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): **August 31, 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 Number)	(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)

N/A
(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:

- 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 8.01 Other Events.

On August 31, 2015, Sunshine Heart, Inc. (the ***"Company"***) issued a press release announcing that the US Food and Drug Administration has approved a key protocol amendment for the Company's COUNTER HF™ pivotal study for its C-Pulse Heart Assist System®. 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 Announces FDA Approves Key Protocol Amendment for COUNTER HF™ US Pivotal Study for 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.

Date: August 31, 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 Announces FDA Approves Key Protocol Amendment for COUNTER HF™ US Pivotal Study for C-Pulse® Heart Assist System

Sunshine Heart Announces FDA Approves Key Protocol Amendment for COUNTER HF™ US Pivotal Study for C-Pulse® Heart Assist System

Eden Prairie, MN: August 31, 2015: Sunshine Heart, Inc. (NASDAQ:SSH) is pleased to announce the US Food and Drug Administration (FDA) has approved an amendment to the stopping rule criteria for the Company's COUNTER HF™ pivotal study for its C-Pulse Heart Assist System®. The Agency has agreed to change this protocol from "all cause" deaths to specifically, mortality associated with device, procedure or therapy.

"Redefining COUNTER HF's stoppage rule to be focused purely on C-Pulse related events is an important study protocol amendment as it greatly reduces our risk of having to pause the trial again due to unrelated C-Pulse mortality events," commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

Sunshine Heart previously announced on March 6, 2015 a temporary enrollment pause in accordance with the study's original "stopping rule." This particular 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. An independent Clinical Events Committee (CEC) determined that all four of the reported deaths were adjudicated as being non-device related and, on May 26th, the Company announced the FDA's approval to resume enrollment in the COUNTER HF study.

Moving forward, the "stopping rule" has been amended such that COUNTER HF will be halted if more than seven of the first twenty implanted subjects pass away during device support within twelve months of implant. Importantly, in order for a study pause to occur, each mortality event will have to be adjudicated as possibly or definitely related to the procedure, therapy or device.

Individuals who are interested in exploring if they might qualify for COUNTER HF can visit www.HFClinicalStudy.com or call 1-888-978-8391.

About the COUNTER HF and OPTIONS HF Studies:

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:

- NYHA Class III or early Class IV heart failure*;
- Ejection fraction ≤ 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.

OPTIONS HF is a post-market, multi-center, prospective, open label study that will include 50 patients in up to 15 European centers. The study is designed to observe clinical outcomes of heart failure patients

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treated with the C-Pulse system. The primary endpoint is comparable to the COUNTER HF study as it evaluates the rate of re-hospitalization due to worsening heart failure and heart failure related death in addition to many other traditional heart failure endpoints.

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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