

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

FORM 10-Q

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

For the quarterly period ended June 30, 2013

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
(State of Incorporation)

26-3636023
(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.

<u>Class</u>	<u>Shares Outstanding as of August 2, 2013</u>
Common Stock, \$0.001 Par Value Per Share	16,449,194

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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, HeartWare France and World Heart Corporation.
- “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” and “World Heart Corporation” refer to World Heart Corporation, a Delaware corporation established on January 1, 2010, and its subsidiaries acquired by the Company 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 “AUS\$” refer to Australian dollars, the lawful currency of the Commonwealth of Australia. References to “Euros” refer to Euros, the single currency of Participating Member States of the European Union. References to “British Pounds” refer to British pound sterling, the lawful currency of the United Kingdom.

Trademarks

HEARTWARE®, HVAD®, MVAD® and PAL™ 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 submissions to and approvals from regulatory bodies, such as the United States Food and Drug Administration (“FDA”);
- our expectations with respect to our clinical trials, including enrollment, completion and outcomes of our clinical trials as well as approval of new clinical trials and additional patient cohorts with respect to our existing clinical trials;
- our expectations with respect to the integrity or strengths 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, functionalities and benefits of these products; and
- our estimates regarding our capital requirements and financial performance, including earnings fluctuation and cash availability.

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

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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, 2012 filed with the SEC on February 27, 2013, and those described from time to time in our other filings with the SEC.

[Table of Contents](#)**PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****HEARTWARE INTERNATIONAL, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)**

	<u>June 30, 2013</u> (unaudited)	<u>December 31, 2012</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 190,024	\$ 85,921
Short-term investments	31,148	16,887
Accounts receivable, net	33,596	25,225
Inventories, net	36,926	38,443
Prepaid expenses and other current assets	7,031	5,925
Total current assets	298,725	172,401
Property, plant and equipment, net	18,103	19,380
Goodwill	1,190	1,190
Other intangible assets, net	7,959	7,794
Deferred financing costs, net	2,152	2,329
Long-term investments	1,225	—
Other assets	3,567	3,405
Total assets	<u>\$ 332,921</u>	<u>\$ 206,499</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 10,836	\$ 12,024
Other accrued liabilities	19,386	22,020
Total current liabilities	30,222	34,044
Convertible senior notes, net	103,618	100,315
Other long-term liabilities	3,889	3,929
Commitments and contingencies - See Note 15		
Stockholders' equity:		
Preferred stock - \$.001 par value; 5,000 shares authorized; no shares issued and outstanding at June 30, 2013 and December 31, 2012	—	—
Common stock - \$.001 par value; 25,000 shares authorized; 16,397 and 14,582 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively	16	15
Additional paid-in capital	498,376	346,301
Accumulated deficit	(295,935)	(270,042)
Accumulated other comprehensive loss:		
Cumulative translation adjustments	(7,197)	(8,039)
Unrealized loss on investments	(68)	(24)
Total accumulated other comprehensive loss	(7,265)	(8,063)
Total stockholders' equity	<u>195,192</u>	<u>68,211</u>
Total liabilities and stockholders' equity	<u>\$ 332,921</u>	<u>\$ 206,499</u>

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

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2013	2012	2013	2012
Revenue, net	\$ 50,836	\$ 29,053	\$100,075	\$ 55,398
Cost of revenue	18,866	12,665	37,646	23,493
Gross profit	31,970	16,388	62,429	31,905
Operating expenses:				
Selling, general and administrative	17,217	14,204	33,704	26,920
Research and development	24,188	20,005	46,330	40,012
Total operating expenses	41,405	34,209	80,034	66,932
Loss from operations	(9,435)	(17,821)	(17,605)	(35,027)
Other income (expense):				
Foreign exchange loss	(619)	(2,175)	(2,498)	(1,090)
Interest expense	(3,030)	(2,824)	(6,005)	(5,601)
Investment income, net	68	57	109	170
Other, net	82	(19)	106	(79)
Loss before income taxes	(12,934)	(22,782)	(25,893)	(41,627)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (12,934)</u>	<u>\$ (22,782)</u>	<u>\$ (25,893)</u>	<u>\$ (41,627)</u>
Net loss per common share - basic and diluted	<u>\$ (0.79)</u>	<u>\$ (1.61)</u>	<u>\$ (1.66)</u>	<u>\$ (2.94)</u>
Weighted average shares outstanding - basic and diluted	<u>16,370</u>	<u>14,157</u>	<u>15,619</u>	<u>14,139</u>

