

**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): **March 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 No.)

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 (see General Instruction A.2. below):

- 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 March 3, 2016, Sunshine Heart, Inc. (the "**Company**") issued a press release reporting its financial results for the fourth quarter and year ended December 31, 2015. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On March 3, 2016, the Company issued a press release announcing changes to the Company's strategic direction. 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.

(d)

Exhibit No.	Description
99.1	Press Release, dated March 3, 2016, reporting the Company's financial results for the fourth quarter and year ended December 31, 2015 and announcing changes to the Company's strategic direction.

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: March 3, 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 Fourth Quarter and Twelve Months 2015 Financial Results and Provides Corporate Update

Eden Prairie, MN: March 3, 2016: (GLOBE NEWSWIRE) Sunshine Heart, Inc. (NASDAQ: SSH) announced today its financial results and provided a corporate update for the fourth quarter and year ended December 31, 2015. 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 corporate 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 59330017. An audio archive of the webcast will be available following the call at <http://ir.sunshineheart.com>.

Business Update:

- Newly announced CEO, John Erb, announced strategic changes
- Pursuing a more optimal clinical strategy focused on expediting U.S. approval of C-Pulse therapy
- Announcing the stopping of enrollment in the COUNTER-HF clinical trial and OPTIONS-HF post-market study in order to re-focus resources on revised strategy
- Recently published data from the OPTIONS HF Study shows clinically meaningful improvement in mean left ventricular ejection fraction along with strong trends on improvement of functional capacity. These results support belief that the C-Pulse mechanism of action may be both hemodynamic and neuromodulatory
- Ended the year with \$23.1 million in cash, \$8.0 million in total debt and focused on reducing operating cash-burn in 2016

"I am excited at the opportunity to lead Sunshine Heart, especially at this critical time for the company," Mr. Erb said. "I am also excited about executing a strategy that realizes the full potential of C-Pulse therapy. In that regard, today we are announcing the need to change our previous clinical and product development strategies. These changes are necessary in order for us to focus our resources on driving a strategy that allows us to capture the sizeable opportunity to serve heart failure patients. The company has learned a great deal so far and we are going to leverage that knowledge. I am confident that we have the talent and know-how necessary to develop and execute a much more effective and efficient strategy."

Financials:

No revenue was recorded during the fourth quarter of 2015 as there were no implants performed during this period that qualified for reimbursement. During the fourth quarter of 2014 we recorded \$177,000 in revenue. We have obtained reimbursement for some, but not all implants, since certain insurance companies and governmental institutions have a non-coverage policy for experimental or investigational procedures.

Product costs incurred for our clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred.

Operating expenses in the fourth quarter of 2015 were \$6.4 million, compared to \$6.8 million in the fourth quarter of 2014. Operating expenses for the quarter reflect lower spending resulting from the

consolidation of certain management positions.

Net loss in the fourth quarter of 2015 was \$6.6 million, or \$0.36 per share, compared to \$6.7 million, or \$0.40 per share, in the fourth quarter of 2014.

We had \$23.1 million in cash on December 31, 2015 and \$8.0 million in short and long term borrowings.

SUNSHINE HEART, INC. AND SUBSIDIARIES Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(In thousands, except per share amounts)

	Three months ended December 31,		Twelve months ended December 31,	
	2015	2014	2015	2014
Net sales	\$ —	\$ 177	\$ 59	\$ 295
Operating expenses				
Selling, general and administrative	2,086	2,243	8,345	9,208
Research and development	4,268	4,590	17,672	16,874
Total operating expenses	6,354	6,833	26,017	26,082
Loss from operations	(6,354)	(6,656)	(25,958)	(25,787)
Other expense, net	(250)	(71)	(749)	(49)
Loss before income taxes	(6,604)	(6,727)	(26,707)	(25,836)
Income tax (benefit) expense	—	16	(124)	(249)
Net loss	\$ (6,604)	\$ (6,743)	\$ (26,583)	\$ (25,587)
Basic and diluted loss per share	\$ (0.36)	\$ (0.40)	\$ (1.47)	\$ (1.51)
Weighted average shares outstanding — basic and diluted	18,341	16,954	18,119	16,899

