
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

July 30, 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 July 30, 2012, Sunshine Heart, Inc. (the "Company") reported its financial results for the quarter and six months ended June 30, 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 July 30, 2012.

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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.

EXHIBIT INDEX

<u>No.</u>	<u>Description</u>	<u>Manner of Filing</u>
99.1	Press release, dated July 30, 2012.	Electronic Transmission



Sunshine Heart Announces 2Q12 Financial Results

Progress on Key Regulatory Milestones

Eden Prairie, MN and Sydney, Australia: July 30, 2012: Sunshine Heart, Inc. (NASDAQ: SSH; ASX: SHC) today announced financial results for the second quarter and six months ended June 30, 2012.

Second Quarter Highlights:

- **Health Canada approves next generation Driver for C-Pulse® Heart Assist System**
- **Substantial progress toward obtaining CE Mark (Achieved in July)**
- **Completed one-year extended follow-up on feasibility study patients**
- **SG&A expense totaled \$1.6 million and \$3.5 million 2Q and YTD 2012 compared to \$1.2 million and \$1.8 million in 2011, respectively**
- **R&D expense totaled \$1.8 million and \$4.0 million 2Q and YTD 2012 compared to \$2.4 million and \$4.7 million in 2011, respectively**
- **\$730,000 Australia R&D tax credit refund received**

“Our second quarter was focused on attaining substantial progress toward achieving key regulatory approvals and laying the groundwork for our post-market trial in Europe,” said Dave Rosa, Sunshine Heart’s CEO. “We are pleased to have achieved CE Mark following the end of the quarter, recognizing the substantial efforts by the Company toward that milestone during the second quarter. As we enter the second half of the year, we remain focused on securing IDE approval for our US FDA pivotal trial and initiating our post-market trial in Europe, beginning in Germany and Italy.”

Operating expenses in the second quarter 2012 totaled \$3.4 million, compared to \$3.6 million in the second quarter of last year and \$4.1 million in the preceding quarter. The decrease was attributable to reduced spending on clinical trials and research and development projects during the period as a result of the timing of certain development activities and clinical trial expenses, partially offset by increased SG&A related to infrastructure development and increased non-cash compensation expense. Operating expenses totaled \$7.5 million in the first six months 2012 compared to \$6.5 million in the prior year’s period. The increase resulted primarily from increased legal, accounting and regulatory expenses associated with the Company’s listing on

Nasdaq in February 2012 and increased non-cash compensation expense. During the second quarter 2012, the Company’s Australian subsidiary received and recognized a \$730,000 research and development tax credit refund related to eligible expenses incurred for the twelve-month tax period ended June 30, 2011. Net loss in the second quarter and year-to-date 2012 was \$2.6 million and \$6.7 million, compared to losses of \$3.5 million and \$6.3 million in 2011, respectively. Current year results are in line with management’s expectations.

The Company ended the second quarter 2012 with a cash balance of \$1.8 million. Cash used in operating activities decreased in the second quarter 2012 and was \$6.8 million in the first six months of 2012, compared to \$6.2 million in 2011.

Upcoming milestones:

- Announcement of EU site selection expected to commence in 3Q12
- IDE approval from the FDA expected in 2H12
- Initiate pivotal trial planned for 2H12

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

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Net sales	\$ —	\$ —	\$ —	\$ —
Cost of goods sold	—	—	—	—
Gross profit	—	—	—	—
Operating expenses				
Selling, general and administrative	1,569	1,178	3,509	1,820
Research and development	1,787	2,374	3,953	4,666
Total operating expenses	3,356	3,552	7,462	6,486
Loss from operations	(3,356)	(3,552)	(7,462)	(6,486)
Interest income	4	80	29	197
Loss before income taxes	(3,352)	(3,472)	(7,433)	(6,289)
Income tax benefit	(730)	—	(730)	—

Net loss	\$ (2,622)	\$ (3,472)	\$ (6,703)	\$ (6,289)
Basic and diluted loss per share	\$ (0.42)	\$ (0.68)	\$ (1.08)	\$ (1.24)
Weighted average shares outstanding — basic and diluted	6,277	5,088	6,223	5,083
Comprehensive loss	\$ (2,610)	\$ (3,352)	\$ (6,637)	\$ (6,104)

SUNSHINE HEART, INC.
Condensed Consolidated Balance Sheets
(Dollars in thousands, except share amounts)

	June 30, 2012 (unaudited)	December 31, 2011
Current assets		
Cash and cash equivalents	\$ 1,772	\$ 6,563
Other current assets	632	346
Total current assets	2,404	6,909
Property, plant and equipment, net	503	522
TOTAL ASSETS	\$ 2,907	\$ 7,431
Current liabilities		
Accounts payable	\$ 1,643	\$ 1,857
Accrued salaries, wages, and other compensation	619	978
Total current liabilities	2,262	2,835
Total liabilities	2,262	2,835
Commitments and contingencies	—	—
Stockholders' equity		
Preferred Stock as of June 30, 2012 and December 31, 2011, par value \$0.0001 per share; authorized 40,000,000 shares	—	—
Common stock as of June 30, 2012 and December 31, 2011, par value \$0.0001 per share; authorized 100,000,000 shares: issued and outstanding 6,277,538 and 6,019,663 shares, respectively	1	1
Additional paid-in capital	71,341	68,652
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	1,195	1,132
Retained earnings	(71,892)	(65,189)
Total stockholders' equity	645	4,596
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 2,907	\$ 7,431

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

	For the six months ended June 30,	
	2012	2011
Net loss	\$ (6,703)	\$ (6,289)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	63	30
Loss on disposal of plant and equipment	63	—
Stock-based compensation expense	621	42
Changes in assets and liabilities		
Accounts receivable	—	223
Other current assets	(286)	(15)
Accounts payable and accrued expenses	(573)	(203)
Net cash used in operating activities	(6,815)	(6,212)
Cash flows used in investing activities:		
Purchases of property and equipment	(107)	(43)
Net cash used in investing activities	(107)	(43)
Cash flows provided by financing activities:		
Net proceeds from the sale of common stock	2,068	183
Net cash provided by financing activities	2,068	183
Effect of exchange rate changes in cash	63	185
Net decrease in cash and cash equivalents	(4,791)	(5,887)
Cash and cash equivalents - beginning of period	6,563	12,350
CASH AND CASH EQUIVALENTS - END OF PERIOD	\$ 1,772	\$ 6,463

The C-Pulse Heart Assist System, an investigational device in the US, 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 Heart Assist 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. We have 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 us that we can move forward with an investigational device exemption (IDE) application. We expect to submit an IDE application to the FDA in the second half of 2012 for approval to initiate our pivotal trial. In July 2012 we received CE Mark for our C-Pulse System. 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 2012. For more information, please visit 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 including within the EU, Latin America and Asia, results of driver evaluation and clinical trials, timing of regulatory filings and approvals and clinical trial activities, 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. These forward-looking statements are subject to numerous risks and uncertainties, including without limitation, the possibility that our clinical trials do not meet their end-points or otherwise fail, 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, 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 (SEC) 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. 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.

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For further information, please contact:

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