

**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): **January 13, 2014 (January 13, 2014)**

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**
(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 January 13, 2014, we issued a press release announcing a corporate update in advance of the 2014 J.P. Morgan Healthcare Conference, taking place January 13 through 17 in San Francisco, California.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in that filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated January 13, 2014.

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: January 13, 2014

SUNSHINE HEART, INC.

By: /S/ JEFFREY MATHIESEN

Name: Jeffrey Mathiesen

Title: Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated January 13, 2014.

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Sunshine Heart Provides Corporate Update

Eden Prairie, MN: January 13, 2014: Sunshine Heart, Inc. (NASDAQ: SSH) today provided a corporate update in advance of the 2014 J.P. Morgan Healthcare Conference, taking place January 13 through 17 in San Francisco.

The Company ended 2013 with cash and cash equivalents exceeding \$54 million and approximately 17 million common shares outstanding (unaudited). The existing equity line of credit was unused and has \$24 million remaining available.

As previously indicated with the release of its third quarter 2013 results, Sunshine Heart expects revenue will be minimal until patient enrollment reaches a predictable rate in the North American pivotal clinical trial and reimbursement is established in select countries in Europe, which the Company has internally modeled to begin in 2015. Sunshine Heart also expects that quarterly operating expenses and cash burn will sequentially increase, commensurate with further trials expansion in both the U.S. and Europe. Quarterly non-cash compensation expense is expected to fluctuate from period to period, based upon the timing and structure of equity awards. The Company plans to issue its fourth quarter and full year 2013 audited results in early March, 2014.

With respect to the European OPTIONS HF Trial, the Company completed the year with 8 implants. With additional sites recently completing their approval process, Sunshine Heart expects to continue to make progress on enrollment in Europe and will provide further updates on its fourth quarter 2013 investor call. In addition, a physician presentation including early results was submitted for the upcoming ISHLT meeting in San Diego, taking place April 10 through 13. The Company will continue to focus on Germany, Italy and the UK while expanding its presence to Austria and Switzerland once the centers have approval to move forward in 2014. A response from the German authorities regarding Sunshine Heart's NUB submission for reimbursement for the C-Pulse System is expected in February. Given that the Company has not built any revenue in its 2014 plan for EU reimbursement, an approval would represent financial upside to internal guidance. Steps have also been taken to have direct representation in Europe to provide clinical support for the OPTIONS HF trial and any support for commercial purposes.

Regarding its U.S. Counter HF trial, Sunshine Heart finished the year with 3 enrollments, 8 activated centers, and 22 additional centers committed to participate. The Company continues to expect to reach its goal of 35 committed sites by the end of the first quarter 2014. 2013 enrollment is currently tracking in line with ongoing competitive trials targeting the same patients. As previously reported, Sunshine Heart expects to see increased activity in 2014. A pilot awareness campaign targeting patients will be launched in the first quarter of this year at select sites to evaluate its impact in helping expedite patient recruitment. The Company has also initiated the hiring of therapy development specialists to focus on patient enrollment. Further enrollment guidance will be provided once a sufficient number of centers in the U.S. demonstrate a steady rate of enrollment. The Company continues to target the end of 2015 to complete

COUNTER HF trial enrollment and expects its current cash to fund the enrollment of both the OPTIONS HF and COUNTER HF trials, given the higher level of funds raised than initially targeted in the last U.S. public financing. Results of the OPTIONS HF trial are expected to be released by end of the second quarter of 2015.

With respect to research and development, the Company will continue to support the development of its fully implantable program. A chronic animal trial was successfully completed with the fully implantable device, demonstrating a comparable level of support as the existing C-Pulse System. The Company also expects to improve the existing technology with software and hardware adjustments and will continue to report on pump development progress with its TETS (Transcutaneous Energy Transmission) System through 2014. The Company has also continued to build in-house expertise in the software and hardware components of the C-Pulse System through additional personnel hires.

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 counterpulsation 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 trial, we also believe that some patients treated with our C-Pulse System will be able to stop using the device due to sustained improvement in their condition 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 trial 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 trial. 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 a wholly owned subsidiary in Australia. 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, future clinical trial activities and results including patient enrollment in trials. These forward-looking statements are subject to numerous risks and uncertainties, including, without limitation, the possibility that our clinical trials 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 SEC. 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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For further information, please contact:

Investor:

Laura Forman
Blueprint Life Science Group
T: +1-415-375-3340

Media:

David Schull
Russo Partners
T: +1-212-845-4271

Jeff Mathiesen
Chief Financial Officer
Sunshine Heart, Inc.
T: +1-952-345-4200

Andreas Marathis
Russo Partners
T: +1-212-845-4235
