ASX ANNOUNCEMENT
2 September 2009

HeartWare International, Inc.
Suspension of Quotation

Framingham, MA and Sydney, Australia, September 2, 2009 – On September 1, 2009, quotation of HeartWare International, Inc.'s (NASDAQ: HTWR) (ASX: HIN) CHESS Depositary Interests ("CDI's") on the Australian Securities Exchange ("ASX") was suspended for the reasons stated below.

On August 14, 2009, the Company filed with ASX its ASX Appendix 4D and attached its Quarterly Report on Form 10-Q for the 3 and 6 month period ended June 30, 2009 ("Quarterly Report"). The Quarterly Report is prepared under U.S. generally accepted accounting principles and otherwise in compliance with the requirements of the Securities Exchange Act of 1934, as amended.

As permitted by ASX Listing Rules, the Company is entitled to file its Quarterly Report with the ASX for the purposes of satisfying certain Australian financial reporting requirements. However, it is a requirement of the ASX Listing Rules that the Company's independent public accountant, Grant Thornton LLP, provide an audit report in connection with its Quarterly Report (where no such equivalent requirement exists under U.S. law).

In filings its Quarterly Report with the ASX, this audit report was omitted and, in consequence, quotation of the Company's securities on the ASX was suspended yesterday.

In accordance with the above, attached is HeartWare's ASX Appendix 4D and Quarterly Report (both of which are unchanged), together with Grant Thornton's audit report (see the final page of this attachment).

Filing of Grant Thornton's audit report does not impact or otherwise affect the Company's results, operations or disclosures as set out in the Quarterly Report and no changes have been made therein. The Company believes that the Quarterly Report fully complies with the requirements of the Securities Exchange Act of 1934, as amended and, in accordance with generally accepted accounting practice, that it fairly presents, in all material respects, the financial condition and results of operations of the Company as at the relevant dates.

About HeartWare International - HeartWare International develops and manufactures miniaturized implantable heart pumps, or left ventricular assist devices, to treat Class IIIb and

Class IV patients suffering from advanced heart failure. The HeartWare® Ventricular Assist System features the HVAD™ pump, a small full-output circulatory support device (up to 10L/min flow) designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. HeartWare has received CE Marking for the HeartWare® Ventricular Assist System in the European Union. The device is currently the subject of a 150-patient clinical trial in the United States for a Bridge-to-Transplant indication.

HeartWare International, Inc. is a member of the Russell 2000(R) and its securities are publicly traded on The NASDAQ Stock Market.

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Forward-Looking Statements

This announcement contains forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management. All statements that address 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 the progress of clinical trials. 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.

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. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in "Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the SEC on February 28, 2008, and those described in other reports filed from time to time with the SEC.

HeartWare International, Inc.

ARBN 132 897 762

and its controlled entities

ASX APPENDIX 4D
HALF-YEAR FINANCIAL REPORT
For the 6 Months Ended
30 June 2009
provided pursuant to ASX Listing Rule 4.2A.

This is the Half-Year Report for the HeartWare Group. The HeartWare Group includes HeartWare International, Inc. (ASX:HIN, NASDAQ:HTWR) and its subsidiaries HeartWare Pty. Limited and HeartWare, Inc.

The HeartWare Group relies on relief available under ASIC Class Order 98/1418, and as such, will lodge its financial results for the half-year ended 30 June 2009, in the form of United States Securities and Exchange Commission ("SEC") Quarterly Report Form 10-Q, which includes financial results for the three and six months ended 30 June 2009, prepared in accordance with United States Generally Accepted Accounting Principles (copy attached).

This Half-Year Report does not include all of the commentary, notes and information that are typically found in an annual financial report. Accordingly, this Half-Year Report should be read in conjunction with any public announcements made by the Company during the half-year in either the United States of America or Australia (all of which are available on the Company's website (www.heartware.com) .

This Half-Year Report provides information as required by Appendix 4D of the ASX Listing Rules.

All amounts in this report are denominated in United States dollars unless otherwise indicated.

HEARTWARE INTERNATIONAL, INC. (ARBN 132 897 762)
& CONTROLLED ENTITIES

RESULTS FOR ANNOUNCEMENT TO THE MARKET

Important information concerning the financial results for the half-year ended 30 June 2009

The HeartWare Group relies on relief available under ASIC Class Order 98/1418, and as such, this report and accompanying financial results on United States Securities and Exchange Commission ("SEC") Quarterly Report on Form 10-Q ("Form 10-Q") are prepared in accordance with United States Generally Accepted Accounting Principles.

The financial results set out in this Half-Year Report and the attached Interim Financial Report on SEC Form 10-Q are the consolidated financial results for the HeartWare Group, being HeartWare International, Inc., ("the Company"), HeartWare Pty. Limited and its subsidiary, HeartWare, Inc.

All amounts in this report are denominated in United States dollars unless otherwise indicated.

Review of Operations and Earnings Results for the Half-Year Ended 30 June 2009

The net loss of the HeartWare Group for the half-year ended 30 June 2009 after providing for income tax was $13,123,439 (2008:$14,935,611). The decrease in the net loss reflects an increase in overall expenses related to continuing research and development of our circulatory devices or "heart pumps", the expansion of our clinical trial in the US and a commercial roll out in Europe of the HeartWare Left Ventricular Assist Device, partly offset by revenue generated for the half-year ended 30 June 2009 for this device. The Company did not generate revenue in the half-year ended 30 June 2008.

	Half-Year Ended 30 June 2009 US$	Half-Year Ended 30 June 2008 US$	Increase / (Decrease) %
Revenues from ordinary activities	$4,446,243	-	N/A
Profit / (Loss) from ordinary activities after tax attributable to members	($13,123,439)	($14,935,611)	(12%)
Net profit / (Loss) for the period attributable to members	($13,123,439)	($14,935,611)	(12%)

NET TANGIBLE ASSETS PER SECURITY

	Half-Year Ended 30 June 2009 US$	Half-Year Ended 30 June 2008 US$
Net tangible assets per share of HeartWare International, Inc. common stock	$2.45	$4.16

COMMENTARY TO THE EARNINGS RESULT

A detailed discussion of our earnings results can be found in the section titled "*Management Discussion and Analysis"* of the attached SEC Form 10-Q

Dividends

The Directors do not recommend that a dividend relating to the interim period ended 30 June 2009 be paid. As such, there is no franking or applicable record date.

COMPLIANCE STATEMENT

The attached interim financial report is not subject to audit dispute or qualification. This Half-Year Report is based on the attached SEC Form 10-Q and has been subject to review procedures as required by the US Securities and Exchange Commission. HeartWare has a formally constituted audit committee.

Please find attached the Company's US SEC Quarterly Report on Form 10-Q for the six months ended 30 June 2009.

Rob Thomas
Chairman
14 August 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☑ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended June 30, 2009

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 001-34256

HEARTWARE INTERNATIONAL, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-3636023**
(State of Incorporation)	(I.R.S. Employer Identification No.)

205 Newbury Street, Suite 101
Framingham, Massachusetts 01701
+1 508 739 0950
(Address of principal executive offices)
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☑

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Shares Outstanding as of July 31, 2009
Common Stock, $0.001 Par Value Per Share	8,949,448

References

Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to:

- "HeartWare," "the Company," "HeartWare Group," "we," "us" and "our" refer to HeartWare International, Inc. and its consolidated subsidiaries, HeartWare Pty. Limited and HeartWare, Inc.
- "HeartWare International, Inc." refers to HeartWare International, Inc., a Delaware corporation incorporated on July 29, 2008.
- "HeartWare Pty. Limited" refers to HeartWare Pty. Limited, an Australian proprietary corporation.
- "HeartWare, Inc." refers to HeartWare, Inc., a Delaware corporation incorporated on April 3, 2003. HeartWare, Inc. was acquired by HeartWare Limited on January 24, 2005.

Dollars

Unless indicated otherwise in this Form 10-Q, all references to "$", "US$" or "dollars" refer to United States dollars, the lawful currency of the United States of America. References to "AU$" refer to Australian dollars, the lawful currency of the Commonwealth of Australia.

