

**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): **January 12, 2015**

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 7.01 Regulation FD Disclosure.

On January 12, 2015, Sunshine Heart, Inc. issued a press release announcing a corporate update in advance of the 2015 J.P. Morgan Healthcare Conference, taking place January 12 through 15 in San Francisco, California.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in that filing.

Item 9.01 Financial Statements and Exhibits.

**Exhibit
No.**

Description

99.1 Press Release dated January 12, 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.

By: /S/ CLAUDIA DRAYTON
Name: Claudia Drayton
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated January 12, 2015



Sunshine Heart Provides Corporate Update

Eden Prairie, MN: January 12, 2015: Sunshine Heart, Inc. (NASDAQ: SSH) today provided an update on the Company's U.S. Counter HF™ and European OPTIONS HF studies along with progress on its next generation, fully implantable C-Pulse® Heart Assist System.

The U.S. Counter HF study concluded 2014 with 40 enrollments, 21 activated centers, and 12 additional centers committed to participate. The Company is pleased to report 13 patients were enrolled in the fourth quarter, which was much higher than projected. In addition, despite challenges during the quarter presented by seasonality, the company continued to experience strong site enthusiasm in identifying potential patients. 15 of the 21 activated centers have enrolled patients with 2 new centers enrolling their first patient. Moving forward, Sunshine Heart is expecting to experience continued growth in enrollment throughout 2015 due to the following: Addition of 2 development therapy specialists (5 total) to accelerate patient enrollment, increased site proficiency in identifying appropriate patients, continued site activations. Furthermore, the Company expects a decision from the FDA on its request to conduct an interim analysis before the end of the first quarter of 2015. If successful in demonstrating efficacy at the time of interim analysis, the Company will be in a position to discuss early PMA submission with FDA. Data was also obtained during device optimization using pulse wave analysis by the AtCor Medical Sphygmograph Key metrics typically used to determine the impact on left ventricular load are: left ventricular (LV) wall stress, LV stroke volume, Wasted Energy (W_E), Tension-Time Index (TTI). Sunshine Heart has published data on the positive effects of C-Pulse on LV stroke volume and wall stress. Recent evaluation of this data demonstrated improvements in reduction of Wasted Energy and Tension-Time index, two key metrics in evaluating myocardial oxygen consumption. These measurements were taken with the C-Pulse system turned-off and then measured once it had been reactivated. These metrics have also been used to assess cardiac resynchronization therapy success.

With respect to the European OPTIONS HF study, Sunshine Heart finished 2014 with 14 implants performed of which two implants were completed in the fourth quarter at newly activated sites in Germany and Austria. The Company expects to see continued growth in European implants in the first quarter of 2015 and beyond and expects to release study results in mid-2016. A response from the German authorities regarding Sunshine Heart's New Diagnostic and Methods (NUB) submission for reimbursement for the C-Pulse System is expected in February. Given that the Company has not built any revenue in its 2015 plan for EU reimbursement, an approval would represent financial upside to internal guidance. The Company currently has direct representation in Europe to provide clinical and future sales support for the OPTIONS HF trial and commercial purposes.

"We are particularly pleased with progress achieved during the fourth quarter with both of the COUNTER HF™ and OPTIONS HF trials. The pace of enrollment in both studies seems to be gaining sustainable momentum and we will continue to provide updates along the way when appropriate," commented Dave Rosa, Chief Executive Officer of Sunshine Heart.

On the research and development front, the next generation, fully implantable C-Pulse System continues to experience exciting progress. During the course of 2014, Sunshine Heart successfully completed both acute and chronic animal trials and has already developed its next, smaller iteration which the Company's physician advisors are confident can be placed via a minimally invasive procedure. Sunshine Heart has also built in-house expertise in the software and hardware components of the C-Pulse System through additional personnel hires to complement independent partners helping with the development of the C-Pulse pump and TETS(Transcutaneous Energy Transfer System). With continued progress, the Company

believes it is well positioned to be the first current mechanical assist company to complete its first in man clinical evaluation. The Company is currently scheduled to meet with the FDA to discuss the fully implantable system on January 15, 2015.

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 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 condition 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, Minnesota 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 trial activities and results including patient enrollment in trials. These forward-looking statements are subject to numerous risks and uncertainties, including, without limitation, the possibility that our clinical trials 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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