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

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

	<u>Three Months Ended</u> <u>June 30,</u>		<u>Six Months Ended</u> <u>June 30,</u>	
	<u>2013</u>	<u>2012</u>	<u>2013</u>	<u>2012</u>
Net loss	\$(12,934)	\$(22,782)	\$(25,893)	\$(41,627)
Other comprehensive income (loss)				
Foreign currency translation adjustments	390	32	842	(70)
Unrealized (loss) gain on investments	(12)	6	(44)	20
Comprehensive loss	<u>\$(12,556)</u>	<u>\$(22,744)</u>	<u>\$(25,095)</u>	<u>\$(41,677)</u>

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	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total
	Shares Issued	Amount				
Balance, December 31, 2012	14,582	\$ 15	\$346,301	\$(270,042)	\$ (8,063)	\$ 68,211
Issuance of common stock pursuant to public offering, net of offering costs	1,725	1	140,994	—	—	140,995
Issuance of common stock pursuant to share-based awards	90	—	1,704	—	—	1,704
Share-based compensation	—	—	9,377	—	—	9,377
Net loss	—	—	—	(25,893)	—	(25,893)
Other comprehensive income	—	—	—	—	798	798
Balance, June 30, 2013	<u>16,397</u>	<u>\$ 16</u>	<u>\$498,376</u>	<u>\$(295,935)</u>	<u>\$ (7,265)</u>	<u>\$195,192</u>

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

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

	Six Months Ended June 30,	
	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (25,893)	\$ (41,627)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	3,204	2,054
Amortization of intangible assets	246	79
Share-based compensation expense	9,377	10,055
Amortization of premium on investments	254	497
Amortization of discount on convertible senior notes	3,303	2,928
Amortization of deferred financing costs	176	157
Other	95	401
Change in operating assets and liabilities:		
Accounts receivable	(8,665)	(6,845)
Inventories, net	410	(3,160)
Prepaid expenses and other current assets	(1,157)	(1,272)
Accounts payable	(1,165)	5,991
Other accrued liabilities	(2,555)	769
Other long-term liabilities	(40)	703
Net cash used in operating activities	(22,410)	(29,270)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(17,965)	(15,000)
Maturities of investments	1,981	89,946
Additions to property, plant and equipment, net	(1,388)	(2,884)
Additions to patents	(410)	(254)
Cash paid for security deposits	—	(750)
Net cash used in investing activities	(17,782)	71,058
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock	149,126	—
Payment of common stock issuance costs	(8,131)	—
Proceeds from exercise of stock options	1,704	1,065
Net cash provided by financing activities	142,699	1,065
Effect of exchange rate changes on cash and cash equivalents	1,596	391
INCREASE IN CASH AND CASH EQUIVALENTS	104,103	43,244
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	85,921	71,257
CASH AND CASH EQUIVALENTS - END OF PERIOD	\$190,024	\$114,501

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

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

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 (and its subsidiaries) 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 these 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, 2012. The accompanying condensed consolidated balance sheet as of December 31, 2012 has been derived from our audited financial statements. The condensed consolidated statements of operations for the three and six months ended June 30, 2013 and cash flows for the six months ended June 30, 2013 are not necessarily indicative of the results to be expected for any future period or for the year ending December 31, 2013.

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 June 30, 2013, we had approximately \$222.4 million of cash, cash equivalents and investments.

We have financed our operations primarily through the issuance of shares of our common stock and the issuance of convertible notes. Most recently, in March 2013, we completed a public offering of 1,725,000 shares of our common stock, including the underwriters’ exercise of their over-allotment option to purchase 225,000 shares, at an offering price of \$86.45 per share for aggregate gross proceeds of approximately \$149.1 million. After fees and related expenses, net proceeds from the offering were approximately \$141.0 million. *See* Note 11 (Stockholders’ Equity) for more information.