Trademarks

HeartWare, the HeartWare® Ventricular Assist System, HVAD™ and MVAD™ are the trademarks of HeartWare, Inc., in the United States, Australia and other countries. All other trademarks and trade names mentioned in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	June 30, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,925,450	$ 20,803,656
Accounts receivable	2,574,257	244,198
Inventories, net	8,353,463	3,508,065
Prepaid expenses and other current assets	1,254,615	1,061,737
Total current assets	18,107,785	25,617,656
Property, plant and equipment, net	3,521,214	3,608,626
Other intangible assets, net	1,075,437	823,495
Restricted cash	288,429	288,429
Total Assets	$ 22,992,865	$ 30,338,206
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,034,582	$ 699,064
Accrued expenses and other current liabilities	4,639,664	2,883,587
Total current liabilities	7,674,246	3,582,651
Commitments and contingencies		
Shareholders' equity:		
Preferred stock — $.001 par value; 5,000,000 shares authorized; no shares issued and outstanding at June 30, 2009 and December 31, 2008	—	—
Common stock — $.001 par value; 25,000,000 shares authorized; 8,929,809 and 8,866,702 shares issued and outstanding at June 30, 2009 and December 31, 2008, respectively	8,930	8,867
Additional paid-in capital	113,332,723	112,400,642
Accumulated deficit	(90,086,226)	(76,962,787)
Accumulated other comprehensive (loss):		
Cumulative translation adjustments	(7,936,808)	(8,691,167)
Total Shareholders' Equity	15,318,619	26,755,555
Total Liabilities and Shareholders' Equity	$ 22,992,865	$ 30,338,206

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenues, net	$ 2,968,447	$ —	$ 4,446,243	$ —
Cost of revenues	1,579,421	—	2,297,729	—
Gross profit	1,389,026	—	2,148,514	—
Operating expenses:				
Selling, general and administrative	4,372,200	2,625,098	8,571,863	4,812,723
Research and development	2,858,514	5,070,212	6,348,294	9,322,927
Total operating expenses	7,230,714	7,695,310	14,920,157	14,135,650
Loss from operations	(5,841,688)	(7,695,310)	(12,771,643)	(14,135,650)
Foreign exchange (loss)	(1,060,206)	(547,321)	(367,658)	(1,270,623)
Interest income, net	11,793	237,003	18,549	562,774
Other, net	(655)	(89,872)	(2,687)	(92,112)
Loss before income taxes	(6,890,756)	(8,095,500)	(13,123,439)	(14,935,611)
Provision for income taxes	—	—	—	—
Net loss	$ (6,890,756)	$ (8,095,500)	$(13,123,439)	$(14,935,611)
Loss per common share — basic and diluted	$ (0.78)	$ (1.14)	$ (1.48)	$ (2.11)
Weighted average shares outstanding — basic and diluted	8,876,398	7,088,579	8,871,685	7,088,579

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2009	2008	2009	2008
Net loss	$ (6,890,756)	$ (8,095,500)	$ (13,123,439)	$ (14,935,611)
Foreign currency translations	1,340,919	848,215	754,359	1,838,715
Comprehensive loss	$ (5,549,837)	$ (7,247,285)	$ (12,369,080)	$ (13,096,896)

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY
(unaudited)

	Common Shares		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss)	Total
	Shares Issued	Amount				
Balance December 31, 2008	8,866,702	$ 8,867	$112,400,642	$ (76,962,787)	$ (8,691,167)	$ 26,755,555
Issuance of common shares pursuant to stock option exercise	63,107	63	431,481	—	—	431,544
Share-based compensation	—	—	500,600	—	—	500,600
Net loss	—	—	—	(13,123,439)	—	(13,123,439)
Accumulated other comprehensive (loss):						
Foreign currency translation adjustment	—	—	—	—	754,359	754,359
Balance June 30, 2009	8,929,809	$ 8,930	$113,332,723	$ (90,086,226)	$ (7,936,808)	$ 15,318,619

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Six Months Ended June 30,	
	2009	**2008**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(13,123,439)	$(14,935,611)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	421,816	293,768
Amortization	34,785	13,983
Share-based compensation expense	500,600	369,954
Loss on disposal of assets	2,687	92,112
Accrued interest on convertible note	—	5,047
Change in operating assets and liabilities:		
Accounts receivable	(2,330,059)	—
Inventories, net	(4,845,398)	—
Prepaid expenses and other current assets	47,602	(52,280)
Accounts payable	2,451,256	159,009
Accrued expenses and other current liabilities	1,745,068	719,771
Net cash used in operating activities	(15,095,082)	(13,334,247)
CASH FLOWS FROM INVESTING ACTIVITIES		
Additions to property, plant and equipment	(335,531)	(992,939)
Additions to patents	(286,727)	(125,273)
Cash paid for security deposits	—	(288,429)
Net cash used in investing activities	(622,258)	(1,406,641)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of stock options	112,062	—
Net cash provided by financing activities	112,062	—
Effect of exchange rate changes on cash	727,072	1,933,461
INCREASE IN CASH AND CASH EQUIVALENTS	(14,878,206)	(12,807,427)
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD	20,803,656	28,276,388
CASH AND CASH EQUIVALENTS — END OF PERIOD	$ 5,925,450	$ 15,468,961

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Basis of Presentation

Interim Financial Statements

The accompanying unaudited interim condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (the "SEC") for reporting of interim financial information. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted. Accordingly, these statements do not include all the disclosures normally required by accounting principles generally accepted in the United States for annual financial statements and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited financial statements and notes thereto for the year ended December 31, 2008 included in our Annual Report on Form 10-K and as amended by Amendment No. 1 on Form 10-K/A. The condensed consolidated statements of operations and cash flows for the three and six months ended June 30, 2009 are not necessarily indicative of the results to be expected for any future period or for the year ending December 31, 2009.

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments (consisting of only normally recurring adjustments) necessary to present fairly the financial position and results of operations as of the dates and for the periods presented.

Development Stage

We develop, manufacture and sell implantable heart pumps for the treatment of congestive heart failure. From inception, November 26, 2004, through the end of fiscal year 2008, activities had primarily been focused on the research and development of these devices. However, in September 2008, we received a full Investigational Device Exemption from the U.S. Food and Drug Administration (the "FDA") for the HeartWare Left Ventricular Assist System (the "HeartWare System") and subsequently began selling the product through our US clinical trial. In January 2009, we received Conformite Europenne ("CE") Marking for the HeartWare System, which allows us to sell the device in Europe.

In accordance with Statement of Financial Accounting Standards No. 7 ("SFAS 7"), *Accounting and Reporting by Development Stage Enterprise,* entities that have not commenced planned principal operations or that have commenced planned principal operations but have no significant revenue from such activities are deemed a development stage entity. As we have commenced planed principal operations and generated significant revenues from these activities through June 30, 2009, we have determined that we are no longer a development stage entity and as such our financial statements are no longer presented on a development stage basis.

Subsequent Events

As reported in a Current Report on Form 8-K filed with the SEC on August 10, 2009, we entered into certain Securities Purchase Agreements (the "Purchase Agreements") separately with a number of institutional and sophisticated investors for the private placement of approximately 2.73 million shares of our common stock at an issue price of $22.00 per share for aggregate gross proceeds of approximately $60.0 million (the "Private Placement"). The placement agent for the transaction received a placement fee of approximately 2% of the gross proceeds.

The Purchase Agreements obligate us to file a registration statement with the SEC registering the shares of common stock issued to investors under the Purchase Agreements. Further, our obligation to issue approximately 1.39 million shares of our common stock in the Private Placement is conditioned upon obtaining shareholder approval as required under the Nasdaq Stock Market Rules and the Australian Securities Exchange Listing Rules. The meeting of shareholders is expected to occur on a date prior to December 15, 2009.

On July 31, 2009, HeartWare International, Inc. and Thoratec Corporation ("Thoratec") mutually agreed to terminate the Agreement and Plan of Merger ("Merger Agreement"), dated February 12, 2009, pursuant to Section 8.01 (a) of the agreement. The decision to terminate the Merger Agreement was made in response to a determination by the United States Federal Trade Commission to file a complaint in US Federal District Court challenging Thoratec's proposed acquisition of HeartWare. A description of the terms of the Merger Agreement was included in the Current Report on Form 8-K as filed by HeartWare with the SEC on February 13, 2009. All costs associated with the merger have been expensed in the financial statements as incurred.

Concurrent with the Merger Agreement, and as described in a Current Report on Form 8-K filed with the SEC on February 13, 2009, we entered into a Loan Agreement ("Loan Agreement") with Thoratec, pursuant to which Thoratec committed to loan us up to $28.0 million through one or more term loans subject to the terms and conditions set forth in the Loan Agreement. The Loan Agreement survives the termination of the Merger Agreement and as of July 31, 2009, we were able to borrow up to $20.0 million under the Loan Agreement. The funds have been deposited into an escrow account to support the commitment. The additional $8.0 million was only to become available if Thoratec exercised an option to extend the Merger Agreement to the outside date for the completion of the proposed merger of January 31, 2010. As the Merger Agreement has been terminated those additional funds will not be available.

The loans to us under the Loan Agreement accrue interest at the rate of 10% per annum. Accrued interest on any amounts outstanding is payable quarterly on March 31, June 30, September 30 and December 31. The loans are due and payable, together with accrued and unpaid interest, on the earlier of (i) November 1, 2011, (ii) the Termination Date, as defined in the Loan Agreement, and (iii) the date on which all of the loans accelerate and become due and payable in full in accordance with the Loan Agreement. The loans may accelerate upon a change in control of the borrower or events of default, all as defined in the Loan Agreement.

The loans, at Thoratec's option, may be converted in whole or in part into shares of HeartWare International common stock prior to the maturity date of the loans subject to a waiting period provided by the Hart-Scott-Rodino Antitrust Improvements Act. In addition, beginning July 31, 2009, the date the Merger Agreement was terminated, Thoratec may convert any escrow funds in whole or in part into shares of HeartWare International common stock at any time prior to termination of the Loan Agreement subject to a waiting period provided by the Hart-Scott-Rodino Antitrust Improvements Act. The number of shares to be issued is determined by dividing the outstanding principal amount of the loans, including any accrued and unpaid interest, or escrow funds by the US dollar equivalent of AU$35.00 at the time of the conversion, which is subject to customary adjustment provisions as defined in the Loan Agreement. For so long as HeartWare International's CHESS Depositary Interests are listed on the Australian Securities Exchange, the loans and escrow funds may not be converted into more than 14.99% in the aggregate of the then authorized and outstanding shares of HeartWare International common stock.

As of June 30, 2009, we had no amounts outstanding under the Loan Agreement. On August 5, 2009, we borrowed $4.0 million under the Loan Agreement.

