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 5, 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 Number)	(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:

- 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 May 5, 2015, Sunshine Heart, Inc. (the ***"Company"***) issued a press release reporting its financial results for the first quarter ended March 31, 2015. The press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The information in this Item 2.02 and the attached exhibit shall be considered filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the ***"Exchange Act"***), and shall be deemed incorporated by reference in the following registration statements (collectively, the ***"Registration Statements"***):

(1) Registration Statement (Form S-8 No. 333-183924) pertaining to the Sunshine Heart, Inc. Amended and Restated 2002 Stock Plan;

(2) Registration Statement (Form S-8 No. 333-183925) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan;

(3) Registration Statement (Form S-8 No. 333-188935) pertaining to the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan;

(4) Registration Statement (Form S-8 No. 333-190499) pertaining to the Sunshine Heart, Inc. New-Hire Equity Incentive Plan;

(5) Registration Statement (Form S-8 No. 333-194642) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan, the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan, and the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, as amended;

(6) Registration Statement (Form S-8 No. 333-202904) pertaining to the Sunshine Heart, Inc. Second Amended and Restated 2011 Equity Incentive Plan, the Sunshine Heart, Inc. 2013 Non-Employee Directors' Equity Incentive Plan, and the Sunshine Heart, Inc. New-Hire Equity Incentive Plan, as amended; and

(7) Registration Statement (Form S-3 No. 333-194731) of Sunshine Heart, Inc. and in the related base prospectus and sales agreement prospectus.

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 5, 2015, reporting the Company's financial results for the first quarter ended March 31, 2015.

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: May 5, 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 May 5, 2015, reporting the Company's financial results for the first quarter ended March 31, 2015.

Sunshine Heart Announces First Quarter 2015 Results and Provides Corporate Update

Eden Prairie, MN: May 5, 2015: Sunshine Heart, Inc. (NASDAQ: SSH) announced today its financial results and provided a corporate update for the first quarter of 2015.

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 33142990. An audio archive of the webcast will be available following the call at http://ir.sunshineheart.com.

"Resuming enrollment in the COUNTER HF™ study was our top priority during the quarter and remains our most important initiative. The Company's proposed minor protocol modifications will enhance an already robust protocol, and should increase the likelihood of study success. We are pleased with progress made with the FDA and remain confident that the Company will resolve this matter within 30 days," commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

First Quarter Corporate Highlights:

- 23 sites activated in the COUNTER HF U.S. pivotal study, up from 21 at the end of the fourth quarter of 2014
- Eight additional patients enrolled prior to pausing enrollment; Company had been trending to 20 enrollments for the first quarter of 2015
- FDA granted approval for an interim analysis for the COUNTER HF study
- Two additional implants completed in the OPTIONS HF EU post-market study bringing the total number of EU implants to 14
- The ISHLT accepted poster presentation authored by Dr. Mark Slaughter of Jewish Hospital in Louisville Kentucky on management of driveline infections for the C-Pulse System
- Hired Claudia Drayton as the Company's Chief Financial Officer

First Quarter Financial Highlights:

- Cash used in operations was $7.1 million in the first quarter 2015 vs. $6.7 million in the first quarter 2014
- Cash and cash equivalents on hand at March 31, 2015 was $37.0 million vs. $31.3 million at year-end 2014

Prior to the temporary pause in COUNTER HF's study enrollment which commenced on March 6, 2015, Sunshine Heart was on pace to record its most successful quarter of enrollment since initiating the study. The Company was trending to reach 20 patients in the first quarter of 2015 as an additional 50 patients were to be evaluated in March. In addition, the Company activated two new centers in the quarter, bringing the total number of activated sites to 23. The Company is also pleased to report that there have been no exit site infections in the study to-date.

In accordance with the temporary pause in enrollment, the Company provided the U.S. Drug and Food Administration (FDA) with site documentation regarding the four patient deaths in the treatment arm of the study in an effort to establish a plan to resume enrollment. The Company reported that the four treatment arm deaths in COUNTER HF were adjudicated by an independent Clinical Events Committee (CEC) as being not device or therapy related. The independent Data Safety Monitoring Board (DSMB) has also recommended continuing the study. Upon review of the findings, the FDA did not indicate

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concern regarding device safety and requested submission of minor protocol changes prior to granting Sunshine Heart approval to resume enrollment.

