

**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 15, 2013 (May 14, 2013)**

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation)

000-35312
(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 2.01 Results of Operations and Financial Condition.

On May 14, 2013, Sunshine Heart, Inc. (Nasdaq: SSH) issued a press release announcing financial results for the quarter ended March 31, 2013. A copy of the release is furnished with this report as Exhibit 99.1.

The information in this Current Report on Form 8-K and the Exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "**Exchange Act**") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Sunshine Heart, Inc. dated May 14, 2013

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.

By: /S/ JEFFREY S. MATHIESEN

Name: Jeffrey S. Mathiesen

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Sunshine Heart, Inc. dated May 14, 2013



Sunshine Heart Announces Corporate Updates and First Quarter 2013 Financial Results

Eden Prairie, MN: May 14, 2013: Sunshine Heart, Inc. (NASDAQ: SSH) today announced corporate updates and financial results for the first quarter ended March 31, 2013.

First Quarter Corporate Highlights:

- First site activated in U.S. C-Pulse® System pivotal trial, COUNTER HF
- Reimbursement approval granted by CMS for first U.S. pivotal trial site
- First site activated in European multi-center C-Pulse® System post-market trial, OPTIONS HF
- Two additional Board members added
- \$25M equity line of credit established with Aspire Capital Fund, LLC

First Quarter Financial Highlights:

- SG&A expense totaled \$2.0M in 1Q13 vs. \$1.9M in 1Q12
- R&D expense totaled \$2.4M in 1Q13 vs. \$2.2M in 1Q12
- Loss per share \$(0.47) in 1Q13 vs. \$(0.66) in 1Q12
- Cash used in operations was \$4.1M in 1Q13 vs. \$4.8M in 1Q12

In the first quarter, Mid America Heart Institute-Saint Luke's Hospital was the first site to be activated in the U.S. COUNTER HF trial. Sunshine Heart has been notified by the site that CMS has already granted reimbursement eligibility for use of the C-Pulse System. Mid America Heart was the leading implanter for the Company's C-Pulse feasibility study. Three additional centers from the Company's feasibility study are currently in the activation process. Additionally, Sunshine Heart received word on May 9, 2013 that its second site, Minneapolis VA Medical Center, has been activated. The Company anticipates a range of enrollments, including control and C-Pulse implanted patients, to total 32 to 44 by year-end 2013.

Sunshine Heart has appointed Dr. Margarita Camacho, Surgical Director Cardiac Transplantation and Mechanical Device Program, Barnabas Health Heart Center at Newark Beth Israel Medical Center, as the National Surgical Principal Investigator (PI) for its COUNTER HF trial. Dr. Camacho was previously a member of the data and safety monitoring board that oversaw the feasibility trial. She joins Dr. William Abraham of the Ohio State University Medical Center, who was previously named as the National Cardiology Principal Investigator for the COUNTER HF trial.

"I am pleased to announce meaningful corporate and clinical progress made in our first quarter of 2013, particularly the initiation of our anticipated pivotal trial, COUNTER HF," said Dave Rosa, Chief Executive Officer of Sunshine Heart. "We are excited and honored to announce Dr. Camacho as our surgical PI for the trial and look forward to her expertise and contributions, as well as those of our new Board members. We are actively adding personnel to support the advancement of our clinical trial. We look forward to updating the market on material pivotal trial enrollment progress, our post-market European study, as well as additional exciting outcomes on existing feasibility patients."

In February, 2013, Sunshine Heart completed the activation of the first site in its European multi-center post-market study, OPTIONS HF. The site, German Heart Institute - Berlin (DHZB), is recognized as a worldwide leading institution for the treatment of late stage heart failure. On May 7, 2013, the first patient was successfully implanted at DHZB and the center is actively recruiting additional patients. The first implant was completed using Sunshine Heart's next generation cuff, which is pre-sutured and pre-marked, decreasing overall procedure time and increasing predictability for cuff securement. Sunshine

Heart continues to move forward with site activation, at seven additional sites in Germany, Italy and the United Kingdom. Final activation for these sites is expected to be completed by September 1, 2013.

Sunshine Heart received communication from its German reimbursement consultant in the first quarter that reimbursement has been denied based on lack of C-Pulse patient data in Germany. However, DHZB will have the opportunity to negotiate reimbursement directly with the German insurance providers. Sunshine Heart intends to re-submit for future German reimbursement in October along with additional accumulated patient data.

Also in the first quarter, the Company announced the addition of Warren Watson and Jon Salvesson to its Board of Directors. Mr. Watson joins Sunshine Heart following a notable 33-year tenure across senior managerial roles at Medtronic (NYSE:MDT). Mr. Salvesson brings extensive corporate transaction and financing experience to the Company and is the current Vice Chairman of Investment Banking and Chairman of Healthcare Investment Banking at Piper Jaffray Companies (NYSE:PJC).

Financials:

Operating expenses in the first quarter totaled \$4.4 million, compared to \$4.1 million in the fourth quarter of 2012. The increase over the prior year period was attributable to increased spending in preparation for the U.S. pivotal trial and EU post-market study, as well as increased non-cash compensation expenses.

Net loss in the first quarter was \$4.4 million, or \$0.47 per share, compared to a loss of \$4.1 million of \$0.66 per share in 2012, respectively.

Cash used in operating activities decreased to \$4.1 million in the first quarter 2013 from \$4.8 million in the comparable period of the prior year, driven primarily by the higher concentration of non-cash expenses in the current year and the reduction of liabilities in the prior year period. The Company ended the

first quarter with \$11.0 million in cash, compared to \$14.2 million at December 31, 2012. The pro-forma cash balance at March 31, 2013, when adjusted to reflect the April 2013 equity financing discussed below, was \$25 million.