We have evaluated events and transactions that occurred subsequent to June 30, 2009 through August 14, 2009, the date the financial statements were issued, for potential recognition or disclosure in the accompanying financial statements. Other than the disclosures above, we did not identify any events or transactions that should be recognized or disclosed in the accompanying financial statements.

2. Liquidity

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States, which contemplate continuation as a going concern. We have sustained substantial losses from operations since our inception, and such losses have continued through June 30, 2009. At June 30, 2009, we had an accumulated deficit of approximately $90.1 million.

As mentioned in Note 1 above, on August 10, 2009, we entered into Purchase Agreements for the private placement of approximately 2.73 million shares of our common stock at an issue price of $22.00 per share for aggregate gross proceeds of approximately $60.0 million. The placement agent for the transaction received a placement fee of approximately 2% of the gross proceeds. Our obligation to issue approximately 1.39 million shares of our common stock in the Private Placement is conditioned upon obtaining shareholder approval and as such a portion of the proceeds will be held in escrow until such time as approval is obtained.

In addition, as mentioned in Note 1 above, on February 12, 2009, we entered into a Loan Agreement concurrent with the Merger Agreement with Thoratec. As of July 31, 2009, we were able to borrow up to an aggregate of $20.0 million under the Loan Agreement and on August 5, 2009 we borrowed $4.0 million of those funds under the terms of the Loan Agreement. In the remainder of 2009, cash on hand, cash received from the Private Placement and borrowings under the Loan Agreement will primarily be applied for the purposes of meeting expected costs associated with establishing a European sales infrastructure, expanding our human clinical trials, continued product development, regulatory and other compliance costs as well as for general working capital. We believe cash on hand, cash received from the Private Placement and cash available under the Loan Agreement are sufficient to support our planned operations throughout 2009 and 2010.

3. Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of HeartWare International, Inc., and its subsidiaries HeartWare Pty. Limited and HeartWare, Inc. All inter-company balances and transactions have been eliminated in consolidation.

Accounting Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("US GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are recorded in the consolidated balance sheets at cost, which approximates fair value. All highly liquid investments purchased with an original maturity of three months or less are considered to be cash equivalents. We maintain the majority of our cash and cash equivalents in Australia, denominated in both Australian and United States dollars. As of June 30, 2009 and December 31, 2008, there was approximately $4.7 million and $17.9 million, respectively, maintained in banks in Australia, as translated into US dollars at the spot rate at the end of the respective period.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost basis which approximates the FIFO method. Work-in-process and finished goods include direct and indirect labor and manufacturing overhead. Provision is made to reduce excess and obsolete inventories to net realizable value.

Prior to September 1, 2008, all costs associated with manufacturing the HeartWare System were included in research and development expense. Effective September 1, 2008, we began to capitalize in inventory the costs of manufacturing. At that time, we had product on hand that had been previously expensed, which is subsequently being utilized in the production and sale of finished goods. Until we sell all inventories for which costs were previously expensed, the carrying value of our inventories and related cost of revenues do not include the cost of this previously expensed inventory. We could be required to expense capitalized costs of the HeartWare System in the event of a denial or delay of approval by US or European regulatory bodies, a delay in commercialization, or other potential factors.

All costs associated with developing and manufacturing products other than the HeartWare System are included in research and development expense.

Property, Plant and Equipment

Property, plant and equipment and leasehold improvements are recorded at historical cost. Expenditures for maintenance and repairs are charged to expense; additions and improvements are capitalized. Depreciation is generally calculated using the straight-line method at rates that approximate the estimated useful lives of the assets. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful life of the improvement or the remaining term of the lease.

Share-Based Payments

We elected to early adopt SFAS No. 123(R), *Share-Based Payment*, effective January 1, 2005. We use a Black-Scholes option pricing method. Under the fair value recognition provisions of SFAS No. 123(R), we recognize share-based compensation net of an estimated forfeiture rate and therefore only recognize compensation cost for those shares expected to vest over the service period of the award.

Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of the expected life of the option, share price volatility and a forfeiture rate.

We estimate the volatility of our shares on the date of grant based on the historical volatility of our publicly-traded shares. When appropriate, we estimate the expected life of an option based upon the simplified method provided under SEC Staff Accounting Bulletin (SAB) No. 110. Under SAB No. 110, the expected life is developed by averaging the contractual term of the stock option grants (up to 10 years) with the associated vesting term (typically 4 years). We estimate the risk-free interest rate based on rates in effect for Australian Government bonds, with similar lives, at the time of grant. We estimate the forfeiture rate based on our historical experience of forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, the share-based compensation expense could be significantly different from what we have recorded in the current period.

The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we are required to use different assumptions, our share-based compensation expense could be materially different in the future.

Impairment of Long-Lived Assets

We review our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable from future undiscounted cash flows. Impairment losses are recorded for the excess, if any, of the carrying value over the fair value of the long-lived assets. As of June 30, 2009, no indicators of impairment existed.

Income Taxes

Income taxes are accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes*, as clarified by FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN No. 48"). Under this method, deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax basis of assets and liabilities given the provisions of enacted tax laws. Deferred income tax provisions and benefits are based on changes to the assets or liabilities from year to year. In providing for deferred taxes, we consider tax regulations of the jurisdictions in which we operate, estimates of future taxable income and available tax planning strategies. If tax regulations, operating results or the ability to implement tax-planning strategies varies, adjustments to the carrying value of the deferred tax assets and liabilities may be required. Valuation allowances are based on the "more likely than not" criteria of SFAS No. 109.

FIN No. 48 requires that we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Translation of Foreign Currency

Assets and liabilities of non-US entities are translated at the period-end exchange rate and revenues and expenses are translated at the average exchange rates in effect during the respective periods. Equity transactions are translated at rates in effect at the time of the transactions. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of shareholders' equity, titled "Accumulated Other Comprehensive (Loss)." Items in Accumulated Other Comprehensive (Loss) are not tax affected as we have incurred a net loss in each period since inception.

HeartWare Pty. Limited, our Australian subsidiary, operates in a functional currency of Australian dollars and holds US dollar cash accounts. Exchange rate fluctuations affect the value of these accounts and may result in foreign currency gains and losses. Such gains and losses are included in the consolidated statements of operations. Any such gains and losses are initially recognized as they occur in AU$ and then converted to US$ at an average exchange rate.

The exchange rate between the US and Australian dollar has fluctuated substantially in the past. This fluctuation has resulted in significant changes in the period end cumulative translation adjustments and foreign exchange gains and losses for those periods.

Research and Development

Research and development costs, including new product development programs, regulatory compliance and clinical research, are expensed as incurred.

Vendor Concentration

For the three and six months ended June 30, 2009, we purchased approximately 76% and 64%, respectively, of our inventory components and supplies from three vendors. In addition, one of the three vendors supplies consulting services and material used in research and development activities. As of June 30, 2009, the amounts due to these vendors totaled approximately $302,000.

Marketing and Advertising Costs

Marketing, advertising and promotional costs are expensed when incurred.

Net Loss Per Common Share

Basic loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period, with the number of shares outstanding for the 2008 period adjusted to reflect the reverse split consummated in November 2008. Diluted loss per common share is computed by dividing net loss for the period by the weighted average number of common shares outstanding during the period, plus the dilutive effect of common share equivalents, such as options. Due to the net loss for all periods presented, all common share equivalents were excluded because their inclusion would have been anti-dilutive.

New Accounting Standards

In June 2009, the FASB issued SFAS No. 168, *The FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles — a replacement of FASB Statement No. 162*, which establishes the FASB Accounting Standards Codification (the "Codification") as the single source of authoritative nongovernmental US GAAP. The Codification will be effective for interim and annual periods ending after September 15, 2009. After the Codification launch on July 1, 2009 only one level of authoritative US GAAP will exist, other than guidance issued by the SEC. All other accounting literature excluded from the Codification will be considered non-authoritative. We do not expect the adoption of the provisions of SFAS No. 168 to have a material impact on our consolidated financial position, results of operations or cash flows.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events*, which establishes general standards of accounting for and disclosure of events that occur after the balance sheet date but before the financial statements are issued or are available to be issued. In particular, SFAS No. 165 sets forth:

- the period after the balance sheet date during which management should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements;
- the circumstances under which we should recognize events or transactions occurring after the balance sheet date in our financial statements; and
- the disclosures that we should make about events or transactions that occur after the balance sheet date, but before the financial statements are issued or are available to be issued.

SFAS No. 165 requires disclosure of the date through which an entity has evaluated subsequent events, as well as whether that date is the date the financial statements were issued or the date the financial statements were available to be issued. We adopted the provisions of SFAS No. 165 for the interim period ended June 30, 2009, which did not have a material impact on our consolidated financial position, results of operations or cash flows.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations,* and SFAS No. 160, *Non-controlling Interests in Consolidated Financial Statements*. SFAS No. 141(R) and SFAS No. 160 introduce significant changes in the accounting for and reporting of business acquisitions and non-controlling interests in a subsidiary. SFAS No. 141(R) continues the movement toward the greater use of fair values in financial reporting and increased transparency through expanded disclosures. SFAS No. 141(R) changes how business acquisitions are accounted for and will impact financial statements at the acquisition date and in subsequent periods. In addition, SFAS No. 141(R) will impact the annual goodwill impairment test associated with acquisitions that close both before and after its effective date. SFAS No. 141(R) and SFAS No. 160 apply prospectively to fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. An entity may not apply SFAS No. 141(R) or SFAS No. 160 before that date. We adopted the provisions of these statements on January 1, 2009, which did not have a material impact on our consolidated financial position, results of operations or cash flows.

