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 17, 2015**

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35312**	**68-0533453**
(State or other jurisdiction of incorporation)	(Commission File No.)	(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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 17, 2015, Sunshine Heart, Inc. (the ***"Company"***) issued a press release reporting its financial results for the fourth quarter and year ended December 31, 2014. The press release is furnished as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	**Description**
99.1	Press Release, dated March 17, 2015, reporting the Company's financial results for the fourth quarter and year ended December 31, 2014.

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 17, 2015

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON
Name: Claudia Drayton

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated March 17, 2015, reporting the Company's financial results for the fourth quarter and year ended December 31, 2014.

Sunshine Heart Announces Fourth Quarter and Twelve Months 2014 Financial Results and Provides Corporate Update

Eden Prairie, MN: March 17, 2015: Sunshine Heart, Inc. (NASDAQ:SSH) today announced its financial results and provided a corporate update for the fourth quarter and year ended December 31, 2014. The Company will host a conference call and webcast at 9:00 AM EST today to discuss its financial results and provide an update on its ongoing clinical studies.

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 96024417. An audio archive of the webcast will be available following the call at http://ir.sunshineheart.com.

"This past quarter has been an important period of growth across clinical and corporate fronts. We continued to make great overall strides in advancing the COUNTER HF and OPTIONS HF trials, bolstered our management team and made significant progress with the development of the fully implantable C-Pulse System. We remain optimistic that the current pause in the COUNTER HF study will be resolved expeditiously. In fact, the CEC (Clinical Events Committee) has adjudicated all four events as non-device and non-procedure related deaths and we look forward to receiving a positive response from the FDA no later than April 16th," commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

Fourth Quarter Corporate Highlights:

- Twenty one sites activated in the C-Pulse COUNTER HF U.S. pivotal study, up from nineteen at the end of third quarter 2014 with 15 sites having enrolled patients by the end of 2014.
- Thirteen additional patients enrolled in the C-Pulse COUNTER HF study in the fourth quarter with two new centers enrolling their first patients.
- Two additional implants completed in the European OPTIONS HF study in the fourth quarter at newly activated sites in Germany and Austria, bringing total EU implants performed to 12.
- Presented data on the positive effects of C-Pulse on Left Ventricular (LV) stroke volume and wall stress demonstrating improvements in reduction of Wasted Energy and Tension Time index, key metrics in assessing myocardial oxygen consumption.
- Hired Dimitrious Georgakopolous as Chief Scientific Officer.

Fourth Quarter and Full Year Financial Highlights:

- Revenue totaled $177,000 in Q4 2014 vs. no revenue in the similar quarter in 2013. For the year, revenue was $295,000 in 2014 and $59,000 in 2013.
- Operating expenses totaled $6.8 million in Q4 2014 vs $7.0 million in a similar period a year ago. Total year operating expenses were $26.1 million in 2014 vs. $22.9 million in 2013.
- Net loss per share was $(0.40) for Q4 2014 vs. $(0.42) for Q4 2013. Total year net loss per share was $(1.51) for 2014 vs. $(1.71) for 2013.
- Cash used in operations was $22.6 million in 2014 vs. $17.4 million in 2013. Cash and cash equivalents at December 31, 2014 were $31.3 million vs. $54.1 million at December 31, 2013.

FINANCIALS

The Company had revenue of $177,000 and $295,000 for the three and twelve months ended December 31, 2014. For the year ended December 31, 2013, revenue was $59,000. There was no revenue in the fourth quarter of 2013. All revenue relates to reimbursement received for implants performed under the Company's U.S. COUNTER HF study. Although the Company's C-Pulse System is not approved for commercial sale in the U.S., the FDA has assigned the C-Pulse System to a Category B designation, making it eligible for reimbursement at some U.S. sites during clinical studies. There are no revenues associated with the Company's post market OPTIONS HF study in Europe.

Operating expenses in the fourth quarter of 2014 totaled $6.8 million, compared to $7.0 million in the similar period of 2013. The decrease in operating expenses over the prior period related to decreased stock compensation expense. Operating expenses for the twelve months ended December 31, 2014 totaled $26.1 million, compared to $22.9 million in the similar period in 2013. The increase in operating expenses over the prior year twelve month period was primarily attributable to increased clinical research expenses and increased development expense associated with our fully-implantable device.

Included in the full year results are income tax benefits from the receipt of R&D tax credit refunds in Australia totaling $0.25 million for 2014 and $1.2 million for 2013.

Net loss in the three and twelve month periods ended December 31, 2014 was $6.7 million or $0.40 per share, and $25.6 million or $1.51 per share, respectively. This compares to losses of $7.1 million or $0.42 per share; and $21.8 million, or $1.71 per share in the comparable periods in 2013. Excluding equity compensation expense, three and twelve month periods ended December 31, 2014 net non-GAAP losses totaled $5.8 million or $0.34 per share, and $22.5 million, or $1.33 per share, respectively. This compares to $5.4 million or $0.32 per share, and $17.9 million, or $1.41 per share, in the comparable periods of 2013.

