

**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): **February 25, 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 7.01 Regulation FD Disclosure.**

On February 25, 2015, Sunshine Heart, Inc. ("**Sunshine Heart**" or the "**Company**") announced that it has received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, the Company's U.S. pivotal 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.**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release - Sunshine Heart Receives FDA Approval for Interim Analysis of U.S. Pivotal Trial 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.

By: /S/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

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**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release - Sunshine Heart Receives FDA Approval for Interim Analysis of U.S. Pivotal Trial of C-Pulse® Heart Assist System

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## Sunshine Heart Receives FDA Approval for Interim Analysis of U.S. Pivotal Trial of C-Pulse® Heart Assist System

**Eden Prairie, MN: February 25, 2015:** Sunshine Heart, Inc. (NASDAQ:SSH) today announced it has received unconditional approval from the FDA to conduct an interim analysis of COUNTER HF, the Company's U.S. pivotal 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.

"Today's announcement is a significant achievement for the company as it offers the potential to dramatically reduce the development timeline for this important solution for heart failure. The FDA decision to approve this interim analysis is not only unconditional but also arrives earlier than the originally anticipated timeframe of end Q1 2015. We are grateful for the FDA's rapid response to our submission and look forward to working with the Agency through the balance of the COUNTER HF study and on the development of the next generation, fully implantable C-Pulse system," commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

A key potential benefit of conducting the analysis is the prospect of reducing the overall duration of the study should COUNTER HF meet the higher statistical threshold of the interim analysis.

The study is a prospective, randomized, multi-center clinical trial. 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:

- 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.

Individuals who are interested in learning more about the trial and if they might qualify for the study can visit [www.HFClinicalStudy.com](http://www.HFClinicalStudy.com) or call 1-888-978-8391.

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### 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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