In April 2009, the FASB issued Staff Position ("FSP") FAS 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies* ("FAS 141(R)-1"). This FSP amends and clarifies SFAS No. 141R and applies to assets acquired and liabilities assumed that arise from contingencies in a business combination. FAS 141(R)-1 must also be applied prospectively to business combinations consummated on or after the first annual reporting period beginning on or after December 15, 2008. We adopted the provisions of FAS 141(R)-1 on January 1, 2009, which did not have a material impact on our consolidated financial position, results of operations or cash flows.

In February 2008, the FASB issued FSP FAS 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement* under Statement 13, which scopes out leasing transactions accounted for under SFAS No. 13, *Accounting for Leases* ("FAS 157-1") . In February 2008, FSP FAS 157-2, *Effective Date of FASB Statement No. 157*, was issued, which delays the effective date of SFAS No. 157 to fiscal years and interim periods within those fiscal years beginning after November 15, 2008 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The implementation of SFAS No. 157 did not have a material impact on our consolidated financial position, results of operations or cash flows.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*. SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under SFAS No. 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. We adopted the provisions of SFAS No. 161 on January 1, 2009, which did not have a material impact on our consolidated financial position, results of operations or cash flows.

In April 2008, the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets* ("FAS 142-3"). FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets* ("SFAS No. 142"). The objective of FAS 142-3 is to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141 (Revised 2007), *Business Combinations* and other US GAAP. FAS 142-3 is effective for fiscal years beginning after December 15, 2008. We adopted the provisions of FAS 142-3 on January 1, 2009, which did not have a material impact on our consolidated financial position, results of operations or cash flows.

4. Inventories, Net

Components of inventories, net are as follows:

	June 30, 2009	December 31, 2008
Raw material	$ 1,831,500	$ 813,276
Work-in-process	2,531,415	1,690,852
Finished goods	3,990,548	1,003,937
	$ 8,353,463	$ 3,508,065

5. Property, Plant and Equipment, Net

Property, plant and equipment, net consists of the following:

Property, Plant and Equipment	Useful Lives	June 30, 2009	December 31, 2008
Machinery and equipment	5 to 7 years	$ 4,643,979	$ 4,428,452
Leasehold improvements	3 to 7 years	219,301	212,891
Office equipment, furniture and fixtures	5 to 7 years	305,558	271,275
Software	5 to 7 years	491,435	406,983
		5,660,273	5,319,601
Less: accumulated depreciation		(2,139,059)	(1,710,975)
		$ 3,521,214	$ 3,608,626

6. Other Intangible Assets

The gross carrying amount of intangible assets and the related accumulated amortization for intangible assets subject to amortization are as follows:

		June 30, 2009		December 31, 2008	
Amortizable Intangible Assets	Life (Years)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents	15	$ 1,199,078	$ (123,641)	$ 912,351	$ (88,856)

Estimated amortization expense for the succeeding five fiscal years based on the intangible asset portfolio at June 30, 2009 is as follows:

Remainder of 2009	$ 39,970
2010	79,939
2011	79,939
2012	79,939
2013	79,939
2014	79,939

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

Accrued expenses and other current liabilities	June 30, 2009	December 31, 2008
Accrued payroll and other employee costs	$ 1,039,092	$ 1,721,506
Accrued material purchases	30,851	417,344
Accrued research and development expenses	1,183,357	494,997
Accrued professional fees	2,243,835	149,146
Other accrued expenses	142,529	100,594
	$ 4,639,664	$ 2,883,587

8. Equity Incentive Plans

We have issued share-based payment awards to employees, non-executive directors and outside consultants through various approved plans and outside of any formal plan. New shares are issued upon the exercise of equity awards.

On November 13, 2008, we completed an Australian court approved redomiciliation, whereby the ultimate parent company of the HeartWare Group became a US Company, HeartWare International, Inc. As part of the redomiciliation all share-based plans of HeartWare Limited (since renamed HeartWare Pty. Limited) were cancelled and new plans were formed under HeartWare International, Inc. All awards outstanding at the time of the redomiciliation were cancelled and reissued by HeartWare International, Inc. The awards were issued on the same terms and conditions with the only exception being the number of shares and exercise prices were adjusted to reflect a reverse split in the ratio of 35 to 1 and any fractional shares were rounded down. The reverse split had no impact on the valuation of the grants and therefore did not result in any additional compensation. To date, the exercise prices of all grants have been denominated in Australian dollars; the amounts below have been translated to US dollars.

On February 24, 2009, HeartWare International's common shares were listed for quotation on The NASDAQ Stock Market. No modifications have been made to the share-based payment awards pursuant to this listing.

A detailed discussion of share-based payment awards granted and outstanding is below. For all periods presented, the current and former plans have been combined. Original issuance dates have been retained but the number of awards issued and exercise prices have been adjusted to give retroactive effect to the November 2008 redomiciliation and reverse split for all periods presented.

HeartWare International, Inc. Employee Stock Option Plan ("ESOP") (formerly HeartWare Limited Employee Share Option Plan)

On August 5, 2008, we adopted the HeartWare International, Inc. Employee Stock Option Plan. All plan issuances were made in accordance with previous grants under the HeartWare Limited Employee Share Option Plan with the exception of adjustments for the reverse split and rounding.

The ESOP allows for the grant of options for common stock to employees and directors. The ESOP provides for the issuance of up to 11% of the then outstanding shares of common stock. At June 30, 2009, there were approximately 411,000 shares available for future awards under the ESOP.

Each option issued under the ESOP allows the holder to subscribe for and be issued one share of common stock. Options may generally be exercised after they have vested and prior to the specified expiry date provided applicable exercise conditions are met, if any. The expiry date can be for periods of up to ten years from the date of grant of the option.

The options vest in accordance with the plan on an individual award basis. Though some options originally issued in 2005 had immediate vesting, the majority of options are granted with vesting on a pro-rata basis over periods ranging from two to four years. Prior to November 2007, all options were granted with time-based vesting.

In November 2007, we granted approximately 83,000 options, approximately 79,000 of which remain outstanding at June 30, 2009, with performance based vesting criteria. The performance based options vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones related primarily to the development of our products and the achievement of certain prescribed clinical and regulatory objectives. We currently estimate that the outstanding tranches will vest over a period of 32 to 55 months commencing on the grant date. Any options not vested after five years from the date of grant automatically expire.

As of June 30, 2009, we determined that vesting of only the first tranche of options (19,633), issued with performance criteria, met the definition of "probable" under SFAS No. 5, *Accounting for Contingencies*. As such, share-based compensation expense has only been recorded for the first tranche of these options. At each reporting period, we will review the likelihood that any of the remaining three tranches will vest, and if the vesting is deemed probable, we will begin to recognize compensation expense at that time. If ultimately performance goals are not met, for any awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

Information related to the ESOP at June 30, 2009 and activity during the six months then ended is as follows (amounts in US$ were converted from AU$ at the then period-end spot rate):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	629,936	$ 18.62	6.39	$ —
Granted	—	—		
Exercised	(46,119)	7.03		
Forfeited	(12,141)	16.19		
Expired	—	—		
Outstanding at June 30, 2009	571,676	$ 23.12	6.26	$ 1,070,252
Exercisable at June 30, 2009	276,394	$ 22.31	4.29	$ 740,078

The aggregate intrinsic value in the table above represents the quoted market value of our Chess Depositary Interests ("CDI's"), as listed on the Australian Securities Exchange (multiplied by 35 to reflect that each CDI is equivalent to 1/35th of a share of common stock), less the weighted average exercise price at period end multiplied by the number of options outstanding and exercisable. As the weighted average exercise price was above the quoted market value at December 31, 2008, as adjusted, there was no aggregate intrinsic value on that date.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing valuation model using the assumptions established at that time. Compensation is recognized on an accelerated accrual method over the estimated vest period.

The intrinsic value for ESOP options exercised during the six months ended June 30, 2009 was approximately $764,000. Cash received from ESOP option exercises for the six months ended June 30, 2009 was approximately $92,000. At June 30, 2009, we recorded a receivable of approximately $231,000 for ESOP option exercise proceeds in transit, which is included in prepaid expenses and other current assets on the accompanying condensed consolidated balance sheet. The amount was subsequently received in July 2009.

At June 30, 2009, there was approximately $1.5 million of unrecognized compensation cost related to non-vested ESOP option awards, including performance based options not yet deemed probable of vesting. The expense is expected to be recognized over a weighted average period of 1.3 years.

HeartWare International, Inc. Restricted Stock Unit Plan (formerly HeartWare Limited Performance Rights Plan)

On August 5, 2008, we adopted the HeartWare International, Inc. Restricted Stock Unit Plan ("RSUP"). The plan replaces the HeartWare Limited Performance Rights Plan. All plan issuances were made in accordance with previous grants under the HeartWare Limited Performance Rights Plan, with the exception of adjustments for the reverse split and rounding). The RSUP allows for the grant of restricted stock units ("RSU's") to employees to acquire common shares at an exercise price of $0.00. The RSUP allows for the issuance of RSU's to acquire up to approximately 149,000 shares of our common stock. Each RSU issued under the RSUP allows the holder to subscribe for and be issued one share of common stock. The RSU's that ultimately vest expire 10 years from the date of grant. At June 30, 2009, there were approximately 6,000 shares available for future awards under the RSUP.