For the remainder of 2013, our cash, cash equivalents and investments are expected to primarily be used to fund our ongoing operations including expanding our sales and marketing capabilities on a global basis, research and development of new products, components and accessories, 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.

The accompanying condensed 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 losses have continued through June 30, 2013. At June 30, 2013, we had an accumulated deficit of approximately \$295.9 million.

Note 3. Significant Accounting Policies

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of HeartWare International, Inc., and its subsidiaries described in Note 1 (Basis of Presentation). All inter-company balances and transactions have been eliminated in consolidation. We hold certain investments in small development-stage entities which are included in other assets on our condensed consolidated balance sheets. In accordance with FASB ASC 810, we analyzed the investments to determine whether the investments are variable interests or interests that give us a controlling financial interest in a variable interest entity ("VIE"). As of June 30, 2013, we determined there were no VIEs 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 we do 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. 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.

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 at purchase beyond one year, but less than twenty-four months, may be classified as short-term based on their highly liquid nature and because these 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 the amortization is included in investment income, net.

Receivables

Accounts receivable consists of amounts due from the sale of our HeartWare® Ventricular Assist System (the "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 generally 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 June 30, 2013 and December 31, 2012, 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 local economic conditions that may affect a customer's ability to pay. Account balances are charged off against the allowance after appropriate collection efforts have been exhausted and we feel it is probable that the receivable will not be recovered.

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The following table summarizes the change in our allowance for doubtful accounts for the six months ended June 30, 2013 and 2012:

	<u>2013</u>	<u>2012</u>
	(in thousands)	
Beginning balance	\$750	\$500
Additions (bad debt expense)	—	250
Deductions (charge-offs)	—	—
Ending balance	<u>\$750</u>	<u>\$750</u>

As of June 30, 2013 and December 31, 2012, 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 10 (Debt). The issuance costs allocated to the convertible senior notes were capitalized within 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 June 30, 2013 and 2012 was approximately \$0.1 million for each period. The amount of amortization for the six months ended June 30, 2013 and 2012 was approximately \$0.2 million for each period. The amount of accumulated amortization at June 30, 2013 and December 31, 2012 was approximately \$0.8 million and \$0.6 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 six months ended June 30, 2013 and 2012.

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The following table summarizes the change in our warranty liability for the six months ended June 30, 2013 and 2012:

	<u>2013</u>	<u>2012</u>
	(in thousands)	
Beginning balance	\$ 543	\$ 203
Accrual for warranty expense	500	449
Warranty costs incurred during the period	(345)	(385)
Ending balance	<u>\$ 698</u>	<u>\$ 267</u>

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 June 30, 2013, the long-term portion of our deferred rent liability of approximately \$2.8 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 June 30, 2013 and December 31, 2012 and are carried at fair value. See Note 4 (Fair Value Measurements) and Note 10 (Debt) for more information.

Vendor Concentration

For the three and six months ended June 30, 2013, we purchased approximately 69% and 67%, respectively, of our inventory components and supplies from three vendors. For the three and six months ended June 30, 2012, we purchased approximately 70% and 71%, 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 June 30, 2013 and 2012, the amounts due to these vendors totaled approximately \$4.1 million and \$2.5 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 generally 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, our ability to achieve widespread acceptance of our products, our ability to manufacture our products in a sufficient volume and at a reasonable cost, our ability to protect our proprietary technologies and develop new products, 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.

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New Accounting Standards

In September 2012, the FASB issued ASU No. 2012-02, *Intangibles – Goodwill and Other (Topic 350), Testing Indefinite-Lived Intangible Assets for Impairment*, which provides an entity the option first to assess qualitative factors to determine whether the existence of events and circumstances indicates that it is more likely than not that an indefinite-lived intangible asset is impaired. If, after assessing the totality of events and circumstances, an entity concludes that it is not more likely than not that the indefinite-lived intangible asset is impaired, then the entity is not required to take further action. The qualitative assessment is optional, allowing companies to go directly to the quantitative assessment. ASU No. 2012-02 is effective for our annual and interim impairment tests performed subsequent to January 1, 2013. The adoption of ASU No. 2012-02 did not affect our consolidated financial position, results of operations or cash flows.

