

**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): **May 21, 2015**

SUNSHINE HEART, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-35312
(Commission File Number)

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)

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:

- 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 5.07 Submission of Matters to a Vote of Security Holders.

At the annual meeting of stockholders of Sunshine Heart, Inc. (the "**Company**") on May 21, 2015, stockholders elected the two Class II director nominees to the Company's Board of Directors to serve three-year terms, and ratified the selection of Ernst & Young LLP as the Company's independent registered public accounting firm for the year ending December 31, 2015.

For Proposal 1, the two nominees receiving the highest number of "FOR" votes at the annual meeting were elected as directors. Proposal 2 required the affirmative vote of the holders of a majority of shares entitled to vote and present at the annual meeting. The Proposals are described in detail in the Company's definitive proxy statement filed on April 10, 2015 with the Securities and Exchange Commission.

The results of the voting are shown below.

Proposal 1—Election of Directors

<u>Class II Nominees</u>	<u>Votes For</u>	<u>Votes Withheld</u>	<u>Broker Non-Votes</u>
David A. Rosa	3,122,963	172,763	11,305,763
Jon W. Salvesson	3,129,439	166,287	11,305,763

Proposal 2—Ratification of Selection of Independent Registered Public Accounting Firm for 2015

<u>Votes For</u>	<u>Votes Against</u>	<u>Votes Abstain</u>
14,524,539	15,826	61,124

Item 8.01 Other Events.

On May 26, 2015, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release - Sunshine Heart Announces FDA Approval to Resume Enrollment in COUNTER HF™ US Pivotal Study for C-Pulse® Heart Assist System

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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: May 26, 2015

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON

Name: Claudia Drayton

Title: Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release - Sunshine Heart Announces FDA Approval to Resume Enrollment in COUNTER HF™ US Pivotal Study for C-Pulse® Heart Assist System

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Sunshine Heart Announces FDA Approval to Resume Enrollment in COUNTER HF™ US Pivotal Study for C-Pulse® Heart Assist System

Eden Prairie, MN: May 26, 2015: Sunshine Heart, Inc. (NASDAQ:SSH) is pleased to announce that the US Food and Drug Administration (FDA) has approved the resumption of patient enrollment in its COUNTER HF US pivotal study for the C-Pulse Heart Assist System. As such, the Company has already begun the process to provide all pivotal study centers with the information required for their Investigational Review Board to approve the continuation of study enrollment.

“Resuming enrollment in COUNTER HF has been our top priority and was accomplished within the timelines originally announced. The proposed protocol modifications have enhanced an already robust protocol, and should increase the likelihood of success. We are encouraged by our investigators’ enthusiasm as witnessed by the high site representation at our recent investigator meeting,” commented Dave Rosa, President and Chief Executive Officer of Sunshine Heart.

Earlier in February 2015 the FDA unconditionally approved an interim analysis for the COUNTER HF study, as a means to potentially reduce the approval timeline for the C-Pulse therapy. FDA approval to resume study enrollment will now allow the Company to progress expeditiously towards that goal.

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 \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.

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 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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