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 September 30, 2012

☐ **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 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 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 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 October 26, 2012**
Common Stock, $0.001 Par Value Per Share	14,423,775

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, HeartWare, Inc., HeartWare GmbH, HeartWare (UK) Limited and HeartWare France.
- "HeartWare International, Inc." refers to HeartWare International, Inc., a Delaware corporation incorporated on July 29, 2008.
- "HeartWare Pty. Limited" refers to HeartWare Pty. Limited (formerly known as HeartWare Limited), an Australian proprietary corporation originally incorporated on November 26, 2004.
- "HeartWare, Inc." refers to HeartWare, Inc., a Delaware corporation incorporated on April 3, 2003. HeartWare, Inc. was acquired by HeartWare Pty. Limited on January 24, 2005.
- "HeartWare GmbH" refers to HeartWare GmbH, a German corporation established on February 19, 2010.
- "HeartWare (UK) Limited" refers to HeartWare (UK) Limited, a limited liability corporation established in the United Kingdom on February 19, 2010.
- "HeartWare France" refers to HeartWare France, a French corporation established on August 16, 2011.
- "World Heart Corporation" refers to World Heart Corporation, a Delaware corporation acquired by HeartWare, International, Inc. on August 2, 2012.

Currency

Unless indicated otherwise in this Quarterly Report on Form 10-Q, all references to "$", "U.S.$" 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. References to "€" or "Euros" means Euros, the single currency of Participating Member States of the European Union. References to "£" or "British Pounds" refer to British pound sterling, the lawful currency of the United Kingdom.

Trademarks

HEARTWARE®, HVAD®, MVAD®, KRITON® and various company logos are the trademarks of the Company in the United States, Europe, 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.

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains 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 forward-looking statements are based on our management's beliefs, assumptions and expectations and on information currently available to our management. Generally, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements, which generally are not historical in nature. All statements that address operating or financial 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 regulatory submissions and approvals, such as United States Food & Drug Administration ("FDA") approval of our premarket approval application for our HeartWare® Ventricular Assist System for a bridge-to-transplant indication;
- our expectations with respect to our clinical trials, including enrollment in or completion of our clinical trials as well as approval of new clinical trials and continued access protocols with respect to our existing clinical trials;
- our expectations with respect to the integrity or capabilities of our intellectual property position;
- our ability and plans to commercialize our existing products;
- our ability and plans to develop and commercialize new products and the expected features and functionalities and possible benefits of these products; and
- our estimates regarding our capital requirements and financial performance, including earnings fluctuation.

Our management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on our 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, except as may be required by federal securities laws and the rules and regulations of the Securities and Exchange Commission (the "SEC"). We may not actually achieve the plans, projections or expectations disclosed in our 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 Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed with the SEC on February 27, 2012, and those described from time to time in our other filings with the SEC.

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	September 30, 2012 (unaudited)	December 31, 2011
ASSETS		
Current assets:		
Cash and cash equivalents	$ 111,883	$ 71,257
Short-term investments, net	5,743	91,925
Accounts receivable, net	16,919	14,953
Inventories, net	38,654	32,005
Prepaid expenses and other current assets	6,237	4,507
Total current assets	179,436	214,647
Property, plant and equipment, net	19,413	18,325
Goodwill	1,190	—
Other intangible assets, net	6,130	2,014
Deferred financing costs, net	2,413	2,653
Other assets	3,431	3,093
Total assets	$ 212,013	$ 240,732
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 9,374	$ 5,025
Other accrued liabilities	15,622	12,436
Total current liabilities	24,996	17,461
Convertible senior notes, net	98,737	94,277
Other long-term liabilities	4,140	2,210
Commitments and contingencies – See Note 16		
Stockholders' equity:		
Preferred stock - $.001 par value; 5,000 shares authorized; no shares issued and outstanding at September 30, 2012 and December 31, 2011	—	—
Common stock - $.001 par value; 25,000 shares authorized; 14,423 and 14,114 shares issued and outstanding at September 30, 2012 and December 31, 2011, respectively	14	14
Additional paid-in capital	340,953	316,748
Accumulated deficit	(248,937)	(182,324)
Accumulated other comprehensive loss:		
Cumulative translation adjustments	(7,890)	(7,631)
Unrealized loss on investments	—	(23)
Total accumulated other comprehensive loss	(7,890)	(7,654)
Total stockholders' equity	84,140	126,784
Total liabilities and stockholders' equity	$ 212,013	$ 240,732

The accompanying notes are an integral part of these financial statements.

HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue, net	$ 22,862	$ 21,340	$ 78,261	$ 59,704
Cost of revenue	10,925	7,884	34,418	23,392
Gross profit	11,937	13,456	43,843	36,312
Operating expenses:				
Selling, general and administrative	13,768	10,833	40,687	29,389
Research and development	21,379	12,705	61,392	32,285
Total operating expenses	35,147	23,538	102,079	61,674
Loss from operations	(23,210)	(10,082)	(58,236)	(25,362)
Other income (expense):				
Foreign exchange gain (loss)	1,153	(1,433)	63	(707)
Interest expense	(2,876)	(2,689)	(8,477)	(7,941)
Investment income, net	28	118	198	413
Other, net	(81)	122	(161)	106
Loss before income taxes	(24,986)	(13,964)	(66,613)	(33,491)
Provision for income taxes	—	—	—	—
Net loss	$(24,986)	$(13,964)	$ (66,613)	$(33,491)
Net loss per common share — basic and diluted	$ (1.75)	$ (1.00)	$ (4.70)	$ (2.41)
Weighted average shares outstanding — basic and diluted	14,274	13,948	14,185	13,924

The accompanying notes are an integral part of these financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net loss	$(24,986)	$(13,964)	$(66,613)	$(33,491)
Other comprehensive income (loss)				
Foreign currency translation adjustments	(189)	(261)	(259)	(170)
Unrealized gain (loss) on investments	3	3	23	(22)
Comprehensive loss	$(25,172)	$(14,222)	$(66,849)	$(33,683)

The accompanying notes are an integral part of these financial statements.

HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
(unaudited)
(In thousands, except per share data)

	Common Shares, $0.001 Par Value Per Share		Additional Paid-In Capital	Accumulate Deficit	Accumulated Other Comprehensive Loss	Stockholders Equity
	Shares Issued	Amount				
Balance, December 31, 2011	14,114	$ 14	$316,748	$(182,324)	$ (7,654)	$ 126,784
Issuance of shares in connection with acquisition of World Heart	83	—	6,942	—	—	6,942
Issuance of common stock pursuant to share-based awards	226	—	2,316	—	—	2,316
Share-based compensation	—	—	14,947	—	—	14,947
Net loss	—	—	—	(66,613)	—	(66,613)
Other comprehensive loss	—	—	—	—	(236)	(236)
Balance, September 30, 2012	14,423	$ 14	$340,953	$(248,937)	$ (7,890)	$ 84,140

The accompanying notes are an integral part of these financial statements.

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

	Nine Months Ended September 30,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (66,613)	$ (33,491)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	3,322	1,675
Amortization of intangible assets	123	99
Share-based compensation expense	14,947	9,995
Amortization of premium on investments	534	680
Amortization of discount on convertible senior notes	4,460	3,955
Amortization of deferred financing costs	239	212
Other	485	221
Change in operating assets and liabilities:		
Accounts receivable	(2,190)	7,397
Inventories, net	(6,684)	(14,020)
Prepaid expenses and other current assets	(1,194)	(2,533)
Accounts payable	4,349	679
Accrued interest on convertible senior notes	1,262	1,258
Other accrued liabilities	(50)	2,983
Other long-term liabilities	672	1,947
Net cash used in operating activities	(46,338)	(18,943)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(15,000)	(120,658)
Maturities of investments	101,507	55,000
Acquisition of World Heart, net of cash acquired	3,687	—
Additions to property, plant and equipment, net	(4,201)	(8,529)
Additions to patents	(376)	(409)
Cash paid for security deposits	(750)	—
Net cash provided by (used in) investing activities	84,867	(74,596)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of stock options	2,316	659
Payment of common stock issuance costs	—	(1)
Net cash provided by financing activities	2,316	658
Effect of exchange rate changes on cash and cash equivalents	(219)	(143)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	40,626	(93,024)
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD	71,257	192,148
CASH AND CASH EQUIVALENTS — END OF PERIOD	$ 111,883	$ 99,124

The accompanying notes are an integral part of these financial statements.

Note 1. Basis of Presentation

HeartWare International, Inc., referred to in these notes collectively with its subsidiaries HeartWare Pty. Limited, HeartWare, Inc., HeartWare (UK) Limited, HeartWare GmbH, HeartWare France and World Heart Corporation as "we," "our," "HeartWare" or the "Company," is a medical device company that develops, manufactures and markets miniaturized implantable heart pumps, or ventricular assist devices, to treat patients suffering from advanced heart failure.

The accompanying unaudited interim condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("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 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011. The accompanying condensed consolidated balance sheet as of December 31, 2011 has been derived from our audited financial statements. The condensed consolidated statements of operations for the three and nine months ended September 30, 2012 and cash flows for the nine months ended September 30, 2012 are not necessarily indicative of the results to be expected for any future period or for the year ending December 31, 2012.

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.

Note 2. Liquidity

At September 30, 2012, we had approximately $117.6 million of cash, cash equivalents and investments. The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, which contemplate continuation of the Company as a going concern. We have incurred substantial losses from operations since our inception, and such losses have continued through September 30, 2012. At September 30, 2012, we had an accumulated deficit of approximately $248.9 million.

We have financed our operations primarily through the issuance of shares of our common stock and the issuance of convertible notes. Most recently, in December 2010, we consummated the issuance and sale of $143.75 million aggregate principal amount of convertible notes. The convertible notes are the senior unsecured obligations of the Company. The convertible notes bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year. The convertible notes will mature on December 15, 2017, unless earlier repurchased or converted. The convertible notes will be convertible at an initial conversion rate of 10 shares of common stock per $1,000 principal amount of convertible notes, which corresponds to an initial conversion price of $100.00 per share of common stock.

For the remainder of 2012, our cash, cash equivalents and investments are expected to primarily be used to fund our ongoing operations including preparing for commercial launch of the HeartWare® Ventricular Assist System (the "HeartWare System") in the United States, which remains subject to FDA approval, research and development of new products, managing on-going and new clinical trials, and regulatory and other compliance functions, as well as for general working capital. We believe our cash, cash equivalents and investment balances are sufficient to support our planned operations for at least the next twelve months.