In July 2013, the FASB issued ASU No. 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists (a consensus of the FASB Emerging Issues Task Force)*. U.S. GAAP does not include explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The amendments in this ASU state that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss carryforward, a similar tax loss, or a tax credit carryforward, except as follows: To the extent a net operating loss carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the applicable jurisdiction to settle any additional income taxes that would result from the disallowance of a tax position or the tax law of the applicable jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. This ASU applies to all entities that have unrecognized tax benefits when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists at the reporting date. The amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2013, with early adoption permitted. We plan to adopt the amendments in this ASU on a prospective basis effective January 1, 2014. The amendments should be applied prospectively to all unrecognized tax benefits that exist at the effective date, although retrospective application is permitted. The adoption of ASU No. 2013-11 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

Note 4. 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 the accompanying 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.

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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 June 30, 2013					
	Carrying Value	Fair Value	Fair Value Measurements at the Reporting Date Using		
			Level 1	Level 2	Level 3
(in thousands)					
Assets					
Short-term investments	\$ 31,148	\$ 31,148	\$ —	\$ 31,148	\$ —
Long-term investments	1,225	1,225	—	1,225	—
Liabilities					
Convertible senior notes	103,618 (1)	174,787	—	174,787	—
Minimum royalty payment obligations	964 (2)	964	—	—	964

At December 31, 2012					
	Carrying Value	Fair Value	Fair Value Measurements at the Reporting Date Using		
			Level 1	Level 2	Level 3
(in thousands)					
Assets					
Short-term investments	\$ 16,887	\$ 16,887	\$ —	\$ 16,887	\$ —
Liabilities					
Convertible senior notes	100,315 (1)	169,122	—	169,122	—
Minimum royalty payment obligations	1,113 (2)	1,113	—	—	1,113

- (1) The carrying amount of our convertible senior notes is net of unamortized discount. See Note 10 (Debt) for more information.
- (2) Minimum royalty obligations represent the fair value of future minimum royalty payments to be made pursuant to agreements related to intellectual property licensed or acquired by World Heart to be paid over the next 3 to 17 years.

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.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. At June 30, 2013 and December 31, 2012, our financial liability categorized as Level 3 consisted of royalty payment obligations due under contractual arrangements related to our acquisition of World Heart in August 2012, because the fair value includes significant management judgment or estimation. The royalty payment obligations were valued using a discounted cash flow model, the future minimum royalty payment amounts and discount rates commensurate with our market risk and the terms of the obligations.

Assets That Are Measured at Fair Value on a Nonrecurring Basis

Non-financial assets such as intangible assets, goodwill and property, plant, and equipment are evaluated for impairment annually or when indicators of impairment exist. No impairment was recorded for the three and six months ended June 30, 2013 and 2012. Non-financial assets such as identified intangibles acquired in connection with our acquisition of World Heart in August 2012 are measured at fair value using Level 3 inputs, which include discounted cash flow methodologies or similar techniques, when there is limited market activity and the determination of fair value requires significant judgment or estimation.

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Note 5. Investments

We have cash investment policies that limit investments to investment grade rated securities. At June 30, 2013 and December 31, 2012, all of our investments were classified as available-for-sale and carried at fair value. At June 30, 2013, our short-term investments had maturity dates of less than twenty-four months, while our long-term investments matured beyond twenty-four months, but within forty-two months.

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

At June 30, 2013	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Short-term investments:				
Corporate debt	\$24,891	\$ —	\$ (68)	\$24,823
Certificates of deposit	6,325	—	—	6,325
Total short-term investments	<u>\$31,216</u>	<u>\$ —</u>	<u>\$ (68)</u>	<u>\$31,148</u>
Long-term investments:				
Certificates of deposit	\$ 1,225	\$ —	\$ —	\$ 1,225
Total long-term investments	<u>\$ 1,225</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,225</u>

At December 31, 2012	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
	(in thousands)			
Short-term investments:				
Corporate debt	\$10,565	\$ —	\$ (25)	\$10,540
Certificates of deposit	6,346	1	—	6,347
Total short-term investments	<u>\$16,911</u>	<u>\$ 1</u>	<u>\$ (25)</u>	<u>\$16,887</u>

For the three and six months ended June 30, 2013 and 2012, we did not have any realized gains or losses on our investments. At June 30, 2013 and December 31, 2012, none of our available-for-sale investments had been in a continuous loss position for more than twelve months.

