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# 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

May 10, 2012

Date of report (Date of earliest event reported)

### SUNSHINE HEART, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State of Incorporation)

001-35312

(Commission File Number)

68-0533453

(I.R.S. Employer Identification No.)

12988 Valley View Road

Eden Prairie, Minnesota

(Address of Principal Executive Offices)

55344

(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))
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#### Item 2.02. Results of Operations and Financial Condition.

On May 10, 2012, Sunshine Heart, Inc. (the "Company") reported its financial results for the quarter ended March 31, 2012. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference in this Item 2.02.

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

99.1 Press release, dated May 10, 2012.

2

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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.

SUNSHINE HEART, INC.

Date: May 10, 2012

By: /s/ Jeffrey Mathiesen  
Jeffrey Mathiesen  
Chief Financial Officer

3

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**EXHIBIT INDEX**

<u>No.</u>	<u>Description</u>	<u>Manner of Filing</u>
99.1	Press release, dated May 10, 2012.	Electronic Transmission

4

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## Sunshine Heart Announces 1Q12 Financial Results

### 2012 Off to Solid Start with Achievement of U.S. NASDAQ Listing; Several Regulatory Milestones on the Horizon

**Sydney, Australia and Eden Prairie, MN: May 10, 2012:** Sunshine Heart, Inc. (NASDAQ: SSH / ASX: SHC) today announced financial results for the first quarter ended March 31, 2012.

#### First Quarter Highlights:

- Feasibility data review completed by FDA for C-Pulse® Heart Assist
- SSH commenced trading on NASDAQ Feb. 16th
- SG&A expense totaled \$1.9 million compared to \$0.6 million in 1Q2011
- R&D expense totaled \$2.2 million compared to \$2.3 million in 1Q2011

“Sunshine Heart began 2012 with an exciting first quarter,” said Dave Rosa, Sunshine Heart’s CEO. “We are pleased to have achieved our NASDAQ listing and we made critical progress toward key regulatory approvals during the quarter. With the FDA’s review of our feasibility data behind us, we look forward to the many important milestones on the horizon for the remainder of 2012, most notably CE Mark and IDE approval for our C-Pulse Heart Assist System.”

Operating expenses in the quarter totaled \$4.1 million, up from \$2.9 million in the first quarter of last year. The increase was attributable to higher selling, general and administrative expenses related to the Company’s completion of the NASDAQ listing process, the change in its fiscal year end, and preparation for the Company’s European trials expected to commence later in the second half of 2012. Research and development expenses decreased from the prior year quarter primarily as a result of the timing of certain development activities and clinical trial expenses. As a result, net loss in the quarter was \$4.1 million compared to a loss of \$2.8 million in the first quarter of 2011. This was in line with management’s expectations.

The Company ended the first quarter with a cash balance of \$3.8 million, having raised \$2.1 million during the quarter. Cash used in operating activities in the quarter was \$4.8 million, up from \$2.8 million in the first quarter of 2011. Management expects the cash burn rate in the second quarter 2012 to be lower than in the first quarter 2012.

#### Upcoming milestones:

- CE Mark achievement expected in 2Q12
- IDE approval from the FDA expected in 3Q12
- Announcement of EU site selection commencing in 3Q12

**SUNSHINE HEART, INC.**  
**Condensed Consolidated Unaudited Statements of Operations**  
(In thousands, except per share amounts)

	Three months ended March 31,	
	2012	2011
<b>Net sales</b>	\$ —	\$ —
Cost of goods sold	—	—
<b>Gross profit</b>	—	—
Operating expenses		
Selling, general and administrative	1,940	642
Research and development	2,166	2,292
Total operating expenses	4,106	2,934
<b>Loss from operations</b>	(4,106)	(2,934)
Interest income	25	117
<b>Loss before income taxes</b>	(4,081)	(2,817)
Income tax benefit	—	—
<b>Net loss</b>	\$ (4,081)	\$ (2,817)
Basic and diluted loss per share	\$ (0.66)	\$ (0.55)
Weighted average shares outstanding – basic and diluted	6,169	5,078
<b>Comprehensive loss</b>	\$ (4,027)	\$ (2,752)

(Dollars in thousands, except share amounts)