Note 3. Significant Accounting Policies

Principles of Consolidation

The condensed consolidated financial statements include the accounts of HeartWare International, Inc., and its subsidiaries described in Note 1. All inter-company balances and transactions have been eliminated in consolidation. We hold certain investments in small development stage entities. In accordance with FASB ASC 810, we analyzed the investments to determine if the investments are variable interests or interests that gave us a controlling financial interest in a variable interest entity ("VIE"). As of September 30, 2012, we determined there were no VIE's required to be consolidated, because we are not the primary beneficiary, as we do not have the power to direct the most meaningful activities of the VIE. Investments where the Company does not exercise operating and financial control are accounted for under the equity method or cost method depending on our ownership interest.

Accounting Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States ("U.S. 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 revenue and expenses during the reporting periods. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are recorded on our condensed consolidated balance sheets at cost, which approximates fair value. All highly liquid investments with an original maturity of three months or less at the date of purchase are considered to be cash equivalents.

Investments

Our investments classified as available-for-sale are stated at fair value with unrealized gains and losses reported in accumulated other comprehensive loss within stockholders' equity. We classify our available-for-sale investments as short-term if their remaining time to maturity at purchase is beyond three months, but less than twenty-four months. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. Interest on investments classified as available-for-sale is included in investment income, net. Premiums paid on our short-term investments are amortized over the remaining term of the investment and such amortization is included in investment income, net.

Receivables

Accounts receivable consists of amounts due from the sale of our HeartWare System to our customers, which include hospitals, health research institutions and medical device distributors. We grant credit to customers in the normal course of business, but do not require collateral or any other security to support credit sales. Our receivables are geographically dispersed, with a significant portion from customers located in Europe and other foreign countries. At September 30, 2012 and December 31, 2011, no customer had an accounts receivable balance greater than 10% of our total accounts receivable.

We maintain allowances for doubtful accounts for estimated losses that may result from an inability to collect payments owed to us for product sales. We regularly review the allowance by considering factors such as historical experience, the age of the accounts receivable balances and current economic conditions that may affect a customer's ability to pay. Account balances are charged off against the allowance after appropriate collection efforts are exhausted and we feel it is probable that the receivable will not be recovered.

The following table summarizes the change in our allowance for doubtful accounts for the nine months ended September 30, 2012 and 2011:

	2012	2011
	(in thousands)	
Beginning balance	$500	$ 600
Additions (bad debt expense)	250	300
Deductions (charge-offs)	—	(573)
Ending balance	$750	$ 327

As of September 30, 2012 and December 31, 2011, we did not have an allowance for returns.

Inventories, net

Inventories are stated at the lower of cost or market. Cost is determined using a first-in, first-out, or FIFO, method. Work-in-process and finished goods manufactured or assembled by us include direct and indirect labor and manufacturing overhead. Finished goods include product which is ready-for-use and which is held by us or by our customers on a consignment basis.

We review our inventory for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value. Obsolescence may occur due to product expiring or product improvements rendering previous versions obsolete.

Deferred Financing Costs

Costs incurred in connection with the issuance of our convertible senior notes have been allocated between the liability component and the equity component as further discussed in Note 11. The liability component of the issuance costs incurred was capitalized and is included in deferred financing costs, net on our condensed consolidated balance sheets. These costs are being amortized using the effective interest method through December 15, 2017, the maturity date of the notes, and such amortization expense is reflected in interest expense on our condensed consolidated statements of operations. The amount of amortization for the three months ended September 30, 2012 and 2011 was approximately $0.1 million for each period. The amount of amortization for the nine months ended September 30, 2012 and 2011 was approximately $0.2 million for each period. The amount of accumulated amortization at September 30, 2012 and December 31, 2011 was approximately $0.5 million and $0.3 million, respectively.

Product Warranty

Certain patient accessories sold with the HeartWare System are covered by a limited warranty ranging from one to two years. Estimated contractual warranty obligations are recorded as an expense when the related revenue is recognized and are included in cost of revenue on our condensed consolidated statements of operations. Factors that affect estimated warranty liability include the number of units sold, historical and anticipated rates of warranty claims, cost per claim, and vendor supported warranty programs. We periodically assess the adequacy of our recorded warranty liabilities and adjust the amounts as necessary.

The amount of the liability recorded is equal to the estimated costs to repair or otherwise satisfy claims made by customers. Accrued warranty expense is included as a component of other accrued liabilities on our condensed consolidated balance sheets.

The costs to repair or replace products associated with product recalls and voluntary service campaigns are recorded when they are determined to be probable and reasonably estimable as a cost of revenue and are not included in product warranty liability. No such costs were incurred in the three and nine months ended September 30, 2012 and 2011.

The following table summarizes the change in our warranty liability for the nine months ended September 30, 2012 and 2011:

	2012	2011
	(in thousands)	
Beginning balance	$ 203	$291
Accrual for (reversal of) warranty expense	668	(21)
Warranty costs incurred during the period	(453)	(34)
Ending balance	$ 418	$236

Leases

We lease all of our administrative and manufacturing facilities. We recognize rent expense on a straight-line basis over the terms of our leases. Any scheduled rent increases, rent holidays and other related incentives are recognized on a straight-line basis over the terms of the leases. The difference between the cash rental payments and the straight-line

recognition of rent expense over the terms of the leases results in a deferred rent asset or liability. As of September 30, 2012, the long-term portion of our deferred rent liability of approximately $2.9 million is included in other long-term liabilities on our condensed consolidated balance sheets.

Fair Value Measurements

The carrying amounts reported on our condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, accounts payable and other accrued liabilities approximate their fair value based on the short-term maturity of these instruments. Investments are considered available-for-sale as of September 30, 2012 and December 31, 2011 and are carried at fair value. See Note 5, "Fair Value Measurements" and Note 11, "Debt" for more information.

Vendor Concentration

For the three and nine months ended September 30, 2012, we purchased approximately 57% and 66%, respectively, of our inventory components and supplies from three vendors. For the three and nine months ended September 30, 2011, we purchased approximately 61% and 59%, respectively of our inventory components and supplies from the same three vendors. In addition, one of these vendors supplies consulting services and material used in research and development activities. As of September 30, 2012 and 2011, the amounts due to these vendors totaled approximately $1.4 million and $0.9 million, respectively.

We purchase certain important components of the HeartWare System from single-source suppliers. We cannot guarantee that we can secure alternative suppliers that could provide similar components on comparable terms and consistent with regulatory requirements. A change in suppliers could cause a delay in manufacturing and a possible loss of product sales or result in higher component costs, all of which would have a negative effect on our results of operations.

Concentration of Credit Risk and other Risks and Uncertainties

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash and cash equivalents, investments and trade accounts receivable. Cash and cash equivalents are primarily on deposit with financial institutions in the United States and these deposits generally exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (the "FDIC"). The Company has not experienced any historical losses on its deposits of cash and cash equivalents. Our investments consist of investment grade rated corporate and government agency debt and time deposits.

Concentration of credit risk with respect to our trade accounts receivable from our customers is primarily limited to hospitals, health research institutions and medical device distributors. Credit is extended to our customers, based on an evaluation of a customer's financial condition and collateral is not required.

We are subject to certain risks and uncertainties including, but not limited to, our ability to achieve profitability, to generate cash flow sufficient to satisfy our indebtedness, to run clinical trials in order to receive and maintain FDA and foreign regulatory approvals for our products, the ability to achieve widespread acceptance of our product, our ability to manufacture our products in a sufficient volume and at a reasonable cost, the ability to protect our proprietary technologies and develop new products, the risks associated with operating in foreign countries, and general competitive and economic conditions. Changes in any of the preceding areas could have a material adverse effect on our business, results of operations or financial position.

New Accounting Standards

In September 2011, the FASB issued ASU No. 2011-08, *Intangibles - Goodwill and Other (Topic 350), Testing Goodwill for Impairment*, which permits an entity to make a qualitative assessment of whether it is more likely than not that a reporting unit's fair value is less than its carrying value before applying the two-step goodwill impairment model that is currently in place. If it is determined through the qualitative assessment that a reporting unit's fair value is more likely than not greater than its carrying value, the remaining impairment steps would be unnecessary. The qualitative assessment is optional, allowing companies to go directly to the quantitative assessment. ASU No. 2011-08 is effective for annual and interim goodwill impairment tests performed in fiscal years beginning after December 15, 2011. The adoption of ASC No. 2011-08 did not affect our consolidated financial position, results of operations or cash flows.

In June 2011, the FASB issued ASU No. 2011-05, *Comprehensive Income (Topic 220): Presentation of Comprehensive Income*. ASU No. 2011-05 requires an entity to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income, or in two separate but consecutive statements. ASU No. 2011-05 eliminates the option to present components of other comprehensive income as part of the statement of stockholders' equity. The presentation requirements became effective for us on January 1, 2012. The adoption of ASU No. 2011-05 did not affect our consolidated financial position, results of operations or cash flows.

Note 4. Acquisition of World Heart

On August 2, 2012, we completed the acquisition of 100% of the outstanding shares of World Heart Corporation ("World Heart") for consideration of approximately 83,000 shares of HeartWare International common stock, valued at approximately $6.9 million. The fair value of the shares issued was determined on the basis of the closing market price of HeartWare International common stock on the acquisition date. The acquisition expands our intellectual property and technology portfolio. In accordance with accounting standards for business combinations, we accounted for the acquisition of World Heart under the acquisition method. Under the acquisition method, the assets and liabilities assumed at the date of acquisition were recorded in the consolidated financial statements at their respective fair values at the date of acquisition. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill. World Heart's results of operations are included in our consolidated financial statements from the date of acquisition.

The determination of the estimated fair value of the acquired assets and liabilities required management to make significant estimates and assumptions. We determined the fair value by applying established valuation techniques, based on information that management believed to be relevant to this determination. We also hired an independent third party to assist in the valuation of purchased intangible assets and goodwill. The following table summarizes the purchase price allocation of the fair value of the assets acquired and liabilities assumed at the date of acquisition:

	(in thousands)
Assets	
Short-term:	
Cash and cash equivalents	$ 3,689
Other current assets	1,116
Long-term:	
Property, plant and equipment	307
In-process research and development	2,536
Intangible assets	1,327
Goodwill	1,190
Total Assets	10,165
Liabilities	
Current	1,964
Non-current	1,258
Net Assets Purchased	$ 6,943

Intangible assets are expected to be amortized on a straight-line based over the useful life of the acquired asset.