Cash used in operating activities totaled $22.6 million for the year ended December 31, 2014 compared to $17.4 million for the similar period in 2013, with the increase driven primarily by higher clinical research and development expenses. The Company had $31.3 million in cash and cash equivalents at December 31, 2014, compared to $54.1 million at December 31, 2013.

In anticipation of the capital needed to fund the fully implantable system, Sunshine Heart began to evaluate the effectiveness of utilizing a $40 million At-the-Market (ATM) equity facility, which was put in place in 2014. Starting November 2014, the Company began utilizing this facility selectively and in the first

two months of 2015, it generated approximately $7 million from equity offerings. In addition, subsequent to year end, the Company secured a debt arrangement with Silicon Valley Bank for proceeds of up to $10 million of which $6 million was funded at closing, an additional $2 million became available upon the announcement that the FDA had granted the Company approval to conduct an interim analysis, and the remaining $2 million will be available upon reaching the 100th patient enrollment milestone in the COUNTER HF study on or before September 30, 2015. The Company believes that the combination of the ATM and the debt facility should provide the Company with sufficient capital to fund its operations through 2016.

CORPORATE UPDATE

Enrollment numbers in the COUNTER HF pivotal study continued enrollment in double digits despite the Company's concerns about seasonality. As previously reported, in the fourth quarter, the Company enrolled 13 additional patients ending 2014 with 40 enrollments, 21 activated centers and 12 additional centers committed to participate. Of the 21 activated centers in COUNTER HF, 15 have enrolled patients with two new centers enrolling their first patient in the fourth quarter. While the COUNTER HF study is currently paused, the Company was tracking toward a third consecutive quarter of double digit enrollment in Q1 2015 with expected growth over the fourth quarter numbers. The Company expected in Q1 2015

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that approximately 100 patients would have been presented the option of enrolling into the study. This would have been a sizable increase over the number of patients considered for therapy in Q3 and Q4 of 2014.

The Company reported on March 6, 2015, that it had notified the FDA after it became aware of three recent all-cause deaths in the treatment arm of the COUNTER HF trial. This brought the total to four all-cause deaths in the treatment arm since the study began. The Company remains optimistic that the current pause in the COUNTER HF study will be resolved expeditiously since all four reported patient deaths have been adjudicated by the CEC as being neither device nor procedure related. On March 16, 2015, the Company, as directed by the FDA, submitted an IDE amendment to the FDA including all data that was requested in order to resume the study. As the amendment includes an up to 30 day review, the Company expects a response from the FDA no later than April 16, 2015.

In the OPTIONS HF EU post-market study, the Company finished the year with 12 implants in Europe. Two of these procedures were done in Q4 in newly activated sites in Germany and Austria with patient discharge occurring within 7 days post-implant. In 2014, the Company applied for reimbursement of its C-Pulse system in Germany and in 2015 it learned that the request was granted a status 4 designation. A major reason for the designation was that individual hospitals in Germany had also submitted for C-Pulse reimbursement utilizing different codes than those submitted by the Company. A status 4 designation, while not mandating reimbursement, allows participating centers to negotiate reimbursement coverage for the C-Pulse procedure with all insurers serving their region.

Also, as previously announced, in the fourth quarter Sunshine Heart submitted a request to the FDA to conduct an interim analysis of the COUNTER HF data after half of the patients have been enrolled in the study. In February 2015, the Company received unconditional approval from the FDA to perform an interim analysis. This approval will allow the Company to review the data after 194 patients have been randomized to either the treatment arm or control arm and the patients have been followed for 12 months. The accrual of the 194 patient cohort is expected to occur in late 2016. With an interim analysis, the Company will be expected to meet a much more rigorous statistical threshold, which is adjusted based on the accrued follow-up data. Therefore, the preset follow-up period of 12 months for the interim analysis cohort was selected to maximize the collection of data towards the primary endpoint.

Throughout 2014, Sunshine Heart successfully completed both acute and chronic animal trials with the fully implantable C-Pulse system. The Company has developed a smaller iteration of the C-Pulse system, which its physician advisors are confident can be implanted via a minimally invasive procedure. The Company believes it is on track to be the first current mechanical assist company to complete a human clinical evaluation utilizing a fully implantable pump and TETS (Transcutaneous Energy Transfer) system.

In 2014 and during the fourth quarter, Sunshine Heart continued to bolster its leadership team. The Company welcomed three top executives from Medtronic, Boston Scientific and CVRx, who bring a wide range of valuable experience and expertise to the management team which will ultimately facilitate corporate growth. Sunshine Heart has also expanded its in-house expertise in software and hardware components of the C-Pulse System and TETS (Transcutaneous Energy Transfer System). In January 2015, the Company also appointed Claudia Drayton as Chief Financial Officer from Medtronic's Integrated Health Solutions Business where she was also CFO.