We granted 89,995 RSU's with original issuance dates from November 2007 and May 2008, 78,567 of which remain outstanding at June 30, 2009. These RSU's vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones consistent with the performance based options granted under the ESOP mentioned above. We currently estimate that the remaining outstanding tranches of the RSU's will vest over a period of 32 to 55 months commencing on the grant date. Any RSU's not vested after five years from the date of grant automatically expire.

On August 13, 2008, we approved the issuance of 64,279 RSU's under an annual equity award grant, all of which remain outstanding at June 30, 2009. These RSU's vest in three tranches, the first being 50% and the remaining two tranches being equal, and all are contingent upon the achievement of pre-determined corporate milestones. We currently estimate that these RSU's will vest over a period of 23 to 44 months commencing on the grant date. Any RSU's not vested after five years from the date of grant automatically expire.

At June 30, 2009, we determined that only the first tranche of awards issued under the RSUP (19,639) with original issuance dates from November 2007 and May 2008, issued with performance criteria, met the definition of "probable" under SFAS No. 5. As such, share-based compensation expense has only been recorded for the first tranche of these awards. At the end of each reporting period, we will review the likelihood that the remaining RSU tranches will vest and if the vesting is deemed probable, we will begin to recognize compensation expense at that time. If ultimately performance goals are not met, for any awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

Information related to the RSUP at June 30, 2009 and activity during the six months then ended is as follows (amounts in US$ were converted from AU$ at the then period-end spot rate):

	Shares	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	142,846	9.32	$ 2,078,238
Granted	—		
Exercised	—		
Forfeited	—		
Expired	—		
Outstanding at June 30, 2009	142,846	8.83	$ 3,569,882
Exercisable at June 30, 2009	—	—	$ —

The aggregate intrinsic value in the table above represents the quoted market value of our CDI's, as listed on the Australian Securities Exchange (multiplied by 35 to reflect that each CDI is equivalent to 1/35th of a share of common stock), multiplied by the number of RSU awards outstanding.

The fair value of each RSU award equals the quoted market value of our common stock on the date of grant. Compensation is recognized on an accelerated accrual method over the estimated vest period.

At June 30, 2009, we had approximately $2.0 million of unrecognized compensation cost related to non-vested RSU awards, including awards not yet deemed probable of vesting that is expected to be recognized over a weighted average period of 1.62 years.

Non-Plan Options

In 2005 and 2007, we granted options outside of any formal plan. These options were granted to three non-executive directors and to third parties for services rendered.

The options granted to the non-executive directors had three-year vest plans and were fully vested as of January 31, 2008. The options granted to third parties in 2005 had immediate vesting. The third party options granted in 2007 vest in three tranches; 40% on the first anniversary, 40% on the second anniversary and 20% on the third anniversary of the date of grant.

Information related to non-plan options at June 30, 2009 and activity during the six months then ended is as follows (amounts in US$ were converted from AU$ at the then period-end spot rate):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	68,438	$ 18.03	2.17	$ —
Granted	—			
Exercised	(16,988)	6.61		
Forfeited	—			
Expired	—			
Outstanding at June 30, 2009	51,450	$ 25.91	2.04	$ —
Exercisable at June 30, 2009	45,450	$ 26.52	1.20	$ —

The aggregate intrinsic value in the table above represents the quoted market value of our CDI's, as listed on the Australian Securities Exchange (multiplied by 35 to reflect that each CDI is equivalent to 1/35th of a share of common stock), less the weighted average exercise price at period end multiplied by the number of options outstanding and exercisable. As the weighted average exercise price was above the quoted market value of our CDI's at June 30, 2009 and December 31, 2008, as adjusted, there was no aggregate intrinsic value on those dates.

The fair value of each non-plan option award was estimated on the date of grant using the Black-Scholes option pricing valuation model using the assumptions established at that time. Compensation is recognized on an accelerated accrual method over the vest period.

The intrinsic value for non-plan options exercised during the six months ended June 30, 2009 was approximately $291,000. Cash received from non-plan option exercises for the six months ended June 30, 2009 was approximately $20,000. At June 30, 2009, we recorded a receivable of approximately $89,000 for non-plan option exercise proceeds in transit, which is included in prepaid expenses and other current assets. This amount was received in July 2009.

At June 30, 2009, there was approximately $22,000 of unrecognized compensation cost related to non-vested non-plan option awards that is expected to be recognized over a weighted average period of 0.71 years.

HeartWare International, Inc. 2008 Stock Incentive Plan

On August 5, 2008, we adopted the HeartWare International, Inc. 2008 Stock Incentive Plan. The 2008 Stock Incentive Plan allows for the issuance of awards representing up to 469,140 shares of our common stock. Through June 30, 2009, there have been no awards granted under this plan.

Summary

The following table summarizes information about all outstanding share-based awards, including the ESOP, RSUP and non-plan options, at June 30, 2009:

	Awards Outstanding			Awards Exercisable		
Range of Exercise Prices	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)
$0.00 – $0.00	142,846	$ —	8.83	—	$ —	—
$5.68 – $17.04	204,276	12.65	5.05	114,007	9.81	1.82
$21.30 – $31.24	399,365	27.88	6.61	188,352	28.80	5.42
$40.04 – $42.60	19,485	42.60	0.62	19,485	42.60	0.62
	765,972	$ 18.99	6.45	321,844	$ 22.91	3.85

We generally recognize compensation expense for our share-based awards deemed probable of vesting using an accelerated accrual method over the substantive vesting period. We allocate share-based compensation expense to cost of revenues, selling, general and administrative expense and research and development expense based on the award holders' employment function.

We recognize share-based compensation expense for the value of the portion of awards that are ultimately expected to vest. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered award. We have applied a forfeiture rate of approximately 12.5% to all unvested share-based awards as of June 30, 2009, which represents the portion that we expect will be forfeited over the vesting period. We re-evaluate this analysis periodically and adjust the forfeiture rate as necessary. Ultimately, we will only recognize expense for those share-based awards that vest.

For the three and six months ended June 30, 2009 and 2008, share-based compensation expense recorded is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2009	2008	2009	2008
Cost of revenues	$ 64	$ —	$ 80	$ —
Selling, general and administrative	81	392	221	665
Research and development	61	(380)	200	(295)
	$ 206	$ 12	$ 501	$ 370

9. Net Loss Per Common Share

Basic earnings (loss) per common share is computed by dividing net income (loss) applicable to common shares by the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per common share adjusts basic earnings (loss) per common share for the dilutive effects of convertible securities, options and other potentially dilutive instruments, only in the periods in which such effect is dilutive. The following securities have been excluded from the calculation of diluted net loss per common share, as their effect would be anti-dilutive.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Common shares issuable upon:				
Exercise of share-based payment awards	765,972	677,899	765,972	677,899
Conversion of convertible note	—	43,155	—	43,155

10. Business Segment, Geographic Areas and Major Customers

For financial reporting purposes, we have one reportable segment which designs, manufactures and markets medical devices for the treatment of advanced heart failure. Products are sold in the US through our clinical trial and as commercial products to customers in Europe and under special access in Australia.

Product sales by geographic location are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2009	2008	2009	2008
Domestic	$ 1,804	$ —	$ 2,929	$ —
International	1,164	—	1,517	—
	$ 2,968	$ —	$ 4,446	$ —

Three customers exceeded 10% of product sales individually and accounted for approximately 65% and 46% of product sales in the aggregate for the three and six months ended June 30, 2009, respectively. The concentration of customers is a result of the early stages of our US clinical trial and international commercial launch. Our US clinical trial has a phased site and patient enrollment. Also, a limited number of customers represent international product sales since receiving CE Marking in late January 2009. As additional customers are acquired outside of the US and additional sites are enrolled in the US clinical trial, the concentration of customers and relative sales volumes by geographic location could change.

11. Commitments and Contingencies

The following contingent liabilities and commitments resulting from the 2003 acquisition by HeartWare, Inc. of a business that previously held our technology exist as of June 30, 2009:

• a milestone payment of $1,250,000 within 6 months of the date when the first circulatory assist device is approved for sale in the United States, provided that we have at least $25,000,000 in cash on hand and, if we do not have $25,000,000 at that time, then the payment is deferred until such time that we have $25,000,000 in cash on hand; and

• a special payment of up to $500,000 upon a sale of HeartWare, Inc. if such sale generates proceeds in excess of the aggregate liquidation preferences of all of HeartWare, Inc.'s then outstanding preferred stock.

At June 30, 2009, we had purchase order commitments of approximately $3.5 million related to product costs and property, plant and equipment purchases.

In addition to the above, we have entered into employment agreements with all of our executive officers, including the Chief Executive Officer and the Chief Financial Officer who is also the Chief Operating Officer. These contracts do not have a fixed term and are constructed on an "at will" basis. Some of these contracts provide executives with the right to receive certain additional payments and benefits if their employment is terminated after a change of control, as defined in such agreements.

ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements can be identified by the words "expects," "projects," "hopes," "believes," "intends," "should," "estimate," "will," "would," "may," "anticipates," "plans," "could" and other similar words. All statements that address 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 the progress of clinical trials or the commercial success of our products. 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. 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. 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. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those described in "Item 1A. Risk Factors" in our Annual Report on Form 10-K filed with the Securities Exchange Commission (the "SEC") on February 26, 2009 and as amended by Amendment No. 1 on Form 10-K/A filed with the SEC on April 29, 2009, and those described in other reports filed from time to time with the SEC.