Valuing components of the acquisition, including intangible assets, required us to make estimates. Due to the short period of time since the acquisition, we are still obtaining and analyzing information necessary for determining the fair value of certain assets and liabilities as of that date. Consequently, the purchase price allocation is considered preliminary.

In-process research and development has an indefinite life. At the time the economic life becomes determinable (upon project completion or abandonment) the amount will be amortized over its expected remaining life. Goodwill will not be amortized but will be reviewed for impairment on an annual basis or sooner if indicators of impairment arise

All legal, consulting and other costs related to the acquisition aggregating approximately $1.1 million have been expensed as incurred and are included in selling, general and administrative expenses in our statements of operations. Pro forma results of operations have not been presented because the effect of this acquisition was not material our consolidated financial position, results of operations or cash flows.

Note 5. Fair Value Measurements

FASB ASC 820 – *Fair Value Measurements and Disclosures,* defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us as of the reporting dates. Accordingly, the estimates presented in these condensed consolidated financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

FASB ASC 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

Level 1 – Quoted prices for identical instruments in active markets.

Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 – Instruments with primarily unobservable value drivers.

The following table represents the fair value of our financial assets and financial liabilities measured at fair value on a recurring basis and which level was used in the fair value hierarchy.

	At September 30, 2012				
			Fair Value Measurements at the Reporting Date Using		
	Carrying Value	Fair Value	Level 1	Level 2	Level 3
			(in thousands)		
Assets					
Short-term investments	$ 5,743	$ 5,743	$ —	$ 5,743	$ —
Liabilities					
Convertible senior notes	98,737(1)	174,699	—	174,699	—

	At December 31, 2011				
			Fair Value Measurements at the Reporting Date Using		
	Carrying Value	Fair Value	Level 1	Level 2	Level 3
			(in thousands)		
Assets					
Short-term investments	$91,925	$ 91,925	$ —	$ 91,925	$ —
Liabilities					
Convertible senior notes	94,277(1)	145,259	—	145,259	—

(1) The carrying amount of our convertible senior notes is net of unamortized discount. See Note 11, “Debt” for more information.

The fair value of our investments and convertible senior notes was determined using quoted prices (including trade data) for the instruments in markets that are not active. The fair value of our convertible senior notes is presented for disclosure purposes only.

Note 6. Investments

We have cash investment policies that limit investments to investment grade rated securities. At September 30, 2012 and December 31, 2011, all of our investments were classified as available-for-sale and carried at fair value. At September 30, 2012, all of our investments had maturity dates of less than twenty-four months.

The amortized cost and fair value of our investments, with gross unrealized gains and losses, were as follows:

At September 30, 2012

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
		(in thousands)		
Short-term investments:				
U.S. government agency debt	$ 502	$ —	$ —	$ 502
Corporate debt	810	—	—	810
Certificates of deposit	4,431	—	—	4,431
Total short-term investments	$ 5,743	$ —	$ —	$ 5,743

At December 31, 2011

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
		(in thousands)		
Short-term investments:				
U.S. government agency debt	$ 31,290	$ 2	$ (28)	$ 31,264
Corporate debt	5,023	3	—	5,026
Certificates of deposit	55,635	—	—	55,635
Total short-term investments	$ 91,948	$ 5	$ (28)	$ 91,925

For the three and nine months ended September 30, 2012 and 2011, we did not have any realized gains or losses on our investments.

Note 7. Inventories, Net

Components of inventories, net are as follows:

	September 30, 2012	December 31, 2011
	(in thousands)	
Raw material	$ 9,106	$ 8,318
Work-in-process	11,295	7,385
Finished goods	18,253	16,302
	$ 38,654	$ 32,005

Finished goods inventories includes inventory held on consignment at customer sites of approximately $8.8 million and $7.2 million at September 30, 2012 and December 31, 2011, respectively.

Note 8. Property, Plant and Equipment, Net

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

	Estimated Useful Lives	September 30, 2012	December 31, 2011
		(in thousands)	
Machinery and equipment	1.5 to 7 years	$ 16,843	$ 14,951
Leasehold improvements	3 to 10 years	7,824	5,747
Office equipment, furniture and fixtures	5 to 7 years	912	1,249
Purchased software	5 to 7 years	3,463	2,733
		29,042	24,680
Less: accumulated depreciation		(9,629)	(6,355)
		$ 19,413	$ 18,325

Note 9. Intangible Assets, Net

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

Amortizable Intangible Assets	Weighted Average Life (Years)	September 30, 2012		December 31, 2011	
		Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
		(in thousands)			
Patents	15.3	$ 4,119	$ (525)	$ 2,416	$ (402)
In-process research and development	Indefinite	2,536	—	—	—

Amortization expense for the three months ended September 30, 2012 and 2011 was approximately $43,000 and $35,000, respectively. Amortization expense for the nine months ended September 30, 2012 and 2011 was approximately $123,000 and $73,000, respectively.

Note 10. Other Accrued Liabilities

Other accrued liabilities consist of the following:

	September 30, 2012	December 31, 2011
	(in thousands)	
Accrued payroll and other employee costs	$ 6,934	$ 6,274
Accrued material purchases	1,955	1,332
Accrued research and development costs	1,679	1,627
Accrued interest payable	1,490	210
Accrued VAT	1,186	390
Accrued litigation settlement	—	1,125
Accrued professional fees	949	1,100
Other accrued expenses	1,429	378
	$ 15,622	$ 12,436

Accrued payroll and other employee costs included estimated year-end employee bonuses of approximately $3.8 million and $4.4 million at September 30, 2012 and December 31, 2011, respectively.

Note 11. Debt

On December 15, 2010, we completed the sale of 3.5% convertible senior notes due 2017 (the “Convertible Notes”) for an aggregate principal amount of $143.75 million pursuant to the terms of an Indenture dated December 15, 2010. The Convertible Notes are the senior unsecured obligations of the Company. The Convertible Notes bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year. The Convertible Notes will mature on December 15, 2017, unless earlier repurchased by us or converted.

The Convertible Notes will be convertible at an initial conversion rate of 10 shares of our common stock per $1,000 principal amount of Convertible Notes, which corresponds to an initial conversion price of $100.00 per share of our common stock. The conversion rate is subject to adjustment from time to time upon the occurrence of certain events.

Prior to June 15, 2017, holders may convert their Convertible Notes at their option only upon satisfaction of one or more conditions relating to the sale price of our common stock, the trading price per $1,000 principal amount of Convertible Notes or specified corporate events. On or after June 15, 2017, until the close of business of the business day immediately preceding the date the Convertible Notes mature, holders may convert their Convertible Notes at any time, regardless of whether any of the foregoing conditions have been met. As of the date of this report, none of the events that would allow holders to convert their Convertible Notes have occurred. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination thereof, at our election.

We may not redeem the Convertible Notes prior to maturity. Holders of the Convertible Notes may require us to purchase for cash all or a part of their Convertible Notes at a repurchase price equal to 100% of the principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, upon the occurrence of certain fundamental changes (as defined in the Indenture) involving the Company. The Indenture does not contain any financial or operating covenants or restrictions on the payments of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by us or any of our subsidiaries.

The Indenture contains customary terms and nonfinancial covenants and defines events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization) involving the Company occurs and is continuing, the Trustee (by notice to the Company) or the holders of at least 25% in principal amount of the outstanding Convertible Notes (by notice to the Company and the Trustee) may declare 100% of the principal of and accrued and unpaid interest, if any, on all the Convertible Notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving the Company, 100% of the principal of and accrued and unpaid interest on the Convertible Notes will automatically become due and payable. Upon a declaration of acceleration, principal and accrued and unpaid interest, if any, will be due and payable immediately. Notwithstanding the foregoing, the Indenture provides that, to the extent we elect, the sole remedy for an event of default relating to certain failures by us to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the Convertible Notes.

In accordance with ASC 470-20, *Debt*, which applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion, we recorded the long-term debt and equity components on our Convertible Notes separately on the issuance date. The amount recorded for long-term debt was determined by measuring the fair value of a similar liability that does not have an associated equity component. The measurement of fair value required the Company to make estimates and assumptions to determine the present value of the cash flows of the Convertible Notes, absent the conversion feature. This treatment increased interest expense associated with our Convertible Notes by adding a non-cash component to interest expense in the form of amortization of a debt discount calculated based on the difference between the 3.5% cash coupon rate and the effective interest rate on debt borrowing of approximately 12.5%. The discount is being amortized to interest expense through the December 15, 2017 maturity date of the Convertible Notes using the effective interest method and is included in interest expense on our condensed consolidated statements of operations. Additionally, we allocated the costs related to issuance of the Convertible Notes on the same percentage as the long-term debt and equity components, such that a portion of the costs is allocated to the long-term debt component and the equity component included in additional paid-in capital. The portion of the costs allocated to the long-term debt component is presented as deferred financing costs, net on our condensed consolidated balance sheets. These deferred financing costs are also being amortized to interest expense through the December 15, 2017 maturity date of the Convertible Notes using the effective interest method and such amortization is included in interest expense on our condensed consolidated statements of operations

The Convertible Notes and the equity component, which is recorded in additional paid-in-capital, consisted of the following:

	September 30, 2012	December 31, 2011
	(in thousands)	
Principal amount	$ 143,750	$ 143,750
Unamortized discount	(45,013)	(49,473)
Net carrying amount	$ 98,737	$ 94,277
Equity component	$ 55,038	$ 55,038

Based on the initial conversion rate of 10 shares of our common stock per $1,000 principal amount of Convertible Notes, which corresponds to an initial conversion price of $100.00 per share of our common stock, the number of shares issuable upon conversion of the Convertible Notes is 1,437,500. The value of these shares, based on the closing price of our common stock on September 28, 2012 of $94.49 per share, was approximately $135.8 million. The fair value of our Convertible Notes as presented in Note 5 was $174.7 million at September 30, 2012.

