

**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 7, 2013 (January 7, 2013)**

SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation)

000-35312
(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 7, 2013, we issued a press release announcing clinical update on the progress of the C-Pulse® Heart Assist System.

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 7, 2013.

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 7, 2013

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 7, 2013.

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Sunshine Heart Provides Clinical Update

Eden Prairie, MN and Sydney, Australia: January 7, 2013: Sunshine Heart, Inc. (NASDAQ: SSH; ASX: SHC) today provided the following clinical update on the progress of the C-Pulse® Heart Assist System.

United States (U.S.) Pivotal Trial

- Seven U.S. sites are currently engaged in contract negotiations and respective institutional review board (IRB) approval processes for the pivotal trial of the C-Pulse System. More than forty additional sites are in discussions or have expressed interest in receiving further information about participating in the trial. Early interest in the U.S. program has been encouraging, with over 80 clinical sites contacted to date.
- Sunshine Heart continues to project that 30 to 40 active sites will participate in the pivotal trial of C-Pulse System.
- The Company expects the first U.S. clinical site to be under contract in February 2013, with patient enrollment set to begin in the first quarter of 2013.

European Post Market Study

- Three sites in Germany are currently engaged in contract negotiations and respective Medical Ethics Committee (MEC) approval processes. The Company is also in discussions with additional sites in Germany and three other European countries relating to the post market study of the C-Pulse System, and is on track with management's expectations to have five sites engaged by the end of the first quarter.
- The Company expects the first European site to be under contract with patient enrollment commencing in the first quarter of 2013.

Year End

- Sunshine Heart ended the year with \$14.2 million in cash and cash equivalents (unaudited), in line with management's expectations. The Company plans to release its fourth quarter and full year 2012 audited results on March 11, 2013.

"It was especially rewarding to see Sunshine Heart achieve its major milestones in 2012," stated CEO Dave Rosa. "After securing both IDE approval for our U.S. pivotal trial and CE Mark for European commercialization, we are well positioned to expand our clinical experience and provide additional data from our European patients while initiating our U.S. pivotal trial. Coupled with this progress was a successful U.S. public financing which has the Company well positioned to meet its key objectives in 2013."

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. Operating outside the patient's bloodstream, the extra-aortic approach of the C-Pulse technology offers greater flexibility, allowing patients to safely disconnect to have intervals of freedom to perform certain activities such as showering. The C-Pulse System may help maintain the patient's current condition and, in some cases, reverse the heart failure process, thereby potentially preventing the need for later stage heart failure therapies, such as left ventricular assist devices (LVADs), artificial hearts or transplants.

Caution: Investigational device, limited by Federal (or United States) Law to Investigational use.

About Sunshine® Heart

Sunshine Heart, Inc. (NASDAQ: SSH / ASX: SHC) is an early-stage global medical device company committed to the commercialization of the C-Pulse System, an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure. The C-Pulse System can be implanted using a minimally invasive procedure and is designed to relieve the symptoms of heart failure through the use of counter-pulsation technology, which enables an increase in cardiac output, an increase in coronary blood flow and a reduction in the heart's pumping load. 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 subsidiary presence in Australia. The Company has been listed on the Australian Securities Exchange (ASX) since September 2004 and on the NASDAQ Capital Market since February 2012. For more information, please visit www.sunshineheart.com.

Forward-Looking Statements

Certain statements in this release are forward-looking statements that are based on management's beliefs, assumptions and 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 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 end-points or otherwise fail, that regulatory authorities do not accept our application or approve the marketing of the C-Pulse System, the possibility 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 and ASX. 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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