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

	Three months ended December 31,		Twelve months ended December 31,	
	2014	2013	2014	2013
Net sales	**$ 177**	**$ —**	**$ 295**	**$ 59**
Operating expenses				
Selling, general and administrative	2,243	2,814	9,208	9,426
Research and development	4,590	4,181	16,874	13,504
Total operating expenses	6,833	6,995	26,082	22,930
Loss from operations	(6,656)	(6,995)	(25,787)	(22,871)
Other expense, net	(71)	(109)	(49)	(100)
Loss before income taxes	(6,727)	(7,104)	(25,836)	(22,971)
Income tax benefit (expense), net	(16)	—	249	1,213
Net loss	**$ (6,743)**	**$ (7,104)**	**$ (25,587)**	**$ (21,758)**
Basic and diluted loss per share	**$ (0.40)**	**$ (0.42)**	**$ (1.51)**	**$ (1.71)**

Weighted average shares outstanding — basic and diluted	16,954	16,831	16,899	12,723
Other comprehensive income:				
Foreign currency translation adjustments	70	112	65	22
Total comprehensive loss	**$ (6,673)**	**$ (6,992)**	$ **(25,522)**	$ **(21,736)**

Condensed Consolidated Balance Sheets
(Dollars in thousands, except share amounts)

	December 31, 2014	December 31, 2013
ASSETS		
Current assets		
Cash and cash equivalents	$ 31,293	$ 54,136
Accounts receivable	59	59
Other current assets	360	448
Total current assets	31,712	54,643
Property, plant and equipment, net	661	587
TOTAL ASSETS	**$ 32,373**	**$ 55,230**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,079	$ 2,188
Accrued salaries, wages, and other compensation	1,079	1,315
Total current liabilities	3,158	3,503
Total liabilities	3,158	3,503
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of December 31, 2014 and December 31, 2013, par value $0.0001 per share; authorized 30,000 Shares, none outstanding	—	—
Preferred stock as of December 31, 2014 and December 31, 2013, par value $0.0001 per share; authorized 39,970,000 shares, none outstanding	—	—
Common stock as of December 31, 2014 and December 31, 2013, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 16,982,642 and 16,825,284 shares, respectively	2	2
Additional paid-in capital	154,540	151,530
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,272	1,207
Accumulated deficit	(126,599)	(101,012)
Total stockholders' equity	29,215	51,727
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 32,373**	**$ 55,230**

Condensed Consolidated Statements of Cash Flows
(in thousands)

	Twelve months ended December 31, 2014	Twelve months ended December 31, 2013
Operating Activities		
Net loss	**$** (25,587)	$ (21,758)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	277	185
Stock-based compensation expense, net	2,678	2,953
Amortization of warrants for service agreements	—	239
Changes in operating assets and liabilities		
Accounts receivable	—	(59)
Other current assets	(5)	(22)
Accounts payable and accrued expenses	(7)	1,100
Net cash used in operations	**(22,644)**	**(17,362)**
Investing activities:		
Purchases of property and equipment	(351)	(293)
Net cash used in investing activities	**(351)**	**(293)**
Financing activities:		
Net proceeds from the sale of common stock	89	57,566
Net cash provided by financing activities	**89**	**57,566**
Effect of exchange rate changes on cash	63	1
Net increase (decrease) in cash and cash equivalents	(22,843)	39,912
Cash and cash equivalents - beginning of period	54,136	14,224
CASH AND CASH EQUIVALENTS - END OF PERIOD	**$ 31,293**	**$ 54,136**

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 the underlying trends in the Company's business over time. Investors should consider these non-GAAP measures in addition to, 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 excluding equity compensation expense, which exclude expenses related to stock options, service 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
(In thousands, except per share amounts)
(Unaudited)

	Three months ended December 31,		Twelve months ended December 31,	
	2014	2013	2014	2013
GAAP operating expenses	$ 6,833	$ 6,995	$ 26,082	$ 22,930
Less: Equity compensation expense	(897)	(1,706)	(3,085)	(3,843)
Non-GAAP operating expenses	$ 5,936	$ 5,289	$ 22,997	$ 19,087
GAAP net loss	$ (6,743)	$ (7,104)	$ (25,587)	$ (21,758)
Less: Equity compensation expense	897	1,706	3,085	3,843
Non-GAAP net loss	$ (5,846)	$ (5,398)	$ (22,502)	$ (17,915)
GAAP basic and diluted loss per share	$ (0.40)	$ (0.42)	$ (1.51)	$ (1.71)
Non-GAAP basic and diluted loss per share	$ (0.34)	$ (0.32)	$ (1.33)	$ (1.41)
Weighted average shares outstanding — basic and diluted	16,954	16,831	16,899	12,723

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

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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, our expectations with respect to future clinical study activities and results including patient enrollment in studies. These forward-looking statements are subject to numerous risks and uncertainties, including, without limitation, the possibility that our clinical studies do not meet their enrollment goals, meet their endpoints or otherwise fail, that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the possibility that we may be unable to raise the funds necessary for the development and commercialization of our products, that we may not be able to commercialize our products successfully in the EU and the other risk factors described under the caption "Risk Factors" and elsewhere in our filings with the U.S. Securities and Exchange Commission. You should not place undue reliance on forward-looking statements because they speak only as of the date when made and may turn out to be inaccurate. 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. We 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.

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