Interest expense related to the Convertible Notes consisted of interest due on the principal amount, amortization of the discount and amortization of the portion of the deferred financing costs allocated to the long-term debt component. For the three and nine months ended September 30, 2012 and 2011, interest expense related to the Convertible Notes was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)			
Stated amount at 3.5% coupon rate	$ 1,258	$ 1,258	$3,774	$3,774
Amortization of discount	1,532	1,358	4,460	3,955
Amortization of deferred financing costs	82	73	239	212
	$ 2,872	$ 2,689	$8,473	$7,941

Note 12. Stockholders' Equity

In addition to the approximately 83,000 shares issued in connection with the acquisition of World Heart, see Note 4, "Acquisition of World Heart", in the nine months ended September 30, 2012, we issued an aggregate of 65,808 shares of our common stock upon the exercise of stock options and an aggregate of 160,830 shares of our common stock upon the vesting of restricted stock units.

In the nine months ended September 30, 2011, we issued an aggregate of 20,364 shares of our common stock upon the exercise of stock options and an aggregate of 154,476 shares of our common stock upon the vesting of restricted stock units.

Note 13. Share-Based Compensation

We recognize share-based compensation expense related to our stock options and restricted stock units ("RSU's) based on the estimated fair value of the awards on the date of the grant, net of estimated forfeitures, using an accelerated accrual method over the vesting period. Vesting of share-based awards issued with performance-based vesting criteria must be probable before we begin recording share-based compensation expense. At each reporting period, we review the likelihood that these awards will vest and if vesting is deemed probable, we 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 expense will be reversed.

We allocate share-based compensation expense to cost of revenue, selling, general and administrative expense and research and development expense based on the award holders' employment function. For the three and nine months ended September 30, 2012 and 2011, we recorded share-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(In thousands)			
Cost of revenue	$ 698	$ 546	$ 2,451	$1,665
Selling, general and administrative	2,746	1,993	8,234	5,647
Research and development	1,449	1,019	4,262	2,683
	$ 4,893	$ 3,558	$14,947	$9,995

The increase in share-based compensation expense for the three and nine months ended September 30, 2012, compared to the same periods of the prior year, is primarily due to the increased number of awards outstanding during 2012 and a reduction in our estimated forfeiture rate recognized in the second quarter of 2012.

No deferred tax benefits were attributed to our share-based compensation expense recorded in the accompanying condensed consolidated financial statements because we are in a net operating loss position and a full valuation allowance is maintained for all net deferred tax assets. We receive a tax deduction for certain stock option exercises during the period the options are exercised, and for the vesting of restricted stock units during the period the restricted stock units vest. For stock options, the amount of the tax deduction is generally for the excess of the fair market value of our shares of common stock over the exercise price of the stock options at the date of exercise. For restricted stock units, the amount of the tax deduction is generally for the fair market value of our shares of common stock at the vesting date. Excess tax benefits are not included in the accompanying condensed consolidated financial statements because we are in a net operating loss position and a full valuation allowance is maintained for all net deferred tax assets.

Equity Plans

We have issued share-based 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 share-based awards.

On August 5, 2008, we adopted the HeartWare International, Inc. 2008 Stock Incentive Plan ("2008 SIP"). The 2008 SIP allowed for the issuance of share-based awards to employees, directors and consultants. We have issued options and RSU's to employees and directors under the 2008 SIP. As noted below, subsequent to adoption of the HeartWare International, Inc. 2012 Incentive Award Plan, no new awards will be granted under the 2008 SIP.

Upon receipt of stockholder approval on May 31, 2012, we adopted the HeartWare International, Inc. 2012 Incentive Award Plan ("2012 Plan"). The 2012 Plan provides for the grant of incentive stock options, non-qualified stock options, restricted stock, restricted stock units, performance awards, dividend equivalent rights, deferred stock, deferred stock units, stock payments and stock appreciation rights (collectively referred to as "Awards"), to our directors, employees and consultants. Under the terms of the 2012 Plan, the total number of shares of our common stock initially reserved for issuance under Awards is 1,375,000, provided that the total number of shares of our common stock that may be issued pursuant to "Full Value Awards" (Awards other than options, SARs or other awards for which the holder pays the intrinsic value existing as of the date of grant whether directly or by forgoing a right to receive a payment from the Company) is 1,275,000. As of September 30, 2012, 27,550 awards had been issued under the 2012 Plan. Subsequent to adoption of the 2012 Plan, no new awards will be granted under the 2008 SIP (or prior plans). Any outstanding awards under the 2008 SIP and any other plans will continue to be subject to the terms and conditions of the plan from which they were granted.

Stock Options

Each option allows the holder to subscribe for and be issued one share of our common stock at a specified price, which is generally the quoted market price of our common stock on the date the option is issued. Options generally vest on a pro-rata basis on each anniversary of the issuance date within four years of the date the option is issued or vest in accordance with performance-based criteria. Options may 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 the option is issued.

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. Any performance-based options that have not vested after five years from the date of grant automatically expire.

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model using the assumptions established at that time. No options were issued in the three months ended September 30, 2012. The following table includes the weighted average assumptions used for options issued in the three months ended September 30, 2011 and the nine months ended September 30, 2012 and 2011.

	Three Months Ended September 30,	Nine Months Ended September 30,	
	2011	2012	2011
Dividend yield	0%	0%	0%
Expected volatility	58.00%	57.00%	58.23%
Risk-free interest rate	1.40%	1.00%	1.97%
Estimated holding period (years)	6.25	6.25	6.25

Information related to options granted under all of our plans at September 30, 2012 and activity in the nine months then ended is as follows (certain amounts in U.S.$ were converted from AU$ at the then period-end spot rate):

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2011	381	$ 34.79		
Granted	7	81.37		
Exercised	(66)	35.20		
Forfeited	(4)	42.26		
Expired	—	—		
Outstanding at September 30, 2012	318	$ 36.21	5.24	$ 18,564
Exercisable at September 30, 2012	257	$ 33.32	4.75	$ 15,736

The aggregate intrinsic values at September 30, 2012 noted in the table above represent the closing price of our common stock traded on NASDAQ, less the weighted average exercise price at period end multiplied by the number of options outstanding or exercisable.

At September 30, 2012, 16,791 of the options outstanding that are not yet exercisable are subject to performance-based vesting criteria as described above.

The weighted average grant date fair value per share of options issued in the nine months ended September 30, 2012 and 2011 was $43.83 and $41.92 per share, respectively.

The total intrinsic value of options exercised in the nine months ended September 30, 2012 was approximately $3.3 million. Cash received from options exercised in the nine months ended September 30, 2012 was approximately $2.3 million. The total intrinsic value of options exercised in the nine months ended September 30, 2011 was approximately $1.1 million. Cash received from options exercised in the nine months ended September 30, 2011 was approximately $0.7 million.

At September 30, 2012, there was approximately $0.9 million of unrecognized compensation expense related to non-vested option awards, including performance-based options not yet deemed probable of vesting. This expense is expected to be recognized over a weighted average period of one year.

Restricted Stock Units

RSU's issued under the plans vest on a pro-rata basis on each anniversary of the issuance date over three or four years or vest in accordance with performance-based criteria. The RSU's with performance-based vesting criteria vest in 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. RSU's with performance-based vesting criteria not vested after five years from the date of grant automatically expire. There is no consideration payable on the vesting or exercise of RSU's issued under the plans. Upon vesting, the RSU's are exercised automatically and settled in shares of our common stock.

Information related to RSU's at September 30, 2012 and activity in the nine months then ended is as follows:

	Number of Units (in thousands)	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2011	635		
Granted	75		
Vested/Exercised	(161)		
Forfeited	(15)		
Expired	—		
Outstanding at September 30, 2012	534	1.53	$ 50,479
Exercisable at September 30, 2012	—	—	$ —

The aggregate intrinsic value at September 30, 2012 noted in the table above represents the closing price of our common stock traded on NASDAQ, multiplied by the number of RSU's outstanding.

At September 30, 2012, 39,617 of the RSU's outstanding that are not yet exercisable are subject to performance-based vesting criteria as described above.

The total intrinsic value of RSU's vested in the nine months ended September 30, 2012 and 2011 was approximately $14.3 million and $9.6 million, respectively.

The fair value of each RSU award equals the closing price of our common stock on the date of grant. The weighted average grant date fair value per share of RSU's granted in the nine months ended September 30, 2012 and 2011 was $85.85 and $76.64, respectively.

At September 30, 2012, we had approximately $19.1 million of unrecognized compensation expense related to non-vested RSU awards, including awards not yet deemed probable of vesting. This expense is expected to be recognized over a weighted average period of 1.5 years.

Note 14. Net Loss Per Common Share

Basic net 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. Diluted net loss per common share adjusts basic net loss per share for the dilutive effects of convertible securities, share-based awards and other potentially dilutive instruments only in the periods in which such effect is dilutive. Due to our net loss for all periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. The following instruments have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive.

	Three and Nine Months Ended September 30,	
	2012	2011
	(in thousands)	
Common shares issuable upon:		
Conversion of convertible senior notes	1,438	1,438
Exercise or vesting of share-based awards	852	840

Note 15. 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 to customers located in the United States through our clinical trials, as commercial products to customers in Europe and under special access in other countries. Product sales attributed to a country or region are based on the location of the customer to whom the products are sold. Long-lived assets are primarily held in the United States.

Product sales by geographic location were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)			
United States	$ 3,627	$ 7,606	$14,264	$19,795
Germany	9,756	8,569	29,570	22,281
International, excluding Germany	9,479	5,165	34,427	17,628
	$22,862	$21,340	$78,261	$59,704

Revenue from U.S. sources for the three and nine months ended September 30, 2012 is lower than comparable periods in 2011 due to variability in clinical enrollment. We completed enrollment in our Destination Therapy trial in May 2012. As the majority of our revenue is generated outside of the U.S., we are dependent on favorable economic and regulatory environments for our products in Europe and other countries outside of the U.S. For the three and nine months ended September 30, 2012 and 2011, no customers exceeded 10% of product sales individually.

Note 16. Commitments and Contingencies

At September 30, 2012, we had purchase order commitments of approximately $29.7 million related to product costs, supplies, services and property, plant and equipment purchases. Many of our materials and supplies require long lead times and as such purchase order commitments reflect materials that may be received up to one year from the date of order.

Litigation

From time to time we may be involved in litigation or other contingencies arising in the ordinary course of business. Except as set forth below or in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011, and based on the information presently available, management believes that there are no contingencies, claims or actions, pending or threatened, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or result of operations.