Note 6. Inventories, Net

Components of inventories, net are as follows:

	June 30, 2013	December 31, 2012
	(in thousands)	
Raw material	\$14,250	\$ 11,192
Work-in-process	11,263	11,123
Finished goods	11,413	16,128
	<u>\$36,926</u>	<u>\$ 38,443</u>

Finished goods inventories includes inventory held on consignment at customer sites of approximately \$4.8 million and \$5.5 million at June 30, 2013 and December 31, 2012, respectively.

[Table of Contents](#)**Note 7. Property, Plant and Equipment, Net**

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

	<u>Estimated Useful Lives</u>	<u>June 30, 2013</u>	<u>December 31, 2012</u>
		(in thousands)	
Machinery and equipment	1.5 to 7 years	\$ 18,022	\$ 17,894
Leasehold improvements	3 to 10 years	8,025	8,082
Office equipment, furniture and fixtures	5 to 7 years	1,025	912
Purchased software	1 to 7 years	4,424	3,572
		31,496	30,460
Less: accumulated depreciation		(13,393)	(11,080)
		<u>\$ 18,103</u>	<u>\$ 19,380</u>

During the quarter ended June 30, 2013, we decided to consolidate certain development activities performed in our Australian facility, and relocate those activities to the United States. This action will result in costs related to the portion of our Australian facility we will no longer utilize as well as the write-off of certain fixed assets upon their discontinued use in the second half of 2013. The net book value of leasehold improvements and other fixed assets within our Australian facility was approximately \$1.6 million as of June 30, 2013. We expect to finalize our plans and estimates of the costs prior to September 30, 2013. This action will not have a material effect on our operations.

Note 8. Goodwill and Intangible Assets, Net

In August 2012, we acquired World Heart and recorded \$1.2 million of goodwill. Goodwill is not amortized but will be reviewed for impairment on an annual basis starting in the fourth quarter of 2013 or sooner if indicators of impairment arise.

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

	<u>June 30, 2013</u>		<u>December 31, 2012</u>	
	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>
	(in thousands)			
Patents	\$ 6,275	\$ (852)	\$ 5,865	\$ (606)

Patents are being amortized using the straight-line method over their estimated useful lives, which range from 8 to 16 years. Amortization expense for the three months ended June 30, 2013 and 2012 was approximately \$125,000 and \$41,000, respectively. Amortization expense for the six months ended June 30, 2013 and 2012 was approximately \$246,000 and \$79,000, respectively.

We recognized approximately \$2.5 million of in-process research and development in connection with our acquisition of World Heart in August 2012. 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.

[Table of Contents](#)**Note 9. Other Accrued Liabilities**

Other accrued liabilities consist of the following:

	June 30, 2013	December 31, 2012
	(in thousands)	
Accrued payroll and other employee costs	\$ 7,013	\$ 8,818
Accrued material purchases	3,391	5,628
Accrued research and development costs	2,499	3,132
Accrued professional fees	1,778	1,340
Accrued VAT	1,317	1,212
Other accrued expenses	3,388	1,890
	<u>\$19,386</u>	<u>\$ 22,020</u>

Accrued payroll and other employee costs included estimated year-end employee bonuses of approximately \$3.1 million and \$5.9 million at June 30, 2013 and December 31, 2012, respectively.

Note 10. 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 “Indenture”). 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 offering was completed pursuant to a prospectus supplement, dated December 9, 2010, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010.

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 of the conditions specified in the Indenture relating to the (i) sale price of our common stock, (ii) the trading price per \$1,000 principal amount of Convertible Notes or (iii) specified corporate events. As of the date of this report, none of the events that would allow holders to convert their Convertible Notes have occurred. 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. 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.

