

**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 21, 2016**

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)

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:

- 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 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On September 21, 2016, Sunshine Heart, Inc. (the "**Company**") received notice from the Listing Qualifications Staff (the "**Staff**") of The NASDAQ Stock Market LLC ("**Nasdaq**") indicating that the Staff had determined to delist the Company's securities from The Nasdaq Capital Market due to the Company's continued non-compliance with the minimum bid price requirement unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "**Panel**"). The Company intends to timely request a hearing before the Panel, which request will stay any delisting action by the Staff.

As previously disclosed in a current report on Form 8-K filed on March 25, 2016, on March 23, 2016, the Staff notified the Company that, based upon the closing bid price of the Company's common stock for the 30 prior consecutive business days, the Company no longer satisfied the minimum \$1.00 closing bid price requirement, as set forth in Nasdaq Listing Rule 5550(a)(2), and had been provided a 180-day grace period to regain compliance with that requirement, through September 19, 2016.

At the hearing, the Company will present its plan to evidence compliance with all applicable criteria for continued listing on The Nasdaq Capital Market and request an extension within which to do so. There can be no assurance that the Panel will determine to continue the Company's listing or that the Company will be able to evidence compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

Item 7.01 Regulation FD Disclosure.

On September 23, 2016, the Company issued a press release regarding the notice from Nasdaq. A copy of the press release is furnished herewith as Exhibit 99.1 hereto and incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is being furnished, shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated September 23, 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.

Dated: September 23, 2016

SUNSHINE HEART, INC.

By: /S/ CLAUDIA DRAYTON
Name: Claudia Drayton
Title: Chief Financial Officer and Secretary

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated September 23, 2016.

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Sunshine Heart Announces Receipt of Nasdaq Staff Determination; To Request Hearing

Eden Prairie, MN: September 23, 2016: (GLOBE NEWSWIRE) Sunshine Heart, Inc. (NASDAQ: SSH) today announced that on September 21, 2016, it received a letter from the Nasdaq Listing Qualifications Staff indicating that the Company did not timely demonstrate compliance with the \$1.00 bid price requirement for continued listing on The Nasdaq Capital Market. In accordance with the Nasdaq listing rules, the Company intends to request a hearing before the Nasdaq hearings panel to present its plan to demonstrate compliance with all requirements for continued listing on The Nasdaq Capital Market and request an extension of time within which to do so. The Company's request for a hearing will stay any action by the Staff with respect to its listing on Nasdaq at least pending the issuance of the Panel's decision following the hearing and the expiration of any extension granted by the Panel. The Company is diligently working on its plan to demonstrate compliance with the continued listing requirements, and will provide a further update when relevant information becomes available. There can be no assurance that the Panel will determine to continue the Company's listing or that the Company will be able to evidence compliance with the applicable listing criteria within the period of time that may be granted by the Panel.

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 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, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, potentially competitive product offerings, the Company's ability to receive a hearing before, and extension from, Nasdaq. 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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