On February 24, 2010, we received a letter from two holders of Series A Preferred Stock in HeartWare, Inc., an indirect subsidiary of HeartWare International, Inc. These holders requested various financial and other information regarding HeartWare, Inc. for the purpose of determining the Company's compliance with their rights as holders of Series A Preferred Stock, including whether a liquidation event has occurred since inception in 2003. HeartWare, Inc. issued Series A-1 and Series A-2 Preferred Stock to certain equity holders of Kriton Medical, Inc. when HeartWare, Inc. purchased out of bankruptcy substantially all of the assets of Kriton in July 2003. The Series A-1 and Series A-2 Preferred Stock do not have voting or dividend rights but, prior to the settlement described below, entitled the holders thereof to receive, upon certain liquidation events of HeartWare, Inc. (but not the liquidation of or change of control of HeartWare International, Inc.), an amount equal to $10 per share of Series A-1 and $21 per share of Series A-2. The aggregate liquidation preference payment obligation totaled approximately $15 million.

On June 27, 2011, HeartWare International, Inc. and HeartWare, Inc., along with HeartWare's directors, certain officers and a significant stockholder, were named as defendants in a putative class action lawsuit filed in Massachusetts state court by two other Series A Preferred Stockholders on behalf of all holders of Series A Preferred Stock. The complaint alleged that the defendants breached their fiduciary and contractual obligations to Series A Preferred Stockholders by preventing them from receiving a payment of the liquidation preference in connection with certain corporate transactions, including a transaction in 2005 in which HeartWare, Inc. was acquired by HeartWare Limited, a subsidiary of HeartWare International, Inc. The plaintiffs sought monetary damages, interest, costs and limited equitable relief. We do not believe HeartWare International, Inc., HeartWare, Inc. or any of our directors, officers or stockholders have abrogated the rights, or in any way failed to satisfy obligations owed to, any of our stockholders, including holders of Series A Preferred Stock. On September 12, 2011, the defendants served on plaintiffs a motion to dismiss the complaint with prejudice. On February 3, 2012, counsel for plaintiffs and defendants entered into a Memorandum of Understanding to settle the matter. Defendants agreed to pay up to $1.1 million to participating putative class members in exchange for a full and unconditional release of all claims asserted in the litigation, including any and all claims arising from any right to receive a payment upon any liquidation or deemed liquidation event that has arisen or may arise in the future. On March 22, 2012, the parties filed with the court a stipulation of settlement formalizing the settlement agreement. Shortly thereafter, plaintiffs caused notice of the settlement to be made to putative class members. Following a hearing on July 25, 2012, the court entered judgment granting plaintiffs' motion to finally approve the settlement, including the full and unconditional release of all present and future claims to receive the liquidation preference, and dismissed the case with prejudice.

In accordance with ASC 450*, Contingencies*, we accrue loss contingencies including costs of settlement, damages and defense related to litigation to the extent they are probable and reasonably estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range. At December 31, 2011, we determined that settlement of the litigation discussed above was probable and that the reasonably estimable settlement amount was $1.1 million. Accordingly, we recorded a liability for the $1.1 million and a $0.2 million receivable from one of the co-defendants, who is a related party. On September 4, 2012, defendants funded the settlement after receiving $0.8 million from our insurance carrier in connection with the settlement of this litigation. The insurance recovery is included in selling, general and administrative expenses in our statement of operations.

Milestone Payment

In connection with the purchase of the assets from Kriton Medical in 2003, we entered into a settlement and release agreement pursuant to which we are required to make a milestone payment of $1.25 million 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 million in cash on hand and, if we do not have $25 million at that time, then the payment is deferred until such time that we have $25 million in cash on hand. We submitted a Premarket Approval (PMA) application to the FDA for the HeartWare System in December 2010. Approval of the PMA application by the FDA would result in this contingent liability being recognized. We will record the effect of this payment obligation when and if this event occurs.

Note 17. Subsequent Events

We have evaluated events and transactions that occurred subsequent to September 30, 2012 through the date the financial statements were issued, for potential recognition or disclosure in the accompanying condensed consolidated financial statements. We did not identify any events or transactions that should be recognized or disclosed in the accompanying condensed consolidated financial statements.

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

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. Certain abbreviated key terms have the meanings defined elsewhere in this Quarterly Report on Form 10-Q.

Overview

HeartWare is a medical device company that develops, manufactures and markets miniaturized implantable heart pumps, or ventricular assist devices, to treat patients suffering from advanced heart failure.

The HeartWare® Ventricular Assist System (the "HeartWare System"), which includes a ventricular assist device ("VAD"), or blood pump, patient accessories and surgical tools, is designed to provide circulatory support for patients in the advanced stage of heart failure. The core of the HeartWare System is a proprietary continuous flow blood pump, the HVAD® Pump, which is a full-support device capable of pumping up to 10 liters of blood per minute. The HeartWare System is designed to be implanted adjacent to the heart, avoiding the abdominal surgery generally required to implant similar devices.

In 2009, we received CE Marking for the HeartWare System in the European Union and in March 2011 we received approval from the Therapeutic Goods Administration in Australia allowing for commercial sale and distribution of our device. In the U.S., our device is the subject of clinical trials for two indications: bridge-to-transplant and destination therapy. Our device is also available in other countries around the world under special access programs and limited commercial availability.

Recent key milestones in the development and commercialization of the HeartWare System include the following:

- On August 2, 2012, we completed the acquisition of 100% of the outstanding shares of World Heart Corporation. The acquisition will expand our intellectual property and technology portfolio.
- In May 2012, we received an expanded European label for long-term use of the HeartWare System in all patients at risk of death from refractory, end-stage heart failure.
- In May 2012, results from our ADVANCE bridge-to-transplant clinical trial were published in the American Heart Association's journal *Circulation.*
- In May 2012, we completed enrollment of our ENDURANCE destination therapy clinical trial.
- On April 25, 2012, the FDA's Circulatory System Devices Advisory Committee voted 9 to 2 that the benefits outweigh the risks for the use of the HeartWare System as a bridge to heart transplantation in patients with end-stage heart failure.

Beyond the HeartWare System, we are also evaluating our next generation device, the MVAD® Pump. The MVAD Pump is a development-stage miniature ventricular assist device, approximately one-third the size of the HVAD Pump. The MVAD Pump is based on the same proprietary impeller suspension technology used in the HVAD Pump, with its single moving part held in place through a combination of passive-magnetic and hydrodynamic forces. Like the HVAD Pump, the MVAD Pump is designed to support the heart's full cardiac output, yet also has the capability for partial support. On September 9, 2011, pre-clinical data was presented at the 19th Congress of the International Society for Rotary Blood Pumps (ISRBP), which demonstrated that the MVAD Pump attained the objectives for system performance, hemocompatability and biocompatibility in Good Laboratory Practice ("GLP") animal studies, a precursor to human clinical trials. The MVAD Pump is designed to be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump.

We began generating revenue from our products in August 2008 and have incurred net losses in each year since our inception. We expect our losses to continue as we continue to develop commercial markets, expand our research and development into next generation products, including the MVAD Pump, and related accessories and support on-going and new clinical trial activity.

We have financed our operations primarily through the issuance of convertible notes and the issuance of shares of our common stock. Most recently, on December 15, 2010, we issued convertible notes with an aggregate principal amount of $143.75 million pursuant to the terms of an Indenture dated as of December 15, 2010. The convertible notes are senior unsecured obligations of the Company. The convertible notes bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year. The convertible notes will mature on December 15, 2017, unless earlier repurchased or converted.

We are headquartered in Framingham, Massachusetts. We have facilities in Miami Lakes, Florida, Sydney, Australia, Hannover, Germany and Salt Lake City, Utah.

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 adopt various accounting policies and to make estimates and assumptions in preparing our financial statements that affect the reported amounts of our assets, liabilities, revenue and expenses. On an ongoing basis, we evaluate our estimates and assumptions. 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 and at the time they are made. 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 significant accounting policies are disclosed in Note 3 to the Consolidated Financial Statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 ("2011 Annual Report on Form 10-K") filed with the Securities and Exchange Commission on February 27, 2012. During the nine months ended September 30, 2012, there were no significant changes to any of our significant accounting policies.

Our most critical accounting policies and estimates include revenue recognition, inventory capitalization and valuation, accounting for share-based compensation, measurement of fair value, and the valuation of tax assets and liabilities. We also have other key accounting policies that are less subjective and, therefore, their application is less subject to variations that would have a material impact on our reported results of operations. There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our 2011 Annual Report on Form 10-K.

Results of Operations

Three and nine months ended September 30, 2012 and 2011

Revenue, net

In the three and nine months ended September 30, 2012 and 2011, we generated revenue from commercial sales outside of the U.S. and sales in connection with our clinical trials in the U.S. The increase in revenue in 2012 is primarily due to increased market penetration outside of the U.S.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
	(in thousands)			(in thousands)		
Revenue, net	$22,862	$21,340	7%	$78,261	$59,704	31%

The growth in revenue is primarily driven by strong international sales as we continue to expand our market reach and penetration on a global basis. Revenue from international markets increased approximately 40% to $19.2 million in the third quarter of 2012, from $13.7 million in the third quarter of 2011. The increase was partially offset by a decrease in revenue generated in the U.S. due to variability of product sales associated with clinical trial enrollment.

Prior to FDA approval of the HeartWare System for sale in the U.S., revenue from U.S. sources has varied and will continue to vary from quarter to quarter as revenue from U.S. clinical trials is dependent on FDA approval of Continued Access Protocols. In March 2012, the FDA approved an Investigational Device Exemption Supplement that allowed us to enroll a fourth allotment, of 54 additional patients, in our ADVANCE bridge-to-transplant clinical trial under a Continued Access Protocol (CAP). We expect to complete enrollment of the fourth allotment in the fourth

quarter of 2012. In May 2012, we completed enrollment of our ENDURANCE destination therapy clinical trial. A request for approval to implant additional patients under a CAP in U.S. centers that implanted a patient in the ENDURANCE trial is in progress.

Domestic revenue decreased approximately 52% to $3.7 million in the third quarter of 2012, from $7.6 million in the third quarter of 2011. In the three months ended September 30, 2012, approximately 16% of our product sales were derived in the U.S. compared to approximately 36% in the three months ended September 30, 2011. In the nine months ended September 30, 2012, approximately 18% of our product sales were derived in the U.S. compared to 33% in the nine months ended September 30, 2011.