The Company submitted the requested minor protocol changes to the FDA on April 22, 2015 and approval of re-initiation of the study is expected by May 23, 2015. The most significant updates provided to the FDA included details on the Company's proposal to incorporate a Physician Subject Selection Committee into the study to ensure that patients meet the study entry criteria and address the targeted population that will most likely benefit from receiving C-Pulse therapy. The new committee will be comprised of cardiology heart failure experts and cardiothoracic surgeons familiar with the therapy. A COUNTER HF study investigator meeting will be held on May 7-8, 2015 to prepare for resumption of study enrollment.

During the first quarter of 2015, the European based OPTIONS HF post-market study continued to advance and the Company is pleased to report that two additional patients were implanted during the period bringing the total number of implants under the European study to 14. Integral to this milestone is that it marks the first implant performed at the Company's German Tübingen site. Furthermore, with the initial patients in the study achieving the milestone of 18 months of therapy, only two of 14 patients have had reported exit site infections to-date.

Also during the quarter, the Company continued to achieve meaningful progress with its next generation, fully implantable C-Pulse Heart Assist System. The first acute animal experiment with the complete fully implantable system was achieved, with successful power transfer through the skin to activate the pump. Finally, in terms of expanded opportunities beyond congestive heart failure, the Company has initiated a research program with Dr. Mark Slaughter and the Jewish Hospital of Louisville, Kentucky for the treatment of Pulmonary Arterial Hypertension.

On the corporate development front, the Company continued to bolster its leadership team with the appointment of Claudia Drayton as its Chief Financial Officer. Prior to joining Sunshine Heart, Ms. Drayton spent fifteen years at Medtronic, Inc, a global leader in the medical device industry. During her tenure, she held multiple senior managerial finance positions culminating with an assignment in Europe serving as Chief Financial Officer of the Peripheral Vascular Business (2010-2012) and, most recently, as Chief Financial Person and Senior Finance Director of the Integrated Health Solutions Business. Another key milestone during the first quarter of 2015 was the closing of a loan and security agreement with Silicon Valley Bank for proceeds of up to $10.0 million.

FINANCIALS

The Company's first quarter 2015 results include reimbursement revenue of $59,000 for an implant of the C-Pulse System under its U.S. COUNTER HF study, a comparable amount to the same period in 2014. 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 certain U.S. sites during clinical studies. Consequently, the Company is able to

invoice some hospitals and clinics that are eligible for reimbursement by Medicare, Medicaid or private insurance companies. Many private insurance companies and certain governmental institutions have a non-coverage policy for experimental or investigational procedures, however, so the Company has not been successful in achieving reimbursement for some of its implant procedures.

Product costs incurred for the Company's clinical studies are deemed to be development costs and, accordingly, are expensed to research and development as incurred.

Operating expenses in the first quarter of 2015 totaled $7.1 million, compared to $6.4 million in the first quarter of 2014. Equity compensation expense included in operating expenses totaled $0.9 million and $0.7 million for the three months ended March 31, 2015 and 2014, respectively. Excluding equity compensation expense, non-GAAP operating expenses totaled $6.2 million and $5.7 million for the three months ended March 31, 2015 and 2014, respectively. The increase over the prior year was primarily

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attributable to increased development expenses associated with the Company's fully-implantable system, increased clinical research expenses related to the U.S. pivotal and EU post-market studies, and increased product purchases related to the manufacture of the C-Pulse System.

Net loss in the first quarter of 2015 was $7.1 million, or $0.40 per share, compared to a net loss of $6.3 million, or $0.38 per share in the first quarter of 2014. Excluding equity compensation expense, first quarter 2015 and 2014 net non-GAAP losses totaled $6.2 million, or $0.35 per share and $5.6 million, or $0.33 per share, respectively.

Cash used in operating activities totaled $7.1 million for the first quarter of 2015 compared to $6.7 million for the first quarter of 2014, with the increase driven primarily by higher research, development and clinical expenses. During the first quarter of 2015, the Company received net proceeds provided by financing activities of $12.9 million, as follows: $6.9 million from the sale of common shares under the Company's existing At-The-Market facility (ATM), and $6.0 million from borrowings under a $10.0 million debt facility with Silicon Valley Bank. In the first quarter of 2014, the Company had $16,000 in proceeds from the exercise of warrants. The Company ended the first quarter of 2015 with $37.0 million in cash and cash equivalents, compared to $31.3 million at December 31, 2014. The Company believes that the combination of the ATM and the debt facility should provide the Company with sufficient capital through 2016, assuming no acceleration to the fully implantable C-Pulse System development timeline.

