

**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): **November 3, 2014 (November 3, 2014)**

**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**  
(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 November 3, 2014, we issued a press release clarifying the third quarter 2014 financial results conference call.

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 liability 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.**

**(d) Exhibits**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 3, 2014.

**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: November 3, 2014

**SUNSHINE HEART, INC.**

By: /S/ JEFFREY MATHIESEN

Name: Jeffrey Mathiesen  
Title: Chief Financial Officer

---

---

3

---

**EXHIBIT INDEX**

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release, dated November 3, 2014.

---

4

---



## Sunshine Heart Provides Clarification Following Third Quarter 2014 Financial Results Conference Call

**Eden Prairie, MN: November 3, 2014:** Sunshine Heart, Inc. (NASDAQ:SSH) today provided a clarification of information covered during its October 30, 2014 third quarter financial results conference call. There were numerous audio interruptions, and as a result, the Company received a number of questions pertaining to information on the call.

In the third quarter, the Company reached agreement with four hospitals participating in the COUNTER HF™ study regarding reimbursement for private insurance patients. As of Friday, October 31<sup>st</sup>, there are 21 activated study centers that are able to enroll patients. To date, the Company has provided or committed to provide financial assistance for a total of three of twenty seven patients that have been enrolled in the COUNTER HF study.

Reimbursement challenges with private insurance companies are common in clinical studies in the United States for technologies that are not commercially approved. However, they have become magnified due to penalties applied to hospitals under the Affordable Care Act. These penalties are based on unplanned hospital readmission occurring within thirty days after discharge for conditions such as heart attack, heart failure, pneumonia, chronic obstructive pulmonary disease, and hip/knee arthroplasty. Approximately 50% of the current hospitals in the COUNTER HF study are being impacted by financial penalties for unplanned heart failure readmissions. The Company believes that C-Pulse may be helpful in reducing hospital readmissions due to worsening heart failure.

“In the third quarter, we enrolled fourteen patients despite these operating conditions. This is the highest number of patients enrolled in any given quarter and represents double the number from the previous quarter. We believe these reimbursement discussions will not have an impact on future enrollment as we have three remaining sites with which to resolve this matter,” commented Dave Rosa, Chief Executive Officer of Sunshine Heart.

### 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 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 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, the ability of the C-Pulse system to help reduce hospital readmissions, the impact of reimbursement on future enrollment, 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.

###

For further information, please contact:

**Investor:**  
Candice Knoll  
Blueprint Life Science Group  
T: +1-415-375-3340 Ext. 105

**Media:**  
David Schull  
Russo Partners  
T: +1-212-845-4271

Jeff Mathiesen  
Chief Financial Officer

Christopher R. Hippolyte  
Russo Partners