Our sales are made in multiple currencies including the Euro. In the three and nine months ended September 30, 2012, our net revenue denominated in foreign currencies increased by $3.0 million, or 23%, and $15.8 million, or 44%, respectively, compared to the three and nine months ended September 30, 2011. Changes in foreign exchange rates unfavorably impacted revenue by approximately $1.8 million, or 8%, and $4.4 million, or 7%, in the three and nine months ended September 30, 2012, respectively, compared to the three and nine months ended September 30, 2011.

Cost of Revenue

Cost of revenue includes costs associated with manufacturing and distributing our product and consists of direct materials, labor and overhead expenses allocated to the manufacturing process. Cost of revenue totaled approximately $10.9 million and $7.9 million in the three months ended September 30, 2012 and 2011, respectively. Cost of revenue totaled approximately $34.4 million and $23.4 million in the nine months ended September 30, 2012 and 2011, respectively.

Gross profit and gross margin percentage are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands)		(in thousands)	
Gross profit	$11,937	$13,456	$43,843	$36,312
Gross margin %	52.2%	63.1%	56.0%	60.8%

Gross margin percentage for the three and nine months ended September 30, 2012 decreased compared to the same periods in 2011 due to an increase in certain reserves including warranty obligations, inventory obsolescence and adjustments to value inventory at the lower of cost or market. We also experienced an increase in overhead expenses that were not offset by a proportional increase in unit sales volume and a negative impact of foreign currency movements upon revenue, principally the Euro.

Selling, General and Administrative

Selling, general and administrative expenses include costs associated with selling and marketing our products and the general corporate administration of the Company. These costs are primarily related to salaries and wages and related employee costs, 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 revenue.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
	(in thousands)			(in thousands)		
Total selling, general and administrative expenses	$ 13,768	$ 10,833	27%	$ 40,687	$ 29,389	38%
% of operating expenses	39.2%	46.0%		39.9%	47.7%	

The increase of $2.9 million for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 was primarily a result of an increase in employee costs, including salaries and wages and related costs, of approximately $0.9 million, due to increased headcount to build our global sales and marketing and administrative functions to support expected future growth. We also experienced an increase in non-cash share-based compensation expense of $0.8 million, due to an increase in the number of outstanding awards and a reduction in our estimated forfeiture rate in 2012. Other contributors included increased costs for taxes of $0.5 million, consultants and contractors of $0.2 million, insurance of $0.2 million, and accounting and tax services of $0.2 million.

The increase of $11.3 million for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 was primarily a result of an increase in employee costs, including salaries and wages and related costs, of approximately $3.6 million, due to increased headcount to build our global sales and marketing and administrative functions to support expected future growth. We also experienced an increase in non-cash share-based compensation expense of $2.6 million, due to an increase in the number of outstanding awards and a reduction in our estimated forfeiture rate in 2012. Other contributors included increased costs for taxes of $1.1 million, consultants and contractors of $0.9 million, travel expenses of $0.7 million, accounting and tax services of $0.4 million, insurance of $0.4 million, marketing expenses of $0.4 million and depreciation of $0.4 million. Increased legal costs of $1.0 million associated with litigation and corporate transaction activity, including the acquisition of World Heart, were mostly offset by an insurance recovery of $0.8 million related to the settlement of litigation discussed in Note 16 to the accompanying condensed consolidated financial statements.

We expect our selling, general and administrative expenses to continue to increase in 2012 compared to 2011 as we prepare for the commercial launch of the HeartWare System in the United States, and continue to expand our administrative capabilities to support our overall corporate growth. We have and will continue to experience an increase in our employee headcount as well as an increase in costs associated with the necessary administrative infrastructure to support this expansion.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products prior to commercialization, including the costs of operating clinical trials, and are expensed as incurred. These expenses fluctuate based on project level activity and consist primarily of salaries and wages and related employee costs of our research and development, clinical and regulatory staff, external research and development costs, and materials and expenses associated with clinical trials. Additional costs include travel, facilities and overhead allocations.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2012	2011	Change	2012	2011	Change
	(in thousands)			(in thousands)		
Total research and development expenses	$ 21,379	$ 12,705	68%	$ 61,392	$ 32,285	90%
% of operating expenses	60.8%	54.0%		60.1%	52.3%	

The increase of $8.7 million for the three months ended September 30, 2012 as compared to the three months ended September 30, 2011 was primarily due to an increase in costs associated with early research and product development projects, including consumables, outside engineering, consultants and contractors, of $4.3 million. Costs associated with our U.S. clinical trials increased by $2.5 million. We also experienced an increase in employee costs, including salaries and wages and related costs, of approximately $1.1 million associated with increased headcount and an increase in non-cash share-based compensation of $0.4 million due to an increase in the number of outstanding awards and a reduction in our estimated forfeiture rate in 2012.

The increase of $29.1 million for the nine months ended September 30, 2012 as compared to the nine months ended September 30, 2011 was primarily due to an increase in costs associated with product development projects, including consumables, outside engineering, consultants and contractors, of $14.5 million. Costs associated with our U.S. clinical trials increased by $7.0 million. We also experienced an increase in employee costs, including salaries and wages and related costs, of approximately $4.1 million associated with increased headcount and an increase in non-cash share-based compensation of $1.6 million due to an increase in the number of outstanding awards and a reduction in our estimated forfeiture rate in 2012.

We expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future related to clinical trials and new product development, including costs related to the development of the MVAD system.

Foreign Exchange

We generate a substantial portion of our revenue and collect receivables in foreign currencies. Fluctuations in the exchange rate of the U.S. dollar against the Euro, British Pound and Australian dollar can result in foreign currency exchange gains and losses that may significantly impact our financial results. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter. In general, we do not currently utilize foreign currency contracts to mitigate foreign exchange gains and losses.

In the three and nine months ended September 30, 2012, our net foreign exchange gains totaled approximately $1.2 million and $0.1 million, respectively, compared to net losses of approximately $1.4 million and $0.7 million in the same periods of 2011. In 2012 and 2011, the majority of our realized and unrealized foreign exchange gains and losses were experienced upon the collection of certain accounts receivable that were denominated in foreign currencies, and the translation to U.S. dollars at period end of certain balance sheet accounts, denominated in foreign currencies, primarily the Euro. We expect to continue to realize foreign exchange gains and losses for the foreseeable future as the majority of our sales denominated in foreign currencies are settled in Euros. We do not currently utilize foreign currency contracts to manage foreign exchange risks.

Interest Expense

Interest expense in 2012 and 2011 primarily consists of interest incurred on the principal amount of our convertible senior notes issued in December 2010, amortization of the related discount and amortization of the portion of the deferred financing costs allocated to the debt component. The convertible senior notes bear interest at a rate of 3.5% per annum. The discount on the convertible senior notes and the deferred financing costs are being amortized to interest expense through the December 15, 2017 maturity date of the convertible senior notes using the effective interest method.

In the three months ended September 30, 2012, interest expense was approximately $2.9 million, which included $1.3 million of interest incurred on the principal amount of the convertible notes at the 3.5% coupon rate and $1.6 million of non-cash amortization of the discount and deferred financing costs. In the three months ended September 30, 2011, interest expense was approximately $2.7 million, which included $1.3 million of interest incurred on the principal amount of the convertible notes at the 3.5% coupon rate and $1.4 million of non-cash amortization of the discount and deferred financing costs.

In the nine months ended September 30, 2012, interest expense was approximately $8.5 million, which included $3.8 million of interest incurred on the principal amount of the convertible notes at the 3.5% coupon rate and $4.7 million of non-cash amortization of the discount and deferred financing costs. In the nine months ended September 30, 2011, interest expense was approximately $7.9 million, which included $3.8 million of interest incurred on the principal amount of the convertible notes at the 3.5% coupon rate and $4.1 million of non-cash amortization of the discount and deferred financing costs.

Investment Income, net

Investment income is primarily derived from investments and cash and short-term deposit accounts held in the U.S. The amortization of premium on our investments is also included in investment income, net. Investment income, net was approximately $0.03 million and $0.2 million in the three and nine months ended September 30, 2012, compared to $0.1 million and $0.4 million in the same periods in the prior year. We have had lower cash and investments balances during 2012 and have experienced lower interest rates compared to 2011.

Income Taxes

We are subject to taxation in the United States and jurisdictions outside of the United States. These jurisdictions have different marginal tax rates. While we have incurred losses since inception, changes in issued capital and 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 September 30, 2012, we did not have earnings which would be sufficient to allow any portion of our deferred tax assets to be recorded. We intend to monitor closely whether to record a deferred tax asset as we further expand the commercialization of our products.

Liquidity and Capital Resources

As of September 30, 2012, our cash and cash equivalents were approximately $111.9 million as compared to $71.3 million at December 31, 2011.

Following is a summary of our cash flow activities:

	Nine Months Ended September 30,	
	2012	2011
	(in thousands)	
Net cash used in operating activities	$ (46,338)	$ (18,943)
Net cash provided by (used in) investing activities	84,867	(74,596)
Net cash provided by financing activities	2,316	658
Effect of exchange rate changes on cash and cash equivalents	(219)	(143)
Net increase (decrease) in cash and cash equivalents	$ 40,626	$ (93,024)

Cash Used in Operating Activities

For the nine months ended September 30, 2012, cash used in operating activities included a net loss of approximately $66.6 million and non-cash adjustments to net loss totaling approximately $24.1 million. The net loss is driven by normal operating activities including the sale of the HeartWare System commercially internationally and in the U.S. through clinical trials. A decrease in gross profit and increased operating expenses contributed to the net loss. Non-cash adjustments include $14.9 million of share-based compensation, $4.5 million for the amortization of the discount on our convertible senior notes and $3.4 million of depreciation and amortization on long-lived assets. Also included in cash used in operating activities in the nine months ended September 30, 2012 is approximately $2.2 million of changes to working capital including an increase in accounts receivable, $6.7 million for the purchase and manufacture of inventories and $1.2 million for prepaid expenses and other current assets. These amounts were partially offset by increases in trade accounts payable of $4.3 million.