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

	Three months ended March 31,	
	2015	**2014**
Net sales	**$ 59**	**$ 59**
Operating expenses:		
Selling, general and administrative	2,186	2,361
Research and development	4,865	4,063
Total operating expenses	7,051	6,424
Loss from operations	(6,992)	(6,365)
Other income (expense), net	(66)	33
Loss before income taxes	(7,058)	(6,332)
Income tax expense	5	—
Net loss	**$ (7,063)**	**$ (6,332)**
Basic and diluted loss per share	**$ (0.40)**	**$ (0.38)**
Weighted average shares outstanding — basic and diluted	17,509	16,859
Other comprehensive income:		
Foreign currency translation adjustments	$ 10	$ (19)
Total comprehensive loss	**$ (7,053)**	**$ (6,351)**

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

	March 31, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets		
Cash and cash equivalents	$ 37,027	$ 31,293
Accounts receivable	59	59
Other current assets	921	360
Total current assets	38,007	31,712
Property, plant and equipment, net	653	661
Other assets	135	—
TOTAL ASSETS	**$ 38,795**	**$ 32,373**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		

Current portion of long-term debt	$ 705	$ —
Accounts payable	2,233	2,079
Accrued salaries, wages, and other compensation	741	1,079
Total current liabilities	3,679	3,158
Long-term debt, net of discount	5,043	—
Total liabilities	8,722	3,158
Commitments and contingencies	—	—
Stockholders' equity		
Series A junior participating preferred stock as of March 31, 2015 and December 31, 2014, par value $0.0001 per share; authorized 30,000 shares, none outstanding	—	—
Preferred stock as of March 31, 2015 and December 31, 2014, par value $0.0001 per share; authorized 39,970,000 shares, none outstanding	—	—
Common stock as of March 31, 2015 and December 31, 2014, par value $0.0001 per share; authorized 100,000,000 shares: issued and outstanding 18,233,185 and 16,982,642 shares, respectively	2	2
Additional paid-in capital	162,451	154,540
Accumulated other comprehensive income:		
Foreign currency translation adjustment	1,282	1,272
Accumulated deficit	(133,662)	(126,599)
Total stockholders' equity	30,073	29,215
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$** 38,795	**32,373**

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Three months ended March 31,	
	2015	**2014**
Operating Activities:		
Net loss	**$** (7,063)	$ (6,332)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation	80	61
Stock-based compensation expense, net	743	632
Amortization of debt discount	14	—
Changes in operating assets and liabilities:		
Other current assets	(561)	(468)
Other assets	(135)	
Accounts payable and accrued expenses	(162)	(580)
Net cash used in operations	**(7,084)**	**(6,687)**
Investing Activities:		
Purchases of property and equipment	(72)	(46)
Net cash used in investing activities	**(72)**	**(46)**
Financing activities:		
Net proceeds from the sale of common stock	6,902	16
Proceeds from borrowings on long-term debt	6,000	**—**
Net cash provided by financing activities	**12,902**	**16**
Effect of exchange rate changes in cash	(12)	2
Net increase (decrease) in cash and cash equivalents	5,734	(6,715)
Cash and cash equivalents - beginning of period	**31,293**	54,136
Cash and cash equivalents - end of period	**$ 37,027**	$ **47,421**
Supplement schedule of non-cash activities		
Stock options and restricted stock units classified as liabilities, net	**$ —**	$ (278)
Warrants issued in connection with debt financing	266	—

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 March 31,	
	2015	**2014**
Operating Expenses		

GAAP operating expenses	$ 7,051	$ 6,424
Equity compensation costs	(867)	(735)
Non-GAAP operating expenses	**$ 6,184**	**$ 5,689**
Net Loss		
GAAP net loss	$ (7,063)	$ (6,332)
Equity compensation costs	867	735
Non-GAAP net loss	**$ (6,196)**	**$ (5,597)**
Loss Per Share		
GAAP basic and diluted loss per share	$ (0.40)	$ (0.38)
Non-GAAP basic and diluted loss per share	**$ (0.35)**	**$ (0.33)**
Weighted average shares outstanding — basic and diluted	17,509	16,859

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, 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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