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited interim condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q.

Overview

HeartWare is a medical device company focused on developing the world's smallest implantable blood pumps for the treatment of advanced heart failure.

The HeartWare Ventricular Assist System (the "HeartWare System"), which includes a left ventricular assist device ("LVAD"), patient accessories and surgical tools, is designed to provide circulatory support for patients with advanced heart failure. The core of the HeartWare System is a proprietary continuous flow blood pump, the HVAD Pump, which is a full-output device capable of pumping up to 10 liters of blood per minute.

In January 2009, the HeartWare System received Conformite Europenne ("CE") Marking, which allows us to market and sell the device in Europe. The HeartWare System is also the subject of a clinical trial in the United States under a U.S. Food & Drug Administration ("FDA") Investigational Device Exemption ("IDE") for a bridge-to-transplant indication.

In 2008, we successfully completed enrollment of a combined European and Australian human clinical trial for the HeartWare System. This international trial began in March 2006 and called for the implantation of 20 patients. The trial was subsequently expanded to permit enrollment of 50 patients so as to provide increased depth of clinical data. Enrollment in this trial was the basis for application for and subsequent receipt of CE Marking for the HeartWare System.

In April 2008, we received conditional IDE approval from the FDA and began enrolling centers for a US bridge-to-transplant clinical study. In August 2008, our first patient in the United States received the HeartWare System at Washington Hospital Center in Washington, DC. This marked the start of our US bridge-to-transplant clinical trial, under which 150 patients awaiting heart transplantation will be enrolled at up to 28 participating centers. Full IDE approval was received in September 2008.

Beyond the HeartWare System, we are also evaluating our next generation device, the Miniaturized Ventricular Assist Device, or MVAD. The MVAD is based on the same technology platform as the HeartWare System but adopts an axial flow, rather than a centrifugal flow, configuration and is being developed in multiple configurations. The MVAD, which is currently at the prototype stage and undergoing animal studies focused on minimally invasive implantation techniques, is approximately one-third the size of the HVAD Pump. We believe that the MVAD will be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump.

We began generating revenue from our product sales in August 2008 and have incurred net losses in each year since our inception. We expect our losses to continue and to increase as we expand our clinical trial activities, seek regulatory approvals and initiate commercialization activities. We have financed our operations primarily through the issuance of common shares. In January 2005, we issued shares through an initial public offering in Australia and a concurrent US private placement of shares which raised aggregate net proceeds of approximately $23.4 million. We also issued shares through private placements to both US and Australian investors, in May 2006, July 2007 and July 2008, which raised net proceeds of approximately $23.4 million, $30.9 million and $29.4 million, respectively.

As described under the heading of "Subsequent Events" of Note 1 of Notes to the Condensed Consolidated Financial Statements, on July 31, 2009, HeartWare International, Inc. and Thoratec Corporation ("Thoratec"), mutually agreed to terminate the Agreement and Plan of Merger ("Merger Agreement"), dated February 12, 2009, pursuant to Section 8.01 (a) of the agreement. The decision to terminate the Merger Agreement was made in response to a determination by the United States Federal Trade Commission to file a complaint in US Federal District Court challenging Thoratec's proposed acquisition of HeartWare. A description of the terms of the Merger Agreement was included in the Current Report on Form 8-K as filed by HeartWare with the SEC on February 13, 2009.

We are headquartered in Framingham, Massachusetts. We have an administrative office in Sydney, Australia and an operations and manufacturing facility in Miami Lakes, Florida.

Critical Accounting Policies and Estimates

We prepare our financial statements in accordance with accounting principles generally accepted in the United States. We are required to make estimates and judgments in preparing our financial statements that affect the reported amounts of our assets, liabilities, revenue and expenses. We base our estimates on our historical experience to the extent practicable and on various other assumptions that we believe are reasonable under the circumstances. If our assumptions prove inaccurate or if our future results are not consistent with our historical experience, we may be required to make adjustments in our policies that affect our reported results. Our most critical accounting policies and estimates include: revenue recognition, inventory capitalization, translation of foreign currency, accounting for research and development costs, accounting for share-based payments and income taxes. We also have other key accounting policies that are less subjective and, therefore, their application would not have a material impact on our reported results of operations. The following is a discussion of our most critical policies, as well as the estimates and judgments involved.

Revenue Recognition

We recognize revenue for product sales in accordance with SEC Staff Accounting Bulletin No. 104 ("SAB 104"), *Revenue Recognition*. Pursuant to written agreements, we ship product to our customers. Revenue from product sales is only recognized when substantially all the risks and rewards of ownership have transferred to our customers, the selling price is fixed and collection is reasonably assured. A majority of product sales are made on a consignment basis and as such revenue is generally recognized on the date the consigned product is implanted or otherwise consumed. Revenue from product sales not sold on a consignment basis is generally recognized upon customer receipt and acceptance of the product. Revenue recognized to date is from sales of our devices in connection with our US clinical trial and commercial sales in Europe and under special access in Australia.

Inventory Capitalization

We expense costs relating to the production of inventories as research and development ("R&D") expense in the period incurred until such time as we believe future commercialization is considered probable and future economic benefit is expected to be recognized, which generally is reliant upon receipt of regulatory approval. We then begin to capitalize subsequent inventory costs relating to that product. We received a full IDE in September 2008 from the FDA for the HeartWare System product line and subsequently began selling our product through our US clinical trial, and subsequently outside of the United States upon receipt of CE Marking. Therefore, effective September 1, 2008, we adopted a policy for capitalizing inventory and recognizing cost of sales.

Prior to September 1, 2008, all costs associated with manufacturing the HeartWare System and related surgical and peripheral products were expensed as R&D costs. However, we had product on hand at September 1, 2008, which had previously been expensed, and which was subsequently used in the production and sale of finished goods. Until we sell the inventory for which costs were previously expensed, the carrying value of our inventories and our cost of revenues does not include the cost of previously expensed inventory. As such, as we sell that portion of our existing inventory we will recognize manufacturing revenue with little or no corresponding cost. Therefore we anticipate our gross margin on sales of our product will fluctuate and will not be comparable from quarter to quarter. We currently estimate that all previously expensed inventory will be consumed by the end of the third quarter of fiscal year 2009.

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost basis which approximates the FIFO method. We review our inventory for excess or obsolete inventory and write down obsolete or otherwise unmarketable inventory to its estimated net realizable value.

Research and Development

Research and development costs, including new product development programs, regulatory compliance and clinical research, are expensed as incurred.

Share-Based Payments

We elected to early adopt SFAS No. 123(R), "*Share-Based Payment*", effective January 1, 2005. We use a Black-Scholes option pricing method. Under the fair value recognition provisions of SFAS No. 123(R), we recognize share-based compensation net of an estimated forfeiture rate and therefore only recognize compensation cost for those shares expected to vest over the service period of the award.

Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of expected life of the option, share price volatility and a forfeiture rate.

We estimate the volatility of our shares on the date of grant based on the historical volatility of our publicly-traded shares. We estimate the forfeiture rate based on our historical experience of past forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, the share-based compensation expense could be significantly different from what we have recorded in the current period. We estimate the risk-free interest rate based on rates in effect at the time of grant for Australian government bonds with similar lives. When appropriate, we estimate the expected life of an option based upon the simplified method provided under SEC Staff Accounting Bulletin (SAB) No. 110. Under SAB No. 110, the expected life is developed by averaging the contractual term of the stock option grants (up to 10 years) with the associated vesting term (typically 4 years).

The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

Income Taxes

We account for income taxes in accordance with Statement of Financial Accounting Standards No. 109, or SFAS 109, *Accounting for Income Taxes*, as clarified by FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN No. 48"). Under this method, deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax basis of assets and liabilities given the provisions of enacted tax laws. Deferred income tax provisions and benefits are based on changes to the assets or liabilities from year to year. In providing for deferred taxes, we consider tax regulations of the jurisdictions in which we operate, estimates of future taxable income, and available tax planning strategies. If tax regulations, operating results or the ability to implement tax-planning strategies vary, adjustments to the carrying value of deferred tax assets and liabilities may be required. Valuation allowances are recorded related to deferred tax assets based on the "more likely than not" criteria of SFAS No. 109.

FIN No. 48 requires that we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the "more-likely-than-not" threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Translation of Foreign Currency

All assets and liabilities of non-US entities are translated at the period-end exchange rate and revenues and expenses are translated at the average exchange rates in effect during the respective periods. Equity transactions are translated at the spot rates on the dates of the original transactions. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of shareholders' equity, titled "Accumulated Other Comprehensive (Loss)." Items in Accumulated Other Comprehensive (Loss) are not tax affected as we have incurred a net loss in each period since inception.

The exchange rate between the US and Australian dollar has fluctuated substantially in the past. The exchange rate was 0.8114 US dollars for each Australian dollar at June 30, 2009 as compared to 0.6928 US dollars for each Australian dollar at December 31, 2008, resulting in a significant change in the cumulative translation adjustment for the three and six months ended June 30, 2009.