For the nine months ended September 30, 2011, cash used in operating activities included a net loss of approximately $33.5 million and non-cash adjustments to net loss totaling approximately $16.8 million, which primarily consisted of $10.0 million of share-based compensation, $4.0 million for the amortization of the discount on our convertible notes and $1.8 million of depreciation and amortization on long-lived assets. Also included in cash used in operating activities in the nine months ended September 30, 2011 is approximately $14.0 million for the purchase and manufacture of inventories and $2.5 million for prepaid expenses. These amounts were partially offset by net collections of trade accounts receivable of $7.4 million, an increase in other current liabilities of $3.0 million, an increase in deferred rent of $1.9 million and an increase in trade accounts payable of $0.7 million.

Cash Used in Investing Activities

In the nine months ended September 30, 2012, net cash provided by investing activities included $86.5 million received upon maturity (net of purchases) of available-for-sale securities, $3.7 million received upon the acquisition of World Heart, $4.2 million used to acquire property, plant and equipment and $0.8 million paid for a security deposit on a facility lease.

In the nine months ended September 30, 2011, net cash used by investing activities included $65.7 million for the purchase (net of maturities) of available-for sale securities. Other investing activities in the nine months ended September 30, 2011 used cash of approximately $8.9 million. These amounts were expended to acquire property, plant and equipment and for capitalized patent costs.

Cash Provided by Financing Activities

The exercise of stock options in the nine months ended September 30, 2012 and 2011 resulted in cash proceeds of approximately $2.3 million and $0.7 million, respectively.

Operating Capital and Capital Expenditure Requirements

We have incurred operating losses to date and anticipate that we will continue to incur substantial net losses as we expand our sales and marketing capabilities, and develop new products. For the remainder of 2012, cash on hand is expected to primarily be used to fund our ongoing operations, including;

- Expanding our sales and marketing capabilities, particularly in the U.S., in preparation for the commercial launch of the HeartWare System,
- continued product development, including first human implants and clinical trials of next generation projects,
- existing and new clinical trials,
- regulatory and other compliance functions, and
- general working capital.

We expect to experience increased cash requirements for inventory and other working capital requirements to support continued growth.

Our convertible notes bear interest at a rate of 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year. During the quarter ended June 30, 2012 we paid the $2.5 million interest payment that was due on June 15, 2012. The $2.5 million interest payments that were due on June 15 and December 15, 2011 were also paid on a timely basis. Based on the outstanding principal amount of our convertible senior notes at September 30, 2012, the semi-annual interest payment due on December 15, 2012 will be approximately $2.5 million. This amount is expected to be paid from cash on hand.

We believe cash on hand and investment balances as of September 30, 2012 are sufficient to support our planned operations for at least the next twelve months.

Because of the numerous risks and uncertainties associated with the development of medical devices we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to maintain regulatory approvals, fund commercial expansion, and develop and obtain regulatory approvals for new products. Our future capital requirements will depend on many factors, including but not limited to the following:

- commercial acceptance of our products;
- costs to manufacture our products;
- expenses required to operate multiple clinical trials;
- further product research and development for next generation products and peripherals and expanding indications for our products as well as efforts to sustain and implement incremental improvements to existing products;
- expanding our sales and marketing capabilities on a global basis, including building a team to support anticipated U.S. commercialization;
- broadening our infrastructure in order to meet the needs of our growing operations;
- expenses related to funding and integrating strategic investments, acquisitions and collaborative arrangements; and
- complying with the requirements related to being a public company in both the United States and Australia.

Contractual Obligations

In the nine months ended September 30, 2012, there were no material changes to our contractual obligations provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* included in our 2011 Annual Report on Form 10-K filed with the SEC on February 27, 2012, outside the ordinary course of business, except as disclosed below.

On October 15, 2012, we notified the principal investigators for the feasibility study REVIVE-IT of our intention to withdraw from participation in the study, effective November 15, 2012. The relevant agreement will terminate and no rights or obligations will have accrued under the agreement that survive the effective date of termination. In January 2011, The University of Michigan Cardiovascular Center and the University of Pittsburgh announced that they had been awarded grants from the National Heart, Lung and Blood Institute and HeartWare to conduct a study exploring the potential benefits of left ventricular assist devices, or LVADs, in non-transplant eligible patients with heart failure less advanced than that of current LVAD recipients. To date, we have funded approximately $0.6 million for the development of the study protocol, recruitment of study sites and other preparatory work.

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 and cash equivalents that are invested in highly liquid money market funds, short-term time deposits, short-term bank notes and short-term commercial paper. The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to generate reasonable 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.

If interest rates rise, the market value of our investment portfolio may decline, which could result in a loss if we choose or are forced to sell an investment before its scheduled maturity. We do not utilize derivative financial instruments to manage interest rate risks.

Our convertible senior notes do not bear interest rate risk as the notes were issued with a fixed interest rate of 3.5% per annum.

Foreign Currency Rate Fluctuations

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

We generate a significant portion of our revenue and collect receivables in foreign currencies. Fluctuations in the exchange rate of the U.S. dollar against major foreign currencies, including the Euro, British Pound and Australian dollar, can result in foreign currency exchange gains and losses that may significantly impact our financial results. These foreign currency transaction and translation gains and losses are presented as a separate line item on our condensed consolidated statements of operations. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter. We do not currently utilize foreign currency contracts to mitigate the gains and losses generated by the re-measurement of non-functional currency assets and liabilities but do hold cash reserves in currencies in which those reserves are anticipated to be expended.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, carried out an evaluation required by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of September 30, 2012. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2012, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2012, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Thus, misstatements due to error or fraud may occur and not be detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of controls.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Except as described in Note 16 to the accompanying condensed consolidated financial statements, the Company is not a party to any material legal proceedings at the date of filing of the Quarterly Report on Form 10-Q.

ITEM 1A. RISK FACTORS

In addition to the information set forth in this report you should carefully consider the risk factors described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2011 filed with the SEC on February 27, 2012 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 filed with the SEC on August 8, 2012.

ITEM 6. EXHIBITS

3.1	Certificate of Incorporation of HeartWare International, Inc. (1)
3.2	Bylaws of HeartWare International, Inc. (1)
10.1	Second Amendment to lease agreement, dated as of April 17, 2008, between JDRP Associates No. 1, Ltd. and HeartWare, Inc., dated October 15, 2012
10.2	Fourth Amendment to business lease, dated as of December 27, 2006, between HeartWare, Inc. and Atlantic-Philadelphia Realty LLC, dated July 30, 2012
10.3	Form of HeartWare International Inc. 2012 Incentive Award Plan Stock Option Notice and Award Agreement (2)
10.4	Form of HeartWare International Inc. 2012 Incentive Award Plan Restricted Stock Unit Notice and Award Agreement (3)
31.1	Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by the 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 by the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Loss, (iv) Condensed Consolidated Statement of Stockholders' Equity, (v) Condensed Consolidated Statements of Cash Flows, and (vi) Notes to the Condensed Consolidated Financial Statements. ***

(1) Incorporated by reference to the respective exhibits filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 13, 2008.

(2) Incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-184358) filed with the Securities and Exchange Commission on October 10, 2012

(3) Incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-184358) filed with the Securities and Exchange Commission on October 10, 2012

*** This exhibit shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any filing, except to the extent the Company specifically incorporates it by reference.

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: November 9, 2012

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

Date: November 9, 2012

/s/ Peter F. McAree
Peter F. McAree
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

10.1	Second Amendment to lease agreement, dated as of April 17, 2008, between JDRP Associates No. 1, Ltd. and HeartWare, Inc., dated October 15, 2012
10.2	Fourth Amendment to business lease, dated as of December 27, 2006, between HeartWare, Inc. and Atlantic-Philadelphia Realty LLC, dated July 30, 2012
31.1	Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification by the 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 by the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Loss, (iv) Condensed Consolidated Statement of Stockholders' Equity, (v) Condensed Consolidated Statements of Cash Flows, and (vi) Notes to the Condensed Consolidated Financial Statements.

MIAMI LAKES BUSINESS PARK-EAST

SECOND AMENDMENT TO LEASE

THIS SECOND AMENDMENT TO LEASE (the "Second Amendment") is made as of the 15th day of October, 2012 by and between **JDRP ASSOCIATES NO. 1, LTD.** ("Lessor") and **HEARTWARE, INC.** ("Lessee") as guaranteed by **HEARTWARE INTERNATIONAL, INC.** ("Guarantor").

RECITALS:

WHEREAS, Lessor and Lessee are parties to that certain Lease Agreement dated April 17, 2008 as amended by the First Amendment to Lease dated September 30, 2010 (collectively, the "Lease"). Pursuant to the Lease, Lessor leased to Lessee and Lessee from Lessor an "agreed upon" 59,165 square feet of gross rentable area located at 14000-14050 NW 57th Court, Miami Lakes, Florida 33014 (the "Demised Premises" or "Premises"). The Demised Premises is located in a Building (the "Building") within the business park commonly known as Miami Lakes Business Park – East; and

WHEREAS, the Lease Term (the "Lease Term") is scheduled to expire June 30, 2013; and

WHEREAS, Lessor and Lessee desire to: (i) extend the Lease Term for a period of Three (3) months; and (ii) make certain other modifications to the Lease.

W I T N E S S E T H:

NOW, **THEREFORE**, in consideration of ten and no/100 dollars ($10.00) in hand paid by each party to the other, the mutual promises herein contained, and other good and valuable consideration, the receipt and sufficiency of which are acknowledged, and intending to be legally bound, the parties agree as follows:

1. Recitals. The recitals contained above are true to the best of the parties' knowledge and are incorporated by reference herein.

2. Defined Terms. Except as otherwise defined herein, all terms and phrases used in this Second Amendment that are defined in the Lease shall have the same meaning as set forth in the Lease. In the event of any conflict between the Lease and this Second Amendment, the terms of this Second Amendment shall control.

3. Lease Term. The Lease Term, as hereby amended, is extended to expire on the last day of September, 2013 and, except as otherwise provided herein, Lessee hereby waives and forever releases any option to renew or extend the Lease Term subsequent to September 30, 2013.

Lessor	Lessee

4. Base Rent. Commencing July 1, 2013, the Base Rent payable by Lessee shall be as follows:

July 1, 2013 through September 30, 2013: Equal monthly installments of $47,076.11 plus sales tax and any other charges pursuant to the Lease.

Base Rent shall be payable in monthly installments due in advance on the first day of each month of the Lease Term, as hereby extended.