In addition to financial results for the first quarter ended 2013, Sunshine Heart also announced several corporate updates with regard to financing, ongoing clinical trials for C-Pulse, and progress made with regard to internal product development.

Additional Corporate Milestones:

- Second site activated in U.S. pivotal trial, COUNTER HF
- Complete Feasibility study data expected to be published in major medical journal
- Two additional patients have been identified as potential candidates to be weaned from the device based on significant symptomatic improvement
- Closed \$15.1M public offering on April 16, 2013
- Progress made in development of fully-implantable pump
- Company evaluating additional therapeutic indications for C-Pulse system
- Sunshine Heart officially de-listed from Australian Stock Exchange (ASX)

On April 16, 2013, the Company announced completion of a \$15.1 million public offering intended for use toward the completion of its European post-market study, which is expected in late 2014. The Company also has the ability to access another \$24 million as a line of credit established in January, 2013 with Aspire Capital.

Following the positive 12-month follow up data for the C-Pulse feasibility study announced at the 2012 Transcatheter Cardiovascular Therapeutics (TCT) conference, the Company expects to submit the trial manuscript titled, “Ambulatory Extra-Aortic Counterpulsation in Patients with Moderate to Advanced Chronic Heart Failure,” to a major medical journal for publication.

Sunshine Heart is currently in discussions with physicians regarding the potential weaning of additional patients from the C-Pulse system, based upon significant improvements since the time of implant. To-date, two patients implanted in the Company’s Feasibility study have been permanently weaned from the device. The Company expects to report on the status of these additional patients in the coming months, as appropriate.

On the research and development front, the Company has executed an agreement with Cirtec Medical Systems, a leader in advanced engineering and manufacturing capabilities specializing in minimally invasive surgical and delivery devices, on a development pathway for its fully implantable C-Pulse pump. The Company is targeting the completion of a chronic animal trial in late 4Q13 for the pump and intends to provide more information as progress is made.

The Company is also pleased to report that it is aware of early stage work being done by a U.S. center evaluating the use of C-Pulse as a technology for Fontan Mechanical Assistance for patients born with single ventricles. In addition, Sunshine Heart has been approached by a separate center that is interested in conducting pre-clinical studies to evaluate C-Pulse as a non-blood contacting right ventricular assist device. Information regarding progress of these potential therapeutic indications for C-Pulse will be provided as data becomes available.

On May 6, 2013, Sunshine Heart completed its requested delisting from the Australian stock exchange. The Company is now traded solely on the NASDAQ Capital Market under symbol “SSH.”

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

	Three months ended March 31,	
	2013	2012
Net sales	\$ —	\$ —
Operating expenses		
Selling, general and administrative	1,976	1,940
Research and development	2,426	2,166
Total operating expenses	4,402	4,106
Loss from operations	(4,402)	(4,106)
Interest income	3	25
Loss before income taxes	(4,399)	(4,081)
Income tax benefit	—	—
Net loss	\$ (4,399)	\$ (4,081)
Basic and diluted loss per share	\$ (0.47)	\$ (0.66)
Weighted average shares outstanding — basic and diluted	9,417	6,169
Comprehensive loss	\$ (4,407)	\$ (4,027)

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

	March 31, 2013 (unaudited)	December 31, 2012
Current assets		
Cash and cash equivalents	\$ 10,970	\$ 14,224
Other current assets	504	333
Total current assets	11,474	14,557
Property, plant and equipment, net	448	479
TOTAL ASSETS	\$ 11,922	\$ 15,036
Current liabilities		
Accounts payable	\$ 1,584	\$ 1,156
Accrued salaries, wages, and other compensation	435	931
Total current liabilities	2,019	2,087
Total liabilities	2,019	2,087
Commitments and contingencies	—	—
Stockholders' equity		
Preferred Stock as of March 31, 2013 and December 31, 2012, par value \$0.0001; per share; authorized 40,000,000 shares	—	—
Common stock as of March 31, 2013 and December 31, 2012, par value \$0.0001 per share; authorized 100,000,000 shares: issued and outstanding 9,509,867 and 9,282,724 shares, respectively	1	1
Additional paid-in capital	92,378	91,017
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	1,177	1,185
Accumulated deficit	(83,653)	(79,254)
Total stockholders' equity	9,903	12,949
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 11,922	\$ 15,036

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

	For the three months ended March 31,	
	2013	2012
Net loss	\$ (4,399)	\$ (4,081)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	40	31
Loss on disposal of plant and equipment	—	63
Stock-based compensation expense	367	318
Amortization of warrants for service agreements	120	—
Changes in assets and liabilities		
Other current assets	(171)	(299)
Accounts payable and accrued expenses	(71)	(800)
Net cash used in operations	(4,114)	(4,768)
Cash flows used in investing activities:		
Purchases of property and equipment	(9)	(89)
Net cash used in investing activities	(9)	(89)
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	874	2,061
Net cash provided by financing activities	874	2,061
Effect of exchange rate changes in cash	(5)	65
Net decrease in cash and cash equivalents	(3,254)	(2,731)
Cash and cash equivalents - beginning of period	14,224	6,563
CASH AND CASH EQUIVALENTS - END OF PERIOD	\$ 10,970	\$ 3,832

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 trial, we also believe that some patients treated with our C-Pulse System will 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 trial 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 trial. 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 a wholly owned subsidiary in Australia. 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 and 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 the net proceeds from the offering, future clinical trial activities and results including patient enrollment in trials. These forward-looking statements are subject to numerous risks and uncertainties, including, without limitation, that the net proceeds may be lower than we currently expect due to increased offering expenses or otherwise, the possibility that our clinical trials do not meet their enrollment goals, meet their end-points 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 SEC. 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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