In addition, our Australian subsidiary, HeartWare Pty. Limited, which operates in a functional currency of Australian dollars, holds US dollar cash accounts. Exchange rate fluctuations affect the value of these accounts and may result in foreign currency gains and losses. Such gains and losses are included in the consolidated statements of operations. Any such gains and losses are initially recognized in AU$ and then converted to US$ at an average exchange rate. When the exchange rate increases, the value in Australian dollars of our US dollar denominated cash holdings held by our Australian subsidiary decreases, resulting in foreign exchange translation losses in that period. As noted above, we saw a significant increase in the exchange rate between AU and US dollars during the first six months of 2009. Foreign exchange gains and losses will continue to fluctuate as the exchange rate varies.

Results of Operations

Three and six months ended June 30, 2009 and 2008

Revenues

We generated revenues of approximately $3.0 million and $4.4 million in the three and six months ended June 30, 2009, respectively, from product sales through our US clinical trial as well as commercial sales in Europe and Australia. The increase is due to commencement of our US clinical trial and receipt of CE Marking.

We had no revenues from product sales prior to August 2008. We completed enrollment of our combined European and Australian clinical trial for the HeartWare System in December 2008 and received CE Marking approval in January 2009.

We expect to continue to generate and grow revenues from our US clinical trial and commercial revenue from product sales outside of the United States. However, even if we receive the necessary regulatory approvals in the United States, future product sales are dependent on many factors, including market acceptance among physicians, patients, health care payers or the medical community as well as our capacity to meet customer demand by manufacturing sufficient quantities of our products.

Gross Profit

Cost of revenues totaled approximately $1.6 million and $2.3 million in the three and six months ended June 30, 2009, respectively. There was no cost of revenues recognized during the same periods in the prior year as no revenues were recognized for those periods.

Gross profit and gross margin percentage are as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2009**	**2008**	**2009**	**2008**
Gross profit	$ 1,389	$ —	$ 2,149	$ —
Gross margin %	47%	—	48%	—

We began capitalizing inventory on September 1, 2008. Prior to that time, product costs were expensed as R&D costs (see Critical Accounting Policies and Estimates — Inventory Capitalization). At September 1, 2008 we had product on hand that was previously expensed as R&D costs but is being utilized in the production and sale of finished goods. Therefore, cost of revenues does not include the cost of this pre-launch inventory. In addition, as we have limited manufacturing experience and we use a standard costing method for determining costs of inventory based on limited historical data our actual results may differ from standards. As a result, gross margins have been and may continue to be inconsistent from quarter to quarter.

Selling, General and Administrative

Selling, general and administrative expenses include office expenses associated with general corporate administration. These costs are primarily related to salaries and wages and related employee costs, depreciation of fixed assets, travel, external consultants and contractors, legal and accounting fees and general infrastructure costs and include all operating costs not associated with or otherwise classified as research and development costs or cost of revenues.

Selling, general and administrative expenses were approximately $4.4 million, or 60% of operating expenses for the three months ended June 30, 2009, as compared to $2.6 million, or 34% of operating expenses for the same period in the prior year. The increase, in dollars and as a percentage of operating expenses, was primarily a result of approximately $2.2 million of direct expenses related to the Thoratec transaction. This amount was partially offset by reductions in other administrative expenses for the three months ended June 30, 2009 as compared to the same period in the prior year, including a decrease in share-based compensation of approximately $0.3 million.

Selling, general and administrative expenses were approximately $8.6 million, or 57%, of operating expenses for the six months ended June 30, 2009, as compared to $4.8 million, or 34% of operating expenses for the same period in the prior year. The increase was primarily a result of approximately $3.8 million of direct expenses related to the Thoratec transaction.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products prior to commercialization. These expenses consist primarily of salaries and wages and related employee costs, external research and development costs, materials and expenses associated with clinical trials associated with our US clinical trial. Additional costs include travel, facilities and overhead allocations.

Even as we attain commercialization of the HeartWare System product line outside of the US, we expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future related to existing product enhancement and new development. In addition, we expect ongoing clinical costs that will be expensed to research and development relating to the HeartWare System for US clinical trials.

Research and development expenses were $2.9 million, or 40%, of operating expenses for the three months ended June 30, 2009, as compared to $5.1 million, or 66% of operating expenses for the same period in the prior year. The decrease of approximately $2.3 million was primarily related to the capitalization of manufacturing activities related to the manufacturing of the HeartWare system as inventory held for sale, and expensed as cost of revenues as units are sold, for the three months ended June 30, 2009 as opposed to being expensed as research and development expenses as incurred for the same period in the prior year. Research and development activities, including those related to the MVAD, continue to be expensed as incurred. For the three months ended June 30, 2009, we experienced an increase in clinical trial costs relating to the US clinical trial of approximately $0.5 million and an increase in share-based compensation of approximately $0.4 million.

Research and development expenses were $6.3 million, or 43%, of operating expenses for the six months ended June 30, 2009, as compared to $9.3 million, or 66% of operating expenses for the same period in the prior year. The decrease of approximately $3.0 million was primarily related to manufacturing activities capitalized as inventory related to the manufacturing of the HeartWare system for sale for the six months ended June 30, 2009 as opposed to being expensed as research and development expenses for the same period in the prior year. However, for the six months ended June 30, 2009, we experienced an increase in clinical trial costs relating to the US clinical trial of approximately $1.0 million, accrued a milestone payment $0.75 million related to a commitment resulting from the 2003 acquisition by HeartWare, Inc. (as described in our Form 10-K as filed on February 28, 2009), and an increase in share-based compensation of approximately $0.5 million partially offset by reduced expenses related to animal studies of $0.2 million.

Other Income (Loss)

Other income (loss) consists of foreign exchange gains or losses, interest income and gains or losses on disposal of assets.

Foreign exchange loss totaled approximately $1.1 million in the three months ended June 30, 2009, as compared to a loss of approximately $0.5 million for the same period in the prior year. Foreign exchange loss was approximately $0.4 million in the six months ended June 30, 2009, as compared to a loss of approximately $1.3 million for the same period in the prior year. The differences were due to fluctuations in the overall balance and value of our US dollar-based cash holdings held by our Australian subsidiary as a result of movements in the exchange rate between the Australian dollar and the US dollar.

Interest income is primarily derived from cash and short-term deposit accounts, denominated in both Australian and United States dollars, held in Australia. Interest income was approximately $12,000 and $19,000 in the three and six months ended June 30, 2009, respectively, as compared to approximately $237,000 and $563,000 in the three and six months ended June 30, 2008, respectively. The decreases were primarily due to lower average cash balances and lower interest rates in 2009.

For the three and six months ended June 30, 2008, we incurred a loss on the disposal of fixed assets of approximately $92,000 primarily in connection with the termination of our lease for our prior manufacturing facility.

Income Taxes

We are subject to taxation in the United States and Australia. We have incurred losses since inception in both jurisdictions. Changes in share ownership, as well as other factors, may limit our ability to utilize any net operating loss carry-forwards, and as such a 100% valuation allowance has been recorded against our net deferred tax assets.

As of June 30, 2009, we did not have revenues or profit which would be sufficient to allow any portion of our deferred tax assets to be recorded. We intend to closely consider whether to record a deferred tax asset as we further expand the commercialization of our products.

Liquidity and Capital Resources

As of June 30, 2009, our cash and cash equivalents were $5.9 million as compared to $20.8 million at December 31, 2008. The decrease is primarily a result of cash used in operating activities.

Cash used in operating activities for the six months ended June 30, 2009 was approximately $15.1 million as compared to $13.3 million for the same period in the prior year. For the six months ended June 30, 2009, this amount included a net loss of $13.1 million and non-cash adjustments to net loss of approximately $1.0 million, which primarily consisted of approximately $0.5 million of depreciation and amortization and $0.5 million of share-based compensation. Included in cash used in operating activities in 2009 is approximately $2.3 million related to accounts receivable and approximately $4.8 million for the purchase and manufacture of inventories. We expect increases in accounts receivable and inventory purchases to continue to be a significant use of cash throughout 2009 in support of our US clinical trial and commercial sales in Europe.

For the six months ended June 30, 2008, cash used in operating activities included a net loss of $14.9 million and non-cash adjustments to net income of approximately $0.8 million, which primarily consisted of approximately $0.3 million of depreciation and amortization and $0.4 million of share-based compensation.

Investing activities used cash of approximately $0.6 million and $1.4 million for the six months ended June 30, 2009 and 2008, respectively. These amounts were primarily to acquire property, plant and equipment and capitalized patent costs.

Cash provided by financing activities for the six months ended June 30, 2009 was approximately $0.1 million as a result of receiving a portion of the proceeds from stock options exercised during the period. There were no financing cash activities during the six months ended June 30, 2008. Additional cash proceeds of $0.3 million were received from the exercise of these stock options in July 2009.

As reported in a Current Report on Form 8-K filed with the SEC on August 10, 2009, we entered into certain Securities Purchase Agreements (the “Purchase Agreements”) separately with a number of institutional and sophisticated investors for the private placement of approximately 2.73 million shares of our common stock at an issue price of $22.00 per share for aggregate gross proceeds of approximately $60.0 million (the “Private Placement”). The placement agent for the transaction received a placement fee of approximately 2% of the gross proceeds.

The Purchase Agreements obligate us to file a registration statement with the SEC registering the shares of common stock issued to investors under the Purchase Agreements. Further, our obligation to issue approximately 1.39 million shares of our common stock in the Private Placement is conditioned upon obtaining shareholder approval as required under the Nasdaq Stock Market Rules and the Australian Securities Exchange Listing Rules and as such a portion of the proceeds will be held in escrow until such time as approval is obtained. The meeting of shareholders is expected to occur on a date prior to December 15, 2009.