Other comprehensive income:				
Foreign currency translation adjustments	\$	(4)	\$	70
Total comprehensive loss	\$	(6,608)	\$	(6,673)
			\$	(26,609)
				\$
				(25,522)

SUNSHINE HEART, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Unaudited)

(Dollars in thousands, except share and per share amounts)

	December 31, 2015	December 31, 2014
ASSETS		
Current assets		
Cash and cash equivalents	\$ 23,113	\$ 31,293
Accounts receivable	—	59
Other current assets	539	360
Total current assets	23,652	31,712
Property, plant and equipment, net	535	661
Other assets	383	—
TOTAL ASSETS	\$ 24,570	\$ 32,373
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Current portion of long-term debt	\$ 3,858	\$ —
Accounts payable and accrued expenses	2,832	2,079
Accrued salaries, wages, and other compensation	1,368	1,079
Total current liabilities	8,058	3,158
Long-term debt, net of discount	3,941	—
Other liabilities	400	—
Total liabilities	12,399	3,158
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2015 and December 31, 2014, par value \$0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Preferred stock as of December 31, 2015 and December 31, 2014, par value \$0.0001 per share; authorized 39,970,000 shares, none outstanding	—	—
Common stock as of December 31, 2015 and December 31, 2014, par value \$0.0001 per share; authorized 100,000,000 shares; issued and outstanding 18,344,478 and 16,982,642 shares, respectively	2	2
Additional paid-in capital	164,105	154,540
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,246	1,272
Accumulated deficit	(153,182)	(126,599)
Total stockholders' equity	12,171	29,215
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 24,570	\$ 32,373

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

(In thousands)

	Twelve months ended December 31,	
	2015	2014
Operating Activities:		
Net loss	\$ (26,583)	\$ (25,587)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	325	277
Stock-based compensation expense, net	2,154	2,678
Amortization of debt discount and financing fees	263	—
Changes in operating assets and liabilities		
Accounts receivable	59	—
Other current assets	(181)	—
Other assets	(92)	(5)
Accounts payable and accrued expenses	1,066	(7)
Net cash used in operations	(22,989)	(22,644)
Investing Activities:		
Purchases of property and equipment	(199)	(351)
Net cash used in investing activities	(199)	(351)
Financing Activities:		
Net proceeds from the sale of common stock	7,055	89

Proceeds from borrowings on long-term debt	8,000	—
Net cash provided by financing activities	15,055	89
Effect of exchange rate changes on cash	(47)	63
Net decrease in cash and cash equivalents	(8,180)	(22,843)
Cash and cash equivalents - beginning of period	31,293	54,136
Cash and cash equivalents - end of period	\$ 23,113	\$ 31,293

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 December 31,		Twelve months ended December 31,	
	2015	2014	2015	2014
Operating Expenses				
GAAP operating expenses	\$ 6,354	\$ 6,833	\$ 26,017	\$ 26,082
Equity compensation expense	(343)	(897)	(2,437)	(3,085)
Non-GAAP operating expenses	\$ 6,011	\$ 5,936	\$ 23,580	\$ 22,997
Net Loss				
GAAP net loss	\$ (6,604)	\$ (6,743)	\$ (26,583)	\$ (25,587)
Equity compensation expense	343	897	2,437	3,085
Non-GAAP net loss	\$ (6,261)	\$ (5,846)	\$ (24,146)	\$ (22,502)
Loss Per Share				
GAAP basic and diluted loss per share	\$ (0.36)	\$ (0.40)	\$ (1.47)	\$ (1.51)
Non-GAAP basic and diluted loss per share	\$ (0.34)	\$ (0.34)	\$ (1.33)	\$ (1.33)
Weighted average shares outstanding — basic and diluted	18,341	16,954	18,119	16,899

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 counter-pulsation 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 treatment of Class III and ambulatory Class IV heart failure. Sunshine Heart has completed an approved U.S. Food and Drug Administration (FDA) feasibility clinical study of the C-Pulse System and presented the results in November 2011. In March 2012, the FDA notified the Company that it could move forward with an investigational device exemption (IDE) application. Sunshine Heart received unconditional approval from the FDA in November 2012 to initiate its pivotal study. In July 2012, Sunshine Heart received CE Mark approval for

its C-Pulse System in Europe. 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:

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