	Mar 31, 2012	Dec 31, 2012
<b>Current assets</b>		
Cash and cash equivalents	\$ 3,832	\$ 6,563
Other current assets	645	346
<b>Total current assets</b>	<u>4,477</u>	<u>6,909</u>
<b>Property, plant and equipment, net</b>	521	522
<b>TOTAL ASSETS</b>	<u>\$ 4,998</u>	<u>\$ 7,431</u>
<b>Current liabilities</b>		
Accounts payable	\$ 1,647	\$ 1,857
Accrued salaries, wages, and other compensation	402	978
<b>Total current liabilities</b>	<u>2,049</u>	<u>2,835</u>
<b>Total liabilities</b>	<u>2,049</u>	<u>2,835</u>
Commitments and contingencies	—	—
<b>Stockholders' equity</b>		
Preferred Stock as of March 31, 2012 and December 31, 2011, par value \$0.0001 per share; authorized 40,000,000 shares	—	—
Common stock as of March 31, 2012 and December 31, 2011, par value \$0.0001 per share; authorized 100,000,000 shares: issued and outstanding 6,276,538 and 6,018,740 shares, respectively	1	1
Additional paid-in capital	71,032	68,652
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	1,186	1,132
Retained earnings	(69,270)	(65,189)
<b>Total stockholders' equity</b>	<u>2,949</u>	<u>4,596</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 4,998</u>	<u>\$ 7,431</u>

**SUNSHINE HEART, INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(Unaudited)**  
(in thousands)

	For the three months ended March 31,	
	2012	2011
Net loss	\$ (4,081)	\$ (2,817)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	31	9
Loss on disposal of plant and equipment	63	—
Stock-based compensation expense	318	19
Changes in assets and liabilities		
Accounts receivable	—	242
Other current assets	(299)	(80)
Accounts payable and accrued expenses	(800)	(175)
<b>Net cash used in operations</b>	<u>(4,768)</u>	<u>(2,802)</u>
Cash flows used in investing activities:		
Purchases of property and equipment	(89)	(7)
<b>Net cash used in investing activities</b>	<u>(89)</u>	<u>(7)</u>
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	2,061	100
<b>Net cash provided by financing activities</b>	<u>2,061</u>	<u>100</u>
Effect of exchange rate changes in cash	65	90
Net decrease in cash and cash equivalents	(2,731)	(2,619)
<b>Cash and cash equivalents - beginning of period</b>	<u>6,563</u>	<u>12,250</u>
<b>CASH AND CASH EQUIVALENTS - END OF PERIOD</b>	<u>\$ 3,832</u>	<u>\$ 9,631</u>

**About the C-Pulse® Heart Assist System**

The C-Pulse Heart Assist System, an investigational device, utilizes the proven 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 novel extra-aortic approach of the C-Pulse technology offers greater flexibility allowing patients to disconnect as necessary or desired. The C-Pulse system's potential benefits may help reverse the heart failure process or maintain the patient's current condition, which may reduce 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 is a global medical device company committed to the commercialization of the C-Pulse Heart Assist System, an implantable, non-blood contacting, heart assist therapy for the treatment of moderate to severe heart failure which can be implanted using a minimally invasive procedure. C-Pulse is designed to relieve the symptoms of heart failure through the use of

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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. The Company has completed an approved U.S. Food and Drug Administration (FDA) feasibility clinical trial with the C-Pulse System with results presented November 2011. Sunshine Heart is a Delaware corporation headquartered in Minneapolis with a subsidiary presence in Australia. The Company has been listed on the ASX since September 2004 and on NASDAQ beginning February of 2012. For more information, please visit [www.sunshineheart.com](http://www.sunshineheart.com).

### **Forward-Looking Statements**

Certain statements in this report 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 product development and commercialization efforts, results of clinical trials, timing of regulatory filings and approvals, regulatory acceptance of our filings, research and development activities, ultimate clinical outcomes and benefits of our products to patients, market and physician acceptance of the products, intellectual property protection, and potentially competitive product offerings. The risk factors described in our filings with the U.S. Securities and Exchange Commission (SEC) and ASX 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 the C-Pulse Heart System, the possibility we may be unable to raise the funds necessary for the development and commercialization of our products, and those described in our filings with the ASX and SEC. We may update our risk factors from time to time.

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For further information, please contact:

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