

**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): **September 29, 2016**

**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 September 29, 2016, Sunshine Heart, Inc. (the "**Company**") issued a press release announcing a strategic refocus. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Current Report on Form 8-K (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 8.01 Other Events.**

On September 29, 2016, the Company announced that it is implementing a strategic refocus of its near term strategy that includes pausing clinical evaluations of the neuromodulation technology to fully focus the Company's resources on its recently acquired Aquadex FlexFlow® System, taking actions to reduce its cash burn in connection with such strategic refocus and reviewing potential strategic alliances and financing alternatives.

**Forward-Looking Statements**

Certain statements in this current report and the attached press 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, potentially competitive product offerings, projected monthly cash burn rates, projected annualized revenue run-

rates, the pursuit of strategic partnerships and alliances and financing alternatives and anticipated business changes as a result of the new strategic direction. 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.

**Item 9.01 Financial Statements and Exhibits.**

(d)

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 29, 2016.

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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: September 29, 2016

**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, dated September 29, 2016.

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## Sunshine Heart Announces Strategic Realignment

Eden Prairie, MN: September 29, 2016: (GLOBE NEWSWIRE) Sunshine Heart, Inc. (NASDAQ: SSH) today announced that it is implementing a strategic realignment of its near term strategy to fully focus the Company's resources on its recently acquired Aquadex FlexFlow® System. The Aquadex system is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization.

"Aquadex was an important strategic investment, which allows Sunshine Heart to strengthen its presence in the heart failure market," said John Erb, Sunshine's Chairman and CEO. "We have been very pleased with the reception and enthusiasm we have received from many current and former Aquadex customers that depend on Aquapheresis® Therapy to manage fluid overload, including patients with congestive heart failure. Aquadex has shown to help reduce the length of stay while in the hospital and the number of unscheduled hospital visits in total."

Key elements of the Company's near-term strategy include:

- Pausing clinical evaluations of the neuromodulation technology
- Reducing cash burn from \$2 million per month in the fourth quarter of 2015 to a targeted cash burn of \$800,000 per month in fourth quarter of 2016
- Continuing the Company's ongoing review of potential partnerships, strategic alliances, and the pursuit of financing alternatives.

The above measures will help the Company to attain targeted fourth quarter 2016 annualized revenue run-rate for the Aquadex business of \$5 million and fourth quarter 2017 annualized revenue run-rate for the Aquadex business of \$10 million.

**Rx Only.** All treatments must be administered by a healthcare provider, under physician prescription, both of whom having received training in extracorporeal therapies

### 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. The Company's main commercial product, the Aquadex system is indicated for temporary (up to eight hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy, and extended (longer than 8 hours) ultrafiltration treatment of patients with fluid overload who have failed diuretic therapy and require hospitalization. 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

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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, potentially competitive product offerings, projected monthly cash burn rates, projected annualized revenue run-rates, the pursuit of strategic partnerships and alliances and financing alternatives and anticipated business changes as a result of the new strategic direction. 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:

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