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): **July 11, 2016**

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 July 11, 2016, Sunshine Heart, Inc. (the ***"Company"***) issued a press release announcing a clinical update and product development strategy, which will focus on neuromodulation rather than counterpulsation. The Company believes its new focus will provide a more cost effective way to develop a fully-implantable system, a faster path to commercialization, and broader access to the NYHA Class III heart failure market.

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 Clinical Update and Product Development Strategy

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: July 11, 2016

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 Clinical Update and Product Development Strategy

Sunshine Heart Announces Clinical Update and Product Development Strategy

EDEN PRAIRIE, Minn., July 11, 2016 (GLOBE NEWSWIRE) — Sunshine Heart, Inc. (NASDAQ:SSH) announced today an update to its clinical strategy that could benefit an underserved population of patients with Class III heart failure and other related conditions.

After months of collecting data and researching an optimal strategic path forward, Sunshine Heart is moving forward with a therapeutic strategy focused on neuromodulation rather than counterpulsation. In the feasibility trial, Sunshine Heart's counterpulsation therapy provided greater benefits to patients than would have been expected through the hemodynamic action of the aortic cuff alone. Sunshine Heart has discovered that the primary mechanism of action providing the clinical benefit was a neuromodulatory effect due to the counterpulsation balloon's placement on the ascending aorta and its activation of the neuro aortic baroreceptors with each expansion. Compared to its prior clinical strategy, Sunshine Heart believes its new focus will provide the following benefits: 1) a more cost effective way to develop a fully-implantable system, 2) a faster path to commercialization, and 3) broader access to the NYHA Class III heart failure market.

"We are confident that we are on the right track," said John Erb, Sunshine Heart's Chairman and CEO. "A neuromodulation-based therapy will provide greater benefits to patients, physicians, and the market than our original C-Pulse System. Furthermore, we believe that the development and ultimate approval of a fully-implantable neuromodulation device can be achieved in half the time and at half the cost of our original system. Our approach targets easy to find anatomical structures which provide an immediate and measurable response. In addition, the mechanism of action is direct, simple and well understood."

The company has identified the following clinical steps, comprised of three primary objectives:

Near Term

The company's near-term clinical objective includes the evaluation of 5 patients using the original C-Pulse device. The physician initiated research, approved by their local institutional review board, is evaluating sympathetic nerve activity with C-Pulse therapy turned on and off to assess response. Initial data from the study has been very positive and a full data set should be completed by the end of the third quarter of this year. This data will be targeted for publication within the scientific community to further correlate reduction of sympathetic activity to improved quality of life for heart failure patients.

Acute Neuromodulatory First-in-Man

The company is pursuing a first-in-man acute study to demonstrate hemodynamic response to a proprietary neuromodulation approach. The study is expected to include approximately 20 patients and will utilize an external pulse generator and prototype leads. Enrollment is estimated to begin in the fourth quarter of 2016 and should be completed by the end of 2016.

Fully-Implantable System

Following the completion of the acute neuromodulatory first-in-man study, the company will pursue a clinical study that will utilize a fully implantable pulse generator and proprietary leads. The purpose of the study will be to establish the chronic benefits of a fully-implantable system. The study will include approximately 30 patients and the clinical endpoints will be based on a 6-month follow-up period. The

---

results will be used to support CE Mark approval as well as an IDE/PMA submission with the FDA. Patient enrollment is expected to begin in 2017.

"We are excited to announce some initial details on our revised clinical strategy, and more information will be released once additional details are finalized," said Mr. Erb.

About Sunshine Heart®

Sunshine Heart, Inc. (Nasdaq: SSH) is an early-stage medical device company focused on developing, a product portfolio to treat moderate to severe heart failure and related conditions. Our objective is to improve the quality of life for heart failure patients and halt the disease progression. 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, clinical and pre-clinical study designs and activities, expected timing for initiation, enrollment and completion of clinical trials, research and development activities, ultimate clinical outcomes and benefits of our products to patients, design and development of future studies, site activations, patient enrollment in studies, timing of regulatory filings and approvals, regulatory acceptance of our filings, our expectations with respect to product development and commercialization efforts, market and physician acceptance of our products, intellectual property protection, and potentially competitive product offerings. The risk factors described in our filings with the SEC could cause actual events to adversely differ from the expectations indicated in these forward-looking statements. Management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. Sunshine Heart does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. Sunshine Heart 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. Forward-looking statements are subject to a

number of risks and uncertainties, including without limitation, the possibility that regulatory authorities do not accept our application or approve the marketing of our therapy, the possibility we may be unable to raise the funds necessary for the development and commercialization of our therapy and other risks and uncertainties described in our filings with the SEC. 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.

For further information, please contact:

Claudia Drayton
Chief Financial Officer
Sunshine Heart, Inc.
T: +1-952-345-4205

Investor Relations
Sunshine Heart Inc.
ir@sunshineheart.com