
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

November 8, 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 November 8, 2012, we reported our financial results for the quarter and nine months ended September 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 November 8, 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

No.	Description	Manner of Filing
99.1	Press release, dated November 8, 2012.	Electronic Transmission



Sunshine Heart Announces 3Q12 Financial Results

Key Regulatory and Financing Milestones Achieved

Eden Prairie, MN and Sydney, Australia: November 8, 2012: Sunshine Heart, Inc. (NASDAQ: SSH; ASX: SHC) today announced financial results for the third quarter and nine months ended September 30, 2012.

Third Quarter Milestones:

- CE Mark obtained for C-Pulse® Heart Assist System
- Public stock offering totaling \$20.8 million
- Conditional IDE approval for U.S. FDA pivotal trial
- Positive efficacy trends reported in 12-month extended follow-up of feasibility study patients
- Seasoned U.S.-based chairman appointed to Board of Directors

Third Quarter Financial Highlights:

- SG&A expense totaled \$1.5 million in the third quarter and \$5.0 million year-to-date 2012 compared to \$1.4 million and \$3.3 million in 2011, respectively
- R&D expense totaled \$1.8 million in the third quarter and \$5.8 million year-to-date 2012 compared to \$3.3 million and \$7.9 million in 2011, respectively
- \$17.4 million cash balance at September 30, 2012, up from \$6.6 million at December 31, 2011

“Our third quarter was truly transformational,” commented Dave Rosa, Sunshine Heart’s CEO. “I am exceptionally proud of our accomplishments, as we achieved significant regulatory milestones in both the EU and the U.S., and successfully completed our initial U.S. public offering. This financing enables the initiation of our U.S. FDA pivotal trial as well as our European post-market trial. Together, these trials provide the opportunity to gather safety and efficacy patient data on our C-Pulse System as we continue our progress toward commercialization of the device in the U.S. and Europe. We continue to be excited about the potential benefit our device may provide to patients and the ultimate market potential in front of us. Our fourth quarter will be focused on securing unconditional IDE approval for our U.S. FDA pivotal trial and initiating sites in Europe,” concluded Rosa.

Operating expenses in the third quarter 2012 totaled \$3.3 million, compared to \$4.7 million in the third quarter of last year. 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.

Operating expenses totaled \$10.8 million in the first nine months 2012 compared to \$11.2 million in the prior year’s period. The decrease resulted primarily from 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, increased legal, accounting and regulatory expenses associated with the Company’s listing on NASDAQ in February 2012 and increased non-cash compensation expense. The Company’s year-to-date results reflect a \$730,000 research and development tax credit refund by the Company’s Australian subsidiary related to eligible expenses incurred for the twelve-month tax period ended June 30, 2011, which was received and recognized in the second quarter of 2012.

Net loss in the third quarter and year-to-date 2012 was \$3.3 million and \$10.0 million, compared to losses of \$4.7 million and \$11.0 million in 2011, respectively. Current year results are consistent with management’s expectations.

The Company ended the third quarter 2012 with a cash balance of \$17.4 million compared to \$6.6 million at December 31, 2011. Cash used in operating activities was \$9.7 million in each the first nine months of 2012 and 2011.

Upcoming milestones:

- Announcement of EU site selection for post-marketing trial for the C-Pulse System expected to commence in the fourth quarter of 2012
- Unconditional IDE approval from the FDA expected in the fourth quarter of 2012
- Initiation of pivotal trial planned for the fourth quarter of 2012

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

Three months ended September 30,	Nine months ended September 30,
2012	2011
2012	2011

Net sales	\$	—	\$	—	\$	—	\$	—
Cost of goods sold		—		—		—		—
Gross profit		—		—		—		—
Operating expenses								
Selling, general and administrative		1,495		1,430		5,004		3,250
Research and development		1,802		3,273		5,755		7,939
Total operating expenses		3,297		4,703		10,759		11,189
Loss from operations		(3,297)		(4,703)		(10,759)		(11,189)
Interest income		1		31		30		228
Loss before income taxes		(3,296)		(4,672)		(10,729)		(10,961)
Income tax benefit		—		—		(730)		—
Net loss	\$	(3,296)	\$	(4,672)	\$	(9,999)	\$	(10,961)
Basic and diluted loss per share	\$	(0.42)	\$	(0.84)	\$	(1.49)	\$	(2.09)
Weighted average shares outstanding — basic and diluted		7,789		5,582		6,727		5,249
Comprehensive loss	\$	(3,308)	\$	(4,812)	\$	(9,948)	\$	(10,916)

Condensed Consolidated Balance Sheets
(Dollars in thousands, except share amounts)

	September 30, 2012 (unaudited)	December 31, 2011
Current assets		
Cash and cash equivalents	\$ 17,446	\$ 6,563
Other current assets	667	346
Total current assets	18,113	6,909
Property, plant and equipment, net	493	522
TOTAL ASSETS	\$ 18,606	\$ 7,431
Current liabilities		
Accounts payable	\$ 1,590	\$ 1,857
Accrued salaries, wages, and other compensation	681	978
Total current liabilities	2,271	2,835
Total liabilities	2,271	2,835
Commitments and contingencies	—	—
Stockholders' equity		
Preferred Stock as of September 30, 2012 and December 31, 2011, par value \$0.0001 per share; authorized 40,000,000 shares	—	—
Common stock as of September 30, 2012 and December 31, 2011, par value \$0.0001 per share; authorized 100,000,000 shares; issued and outstanding 9,247,388 and 6,019,663 shares, respectively	1	1
Additional paid-in capital	90,339	68,652
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	1,183	1,132
Retained earnings	(75,188)	(65,189)
Total stockholders' equity	16,335	4,596
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 18,606	\$ 7,431

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	For the nine months ended September 30,	
	2012	2011
Cash flows used in operating activities:		
Net loss	\$ (9,999)	\$ (10,961)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Depreciation and amortization	98	25
Loss on disposal of plant and equipment	63	6
Stock-based compensation expense	907	555
Expense for warrants issued in conjunction with service agreement	160	—
Changes in assets and liabilities		
Accounts receivable	—	259
Other current assets	(321)	(24)
Accounts payable and accrued expenses	(574)	480
Net cash used in operations	(9,666)	(9,660)
Cash flows used in investing activities:		
Purchases of property and equipment	(132)	(34)
Net cash used in investing activities	(132)	(34)
Cash flows provided by financing activities:		

Net proceeds from the sale of common stock	20,620	7,650
Net cash provided by financing activities	20,620	7,650
Effect of exchange rate changes in cash	61	38
Net increase (decrease) in cash and cash equivalents	10,883	(2,006)
Cash and cash equivalents - beginning of period	6,563	12,350
CASH AND CASH EQUIVALENTS - END OF PERIOD	\$ 17,446	\$ 10,344

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 conditional approval from the FDA in September 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 product development, commercialization efforts and future clinical trial activities and results. 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 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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