5. Condition of the Premises. Lessor shall not be required to do any work in or upon the Premises or the Building to ready the same for Lessee's continued use or occupancy of the Premises. Lessee agrees to accept the Premises in its "as-is" condition, it being acknowledged that Lessee is fully familiar with the condition of the Premises.

6. Option To Renew, Expansion Right. Effective upon the full execution of this Second Amendment, Section 7 of the First Amendment (Option to Renew) and Section 8 of the First Amendment (Expansion Right) shall be deleted in their entirety and be of no further force and effect.

7. Brokerage. Lessor and Lessee each warrant and represent that it dealt with no brokers in connection with this transaction other than CBRE, Inc. and N/A (hereinafter referred to as "Brokers") and had no conversations or dealings with any broker other than the Brokers in connection with this transaction. Lessee hereby indemnifies Lessor against any claims of any broker with whom Lessee had any dealings other than the Brokers and agrees to reimburse Lessor for any damages Lessor might sustain by reason of such claims, including Lessor's cost of defending any action in connection therewith and any reasonable legal fees of Lessor in connection therewith. Lessor is responsible for the payment of all brokerage commissions to the Brokers. Lessor hereby indemnifies Lessee against any claims of any broker with whom Lessor had any dealings other than the Brokers and agrees to reimburse Lessee for any damages Lessee might sustain by reason of such claims, including Lessee's cost of defending any action in connection therewith and any reasonable legal fees of Lessee in connection therewith.

8. Ratification. Except as amended hereby, all the terms and conditions of the Lease, as heretofore in effect, shall remain in full force and effect and all the terms and conditions of the Lease, as hereby amended, are hereby ratified and confirmed in all respects.

9. Authority. Each of the persons executing this Second Amendment hereby covenants and warrants to the other parties that Lessor, Lessee, or Guarantor, as the case may be, has the full right and authority to enter into this Second Amendment, and that the person signing on behalf of Lessor, Lessee, or Guarantor, as the case may be, is authorized to do so.

Lessor	Lessee

10. Partial Invalidity. If any provision of this Second Amendment or application thereof to any person or circumstance shall to any extent be invalid, the remainder of this Second Amendment or the application of such provision to persons or circumstances other than those as to which it is held invalid shall not be affected thereby and each provision of this Second Amendment shall be valid and enforced to the fullest extent permitted by law.

11. Counterparts. This Second Amendment may be executed in multiple counterparts, each of which shall be deemed an original, but all of which, together, shall constitute but one and the same instrument.

{Balance of Page Intentionally Left Blank}

Lessor	Lessee

IN WITNESS WHEREOF, the parties hereto have, or have caused to be, executed this Second Amendment as of the day and year first set forth above.

WITNESSES:

/s/ M.A. Carlevale

Print Name: M.A. Carlevale

/s/ Beverly Nesmith

Print Name: Beverly Nesmith

LESSOR:
JDRP ASSOCIATES NO. 1, LTD.,
by its Agent, Peter Lawrence
Commercial Real Estate, Inc.

By: /s/ Kristopher M. Hoover
Kristopher M. Hoover
President

WITNESSES:

/s/ Andres Toledo

Print Name: Andres Toledo

/s/ Cary DeBien

Print Name: Cary DeBien

LESSEE:
HEARTWARE, INC.,
a Delaware corporation

By: /s/ Larry Knopf

Name: Larry Knopf

Title: SVP

Acknowledged by the undersigned as guarantor:

WITNESSES:

/s/ Andres Toledo

Print Name: Andres Toledo

/s/ Cary DeBien

Print Name: Cary DeBien

GUARANTOR:
HEARTWARE INTERNATIONAL, INC.,
a Delaware corporation

By: /s/ Larry Knopf

Name: Larry Knopf

Title: SVP

Lessor	Lessee

Exhibit 10.2

FOURTH AMENDMENT TO LEASE

ATLANTIC-PHILADELPHIA REALTY LLC, LANDLORD
AND
HEARTWARE, INC., TENANT

This Fourth Amendment to Lease (this "Fourth Amendment"), dated July 30, 2012, and is entered into by and between ATLANTIC-PHILADELPHIA REALTY LLC, c/o Atlantic Management Corporation, 205 Newbury Street, Framingham, MA 01701, hereinafter referred to as "Landlord" and HEARTWARE, INC., a Delaware corporation, hereinafter referred to as "Tenant."

WITNESSETH:

WHEREAS, Tenant and Landlord executed a lease dated December 27, 2006 (the "Initial Lease"), of certain premises situated on the first floor of the building and referenced as Suite 101 (the "Original Premises"), located at 205 Newbury Street, Framingham, Massachusetts (the "Building"); and

WHEREAS, the Initial Lease was amended by the First Amendment to Lease dated August 19, 2008, by a Second Amendment to Lease dated August 9, 2010, and by a Third Amendment to Lease dated June 30, 2011 (the Initial Lease, as amended through the Third Amendment to Lease, is referred to hereinafter as the "Lease"); and

WHEREAS, the Tenant has requested and the Landlord agrees to lease to the Tenant additional space on the second floor totaling 3,470 square feet of space (Suite 203 - hereinafter referred to as the "New Additional Premises" under the Lease; and

WHEREAS, the Landlord and Tenant have agreed to amend the defined terms and other sections of the Lease to reflect certain agreements relating to the New Additional Premises, such as the Term, Delivery Date, Rent, Tenant Improvements, Operating Expenses and Tenant's Percentage of CAM and Tax costs to reflect their agreements regarding the New Additional Premises, all as hereinafter set forth;

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Effective Date. This Fourth Amendment shall be effective on the date that Landlord delivers the New Additional Premises to Tenant (substantially completed with the Tenant Improvements as outlined in Section 4. hereof), which is expected to occur on or about January 1, 2013,

2. Amendment of Article 1 of the Lease – Section 1.1. Section 1.1 of the Lease is hereby amended as follows:

a. The term "TENANT SPACE" is hereby amended by adding to the Premises the New Additional Premises, as previously defined and shown on the attached plan of premises marked "Exhibit A", hereby replacing all previous plans depicting Tenant's premises.

b. The subject "RENTABLE FLOOR AREA OF TENANT SPACE" is hereby amended by adding 3,470 rentable square feet, being the New Additional Premises."

c. The subject "RENT AND TERM COMMENCEMENT DATE" is hereby amended by adding, relative to the New Additional Premises only, the date that Landlord delivers the New Additional Premises to Tenant, which is expected to occur on or about January 1, 2013.

d. The subject “TERM” is hereby amended, with respect to the New Additional Premises only, as follows: Beginning on the date of delivery of the New Additional Premises to Tenant, and terminating June 30, 2015. The Lease terminates, as to all other premises leased, on December 31, 2014.

e. The subject “TENANT’S PROPORTIONATE SHARE” is hereby amended by deleting reference to “31.28%” and replacing it with “37.4%, which percentage shall be effective on the Effective Date**.** The New Additional Premises represent a Tenant’s Proportionate Share, from and after January 1, 2015, of 6.1%.

f. The subject **“**TERMINATION DATE**”** is hereby amended, with respect only to the New Additional Premises, to be June 30, 2015. With respect to all other premises leased by Tenant, the Termination Date remains December 31, 2014.

g. The subject **“**BASE YEAR FOR CALCULATING LANDLORD’S OPERATING EXPENSES**”** is hereby amended by adding the following: “Relative to the New Additional Premises only, the Base Year for calculating Landlord’s Operating Expenses shall be 2012.”

h. The subject **“**REAL ESTATE TAX BASE YEAR**”** is hereby amended by adding the following: “Relative to the New Additional Premises only, the Real Estate Tax Base Year shall be fiscal year 2013.”

i. The subject “ANNUAL BASE RENT” is hereby amended by adding to the schedule set forth in the Third Amendment the following:

(i) For the New Additional Premises, $21.75 per rentable square foot from January 1, 2013 through June 30, 2014 and then $22.25 per rentable square foot from July 1, 2014 through June 30, 2015;

j. The subject "PARKING" is hereby amended by adding the following: "Tenant will receive an additional 3.8 parking spaces per 1,000 square feet rented, being 13 additional parking spaces, for the New Additional Premises only, on a first come first serve basis."

3. Further Amendment of Article 1 of the Lease. Section 1.2 Exhibits is hereby amended by adding Exhibit B-5, showing the New Additional Premises.

4. Tenant Improvements. At Landlord's expense, Landlord does hereby agree to complete the following improvements to the New Additional Premises: (i) create openings between the New Additional Premises and the contiguous premises currently leased by Tenant, Suite 202 and Suite 204, (ii) remove the existing kitchen area from the New Additional Premises; (iii) paint the New Additional Premises, and (iv) remove existing carpet and baseboard, and re-carpet and add baseboard to the New Additional Premises, including what is now the kitchen area.

5. Additional Security Deposit. The Tenant shall deliver to the Landlord a security deposit for the New Additional Premises only, equal to $6,289.38, representing one month's rent. This additional security deposit will apply only to the New Additional Premises but will otherwise be governed in accordance with the terms of Section 10.16 of the Lease.

6. Brokers. Landlord shall be responsible for the payment of all brokerage fees due to R. W. Holmes Realty ("Holmes") in connection with this Fourth Amendment pursuant to a separate agreement between Landlord and Holmes.

7. No Other Amendments. Except as otherwise provided herein, the Lease is hereby ratified and confirmed and shall remain unmodified and in full force and effect.

Executed as a sealed instrument by the duly authorized signatories of the parties hereto in two or more counterparts as of the day and year first above written.

LANDLORD:

ATLANTIC-PHILADELPHIA REALTY, LLC
By its Managing Agent,
Atlantic Management Corporation

By: /s/ David A. Capobianco
Its: David A. Capobianco

TENANT:

HEARTWARE, INC.

By: /s/ Douglas Godshall
Its: Douglas Godshall
CEO

Exhibit 31.1

CERTIFICATION BY THE CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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: November 9, 2012

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

Exhibit 31.2

CERTIFICATION BY THE CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter F. McAree, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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: November 9, 2012

/s/ Peter F. McAree
Peter F. McAree
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION BY THE 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 September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned President and 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: November 9, 2012

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

Exhibit 32.2

CERTIFICATION BY THE 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 September 30, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Executive Vice President and 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: November 9, 2012

/s/ Peter F. McAree
Peter F. McAree
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)