therapy.

Caution: Investigational device, limited by Federal (or United States) Law to Investigational use.

About Sunshine® Heart

Sunshine Heart, Inc. (Nasdaq:SSH) is an early-stage medical device company focused on developing, manufacturing and commercializing the C-Pulse System for moderate to severe heart failure patients. In July 2012, Sunshine Heart received CE Mark approval for its C-Pulse System in Europe. After terminating enrollment in its US pivotal study, COUNTER HF, Sunshine Heart will be finalizing a short term clinical strategy to begin a study of the C-Pulse Heart Assist System in the United States. A long-term path is being developed in parallel that will focus on accelerating the development of a fully implantable system, which will be critical to driving the adoption of C-Pulse therapy. 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, 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, and potentially competitive product offerings. The risk factors described in our filings with the SEC could cause actual events to adversely differ from the expectations indicated in these forward-looking statements. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. Sunshine Heart does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Sunshine Heart may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the possibility we may be unable to raise the funds necessary for the development and commercialization of the C-Pulse System 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:

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

Investor Relations
Sunshine Heart Inc.
ir@sunshineheart.com

