

**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): **April 16, 2015**

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 8.01 Other Events.

On April 16, 2015, Sunshine Heart, Inc. ("**Sunshine Heart**" or the "**Company**") issued a press release regarding an update on the COUNTER HF study. The COUNTER HF study is a prospective, randomized, multi-center, controlled study that evaluates the safety and efficacy of the C-Pulse system for the treatment of NYHA Class III and ambulatory Class IV heart failure. Integral to the COUNTER HF study is the assessment of C-Pulse's unique balloon counterpulsation treatment designed to improve heart function and reduce re-hospitalizations due to worsening heart failure. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release - Sunshine Heart Provides Update on U.S. Pivotal Study of C-Pulse® Heart Assist System

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.

Dated: April 17, 2015

SUNSHINE HEART, INC.

By: /S/ DAVE ROSA
Name: Dave Rosa
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release - Sunshine Heart Provides Update on U.S. Pivotal Study of C-Pulse® Heart Assist System



Sunshine Heart Provides Update on U.S. Pivotal Study of C-Pulse® Heart Assist System

Eden Prairie, MN: April 16, 2015: Sunshine Heart, Inc. (NASDAQ:SSH) announced today that the U.S. Food and Drug Administration (FDA) has reviewed the Company's submission regarding the COUNTER HF's U.S. pivotal study pause and requested minor protocol changes be submitted in order to receive approval to resume patient enrollment. The FDA did not indicate concerns regarding safety of the device and requested the updated protocol include information on several minor items, the most significant of which are the details regarding the Company's proposal to incorporate a Physician Subject Selection Committee. Furthermore, the Data Safety Monitoring Board (DSMB), reviewed COUNTER HF's data and recommended continuing the Study.

"We are pleased the FDA has offered a collaborative process to enable the Study to commence in a timely manner. We were prepared for these types of minor protocol modifications and as such, we'll be submitting these amendments by early next week," commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

Sunshine Heart previously announced on March 6, 2015, a temporary pause from enrollment in accordance with the study protocol. The protocol indicated that in the event more than three of the first twenty subjects pass away for any reason, including non-device related deaths, the Company would work with the FDA to establish a plan before resuming enrollment. All four of the reported patient deaths have been adjudicated by an independent Clinical Events Committee (CEC) as being non-device related.

COUNTER HF is a prospective, randomized, multi-center, controlled study evaluating the safety and efficacy of the C-Pulse system for the treatment of NYHA Class III and ambulatory Class IV heart failure. The Study is being conducted by heart failure, electrophysiologists and cardiac surgeon specialists in the United States. It is expected to randomize 388 patients in up to 40 clinical sites. The purpose of the study is to determine whether the C-Pulse System is a safe and effective treatment for heart failure patients who meet the following key study qualifications:

- NYHA Class III or early Class IV heart failure*;
- Ejection fraction \leq 35% (measure of how well the heart pumps blood);
- Taking appropriate heart failure medications as prescribed by doctor; and
- Have been evaluated for cardiac resynchronization therapy with or without defibrillation (CRT, CRT-D) or implantable cardioverter defibrillator (ICD) therapy.

*New York Heart Class (NYHA) Class III or early Class IV: Very limited in daily activities or unable to do activities without discomfort. Become tired, short of breath, and have heart palpitations during physical activity. Note: Other qualifications apply and study doctors will determine who is eligible for the study.

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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