# 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 6, 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 7.01 Regulation FD Disclosure.**

On March 6, 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 furnished and attached hereto as Exhibit 99.1.

*Limitation of Incorporation by Reference*

In accordance with General Instruction B.2. of Form 8-K, this information including Exhibit 99.1, is furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information in this Item 7.01 of this Current Report on Form 8-K will not be deemed an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

**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: March 6, 2015

**SUNSHINE HEART, INC.**

By: /S/ CLAUDIA DRAYTON
Name: Claudia Drayton
Title: Chief Financial 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: March 6, 2015:** Sunshine Heart, Inc. (NASDAQ:SSH) today announced an update on COUNTER HF™, the Company's U.S. pivotal study which 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 Company continues to experience increased interest from the medical and patient community regarding participation in the COUNTER HF study. In fact, over the past twelve months, the number of patients considering enrollment in this study has dramatically increased from 7 in Q1 2014 to approaching 100 for the first quarter in 2015.

While Sunshine Heart is pleased with the study's progress in terms of the recent enrollment pace and site interest, it will be taking a temporary pause from enrollment. This is in accordance with the study protocol where in the event more than three of the first twenty subjects pass away for any reason, including non-device related deaths, the Company will work with the FDA to discuss a plan to resume enrollment. To date, of the four reported patient deaths, two have been adjudicated by an independent Clinical Events Committee (CEC) as being non-device related. The Company has received study documentation from the sites that reported the most recent two deaths that these were also non-device related. Patients already in the trial will continue follow-up according to the protocol.

The FDA has responded to Sunshine Heart's notification and has advised the Company to file an IDE supplement that discusses the reasons for the temporary study suspension and a plan for study resumption. A supplement carries up to a 30-day review period by the FDA and the Company expects to submit the document by March 16, 2015.

"We are confident this matter will be resolved in a very short timeframe. While the current data suggest these incidents are non-device related, we have decided that in the absolute interest of patient safety, having a temporary pause in enrollment is the right course of action while we work with the FDA to discuss the findings. We remain excited by the increasing number of patients who are being presented for study review and are pleased that the screening process for enrollment will continue while we resolve this matter," commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

Sunshine Heart will host its 2014 Q4 results conference call on March 17, 2015 following the submission of the COUNTER HF supplement document to the FDA. At this time, the Company's management team and Dr. Bill Abraham, one of the Study's Principal Investigators, will be available to address questions as part of the standard quarterly conference call format.

**About the COUNTER HF™ Study:**

COUNTER HF™ is a prospective, randomized, multi-center clinical study. It is being conducted by heart failure 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:

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- 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.

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*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.

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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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