On February 12, 2009, we entered into a Loan Agreement ("Loan Agreement") with Thoratec, pursuant to which Thoratec committed to loan us up to $28.0 million through one or more term loans subject to the terms and conditions set forth in the Loan Agreement. The Loan Agreement survives the termination of the Merger Agreement, as described above, and as of July 31, 2009, we were able to borrow up to $20.0 million under the Loan Agreement. The funds have been deposited into an escrow account to support the commitment. The additional $8.0 million was only to become available if Thoratec exercised an option to extend the Merger Agreement to the outside date for the completion of the proposed merger of January 31, 2010. As the Merger Agreement has been terminated those additional funds will not be available.

The loans, at Thoratec's option, may be converted in whole or in part into shares of HeartWare International common stock prior to the maturity date of the loan subject to a waiting period provided by the Hart-Scott-Rodino Antitrust Improvements Act. In addition, beginning July 31, 2009, the date the Merger Agreement was terminated, Thoratec may convert any escrow funds in whole or in part into shares of HeartWare International common stock at any time prior to termination of the Loan Agreement subject to a waiting period provided by the Hart-Scott-Rodino Antitrust Improvements Act. The number of shares to be issued is determined by dividing the outstanding principal amount of the loans, including any accrued and unpaid interest, or escrow funds by the US dollar equivalent of AU$35.00 on the date of conversion, which is subject to customary adjustment provisions as defined in the Loan Agreement. For so long as HeartWare International's CHESS Depositary Interests are listed on the Australian Securities Exchange, the loans and escrow funds may not be converted into more than 14.99% in the aggregate of the then authorized and outstanding shares of HeartWare International common stock.

As of June 30, 2009, we had no amounts outstanding under the Loan Agreement. On August 5, 2009 we borrowed $4.0 million under the Loan Agreement.

The loans to us under the Loan Agreement accrue interest at the rate of 10% per annum. Accrued interest on any amounts outstanding is payable quarterly on March 31, June 30, September 30 and December 31. The loans are due and payable, together with accrued and unpaid interest, on the earlier of (i) November 1, 2011, (ii) the Termination Date, as defined in the Loan Agreement, and (iii) the date on which all of the loans accelerate and become due and payable in full in accordance with the Loan Agreement. The loans may accelerate upon a change in control of HeartWare or upon certain events of default, all as defined in the Loan Agreement.

We believe that cash and cash equivalents on hand, cash received from the above described Private Placement, expected cash flows from operations and the access to capital pursuant to the above described Loan Agreement will be sufficient to fund our operations for at least the next twelve months.

We began generating revenue in August 2008 with the commencement of our US clinical trial. Continued revenue is contingent upon, among other things, market acceptance of our products among physicians, patients, health care payers or the medical community as well as our capacity to successfully and efficiently manufacture our products. We expect to continue to incur significant spending due to increased selling and marketing costs, on-going regulatory and compliance requirements, increased clinical trial costs associated with our US clinical trial and additional operating expenses related to continued corporate growth.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk represents the risk of changes in the value of market risk sensitive instruments caused by fluctuations in interest rates, foreign exchange rates and commodity prices. Changes in these factors could cause fluctuations in our results of operations and cash flows.

Interest Rate Risk

Our exposure to interest rate risk is currently confined to interest earnings on our cash that is invested in highly liquid money market funds. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. We do not presently use derivative financial instruments in our investment portfolio. Our cash and investments policy emphasizes liquidity and preservation of principal over other portfolio considerations.

Foreign Currency Rate Fluctuations

We conduct business in foreign countries. For US reporting purposes, we translate all assets and liabilities of its non-US entities at the period-end exchange rate and revenue and expenses at the average exchange rates in effect during the period. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of shareholders' equity.

Our Australian subsidiary holds US and Australian dollar denominated cash accounts. Fluctuations in the exchange rate of the US dollar against the Australian dollar can result in foreign currency exchange gains and losses that impact our financial results and our overall cash position. These foreign currency transaction gains and losses are included in other income (loss), net in the consolidated statements of operations. The gains and losses are recorded in Australian dollars, the functional currency of the Australian entity, and translated to US dollars, at an average exchange rate, upon consolidation, for US reporting purposes. Continued fluctuation of the exchange rate could result in financial results that are not comparable from quarter to quarter.

We do not presently utilize foreign currency forward contracts and instead hold cash reserves in the currency in which those reserves are anticipated to be expended.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) under the Securities Exchange Act of 1934. Based on such evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of June 30, 2009.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the three months ended June 30, 2009 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

In addition to the information set forth in this report you should carefully consider the risk factors discussed in Item 1A — Risk Factors in our Annual Report on Form 10-K and as amended by Amendment No. 1 on Form 10-K/A.

The following risk factor reflects a material change to the Risk Factors set forth in our 2008 Annual Report on Form 10-K and as amended by Amendment No. 1 on Form 10-K/A.

If we fail to obtain an adequate level of reimbursement for our products by third party payers, there may be no commercially viable markets for our product candidates or the markets may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third party payers affect the market for our product candidates. Reimbursement and health care payment systems vary significantly by country, and include both government sponsored health care and private insurance. Payers may attempt to limit coverage and the level of reimbursement of new therapeutic products. Government and other third party payers also continually attempt to contain or reduce the costs of health care by challenging prices charged for health care products and services.

To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials, that compares the cost-effectiveness of our products to other available therapies. In addition, the efficacy, safety, performance and cost-effectiveness of our product candidates and of any competing products will determine the availability and level of reimbursement.

We believe that future reimbursement may be subject to increased restrictions both in the United States and in international markets. Future legislation, regulation or reimbursement policies of third party payers may adversely affect the demand for our products currently under development and limit our ability to sell our product candidates on a profitable basis. The current US administration has set forth a number of proposed initiatives to reform healthcare and contain costs and the US Congress is currently considering health care reform legislation. We cannot predict how pending or future legislative and regulatory proposals would influence the manner in which medical devices, including ours, are purchased or covered and reimbursed. For example, the American Recovery and Reinvestment Act of 2009 includes funding to study the comparative effectiveness of health care treatments and strategies. This funding will be used, among other things, to conduct, support or synthesize research that compares and evaluates the risk and benefits, clinical outcomes, effectiveness and appropriateness of medical products. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact coverage, reimbursement or other third-party payer policies.

If reimbursement for our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired and our future revenues would be adversely affected.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 6. EXHIBITS

31.1	Certification of Chief Executive Officer pursuant to Rule 13A-14(a) or Rule 15d-14(a) of the Securities Exchange Act
31.2	Certification of Chief Financial Officer pursuant to Rule 13A-14(a) or Rule 15d-14(a) of the Securities Exchange Act
31.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Signatures

In accordance with 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, thereunto duly authorized.

HEARTWARE INTERNATIONAL, INC.

Date: August 14, 2009

/s/ Douglas Godshall
Douglas Godshall
Chief Executive Officer

Date: August 14, 2009

/s/ David McIntyre
David McIntyre
Chief Financial Officer and Chief Operating Officer

EXHIBIT INDEX

31.1	Certification of Chief Executive Officer pursuant to Rule 13A-14(a) or Rule 15d-14(a) of the Securities Exchange Act
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32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13A-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Douglas Godshall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HeartWare International, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2009

/s/ Douglas Godshall
Douglas Godshall
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIALOFFICER PURSUANT TO RULE 13A-14(a) OR RULE 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, David McIntyre, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HeartWare International, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 14, 2009

/s/ David McIntyre
David McIntyre
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of HeartWare International, Inc. (the "Company") for the quarterly period ended June 30, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2009

/s/ Douglas Godshall
Douglas Godshall
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of HeartWare International, Inc. (the "Company") for the quarterly period ended June 30, 2009 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Chief Financial Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 14, 2009

/s/ David McIntyre
David McIntyre
Chief Financial Officer
(Principal Financial Officer)

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Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
HeartWare International, Inc.

We have reviewed the accompanying condensed consolidated balance sheet of HeartWare International, Inc. (a Delaware Corporation) as of June 30, 2009, the related condensed consolidated statements of operations and comprehensive loss for the three-month and six-month periods ended June 30, 2009 and 2008, and the related condensed consolidated statements of shareholders' equity and cash flows for the six-month periods ended June 30, 2009 and 2008. These condensed consolidated financial statements are the responsibility of the Company's management.

We conducted our reviews in accordance with the standards of the Public Company Accounting Oversight Board (United States). A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with the standards of the Public Company Accounting Oversight Board (United States), the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our reviews, we are not aware of any material modifications that should be made to the accompanying condensed consolidated financial statements for them to be in conformity with accounting principles generally accepted in the United States of America.

We have previously audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of the Company as of December 31, 2008, and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the year then ended (not presented herein); and in our report dated February 25, 2009, we expressed an unqualified opinion on those consolidated financial statements and included an explanatory paragraph for the adoption of Statement of Financial Accounting Standards No. 123(R), "Share-Based Payment", on a prospective basis on January 1, 2005, and the adoption of Financial Accounting Standards Board Interpretation No. 48, "Accounting for Uncertainty in Income Taxes", on a prospective basis on January 1, 2007. In our opinion, the information set forth in the accompanying condensed consolidated balance sheet as of December 31, 2008, is fairly stated, in all material respects, in relation to the balance sheet from which it has been derived.

Grant Thornton LLP

Fort Lauderdale, Florida
August 14, 2009