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In accordance with FASB ASC 470-20, *Debt with Conversion and Other Options*, 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 the 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:

	June 30, 2013	December 31, 2012
	(in thousands)	
Principal amount	\$143,750	\$ 143,750
Unamortized discount	(40,132)	(43,435)
Net carrying amount	<u>\$103,618</u>	<u>\$ 100,315</u>
Equity component	<u>\$ 55,038</u>	<u>\$ 55,038</u>

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 June 28, 2013 of \$95.11 per share, was approximately \$136.7 million. The fair value of our Convertible Notes as presented in Note 4 was \$174.8 million at June 30, 2013.

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 six months ended June 30, 2013 and 2012, interest expense related to the Convertible Notes was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(in thousands)			
Stated amount at 3.5% coupon rate	\$ 1,258	\$ 1,258	\$2,516	\$2,516
Amortization of discount	1,676	1,486	3,303	2,928
Amortization of deferred financing costs	90	80	176	157
	<u>\$3,024</u>	<u>\$ 2,824</u>	<u>\$5,995</u>	<u>\$5,601</u>

[Table of Contents](#)**Note 11. Stockholders' Equity**

On March 12, 2013, we entered into an Underwriting Agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC, as representative of the several underwriters named in the Underwriting Agreement (the "Underwriters"), pursuant to which we agreed to sell and the Underwriters agreed to purchase, subject to and upon terms and conditions set forth therein, an aggregate of 1,500,000 shares of our common stock at a net sales price of \$81.9114 per share (the public offering price of \$86.45 per share minus the underwriting discount). We also granted the Underwriters an option to purchase 225,000 additional shares of our common stock at the public offering price less the underwriting discount, which the Underwriters exercised in full on March 13, 2013. The closing of the offering occurred on March 18, 2013. After fees and related expenses, net proceeds from the offering were approximately \$141.0 million.

The offering was completed pursuant to a prospectus supplement, dated March 12, 2013, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010. This shelf registration statement allows us to offer and sell from time to time, in one or more series or issuances and on terms that we determine at the time of the offering, any combination and amount of the securities described in the prospectus contained in the registration statement.

In the six months ended June 30, 2013, we issued an aggregate of 68,207 shares of our common stock upon the exercise of stock options and an aggregate of 21,661 shares of our common stock upon the vesting of restricted stock units.

In the six months ended June 30, 2012, we issued an aggregate of 31,820 shares of our common stock upon the exercise of stock options and an aggregate of 34,721 shares of our common stock upon the vesting of restricted stock units.

Note 12. Share-Based Compensation

We recognize share-based compensation expense related to our stock options and restricted stock units ("RSUs") 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 holder's employment function. For the three and six months ended June 30, 2013 and 2012, we recorded share-based compensation expense as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(In thousands)			
Cost of revenues	\$ 611	\$ 1,022	\$1,142	\$ 1,754
Selling, general and administrative	2,792	3,606	5,219	5,487
Research and development	1,526	1,713	3,016	2,814
	<u>\$4,929</u>	<u>\$ 6,341</u>	<u>\$9,377</u>	<u>\$10,055</u>

The decrease in share-based compensation expense for the three and six months ended June 30, 2013, compared to the same periods of the prior year, is primarily due to catch-up expense on historical awards recognized in the second quarter of 2012 in connection with a reduction in our estimated forfeiture rate in that period.

Deferred tax benefits attributed to our share-based compensation expense are not recognized 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 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 the fair market value of our shares of common stock at the vesting date. Excess tax benefits are not recognized in the accompanying condensed consolidated financial statements because we are in a net operating loss position and we do not currently realize a benefit from the deduction.

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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.

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 June 30, 2013, Awards with respect to 296,500 shares were issued and outstanding under the 2012 Plan. Subsequent to adoption of the 2012 Plan, no new Awards will be granted under our prior plans. Any outstanding Awards under the prior plans will continue to be subject to the terms and conditions of the plan under 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. 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.

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions established at that time. The following table includes the weighted average assumptions used for options issued in the three and six months ended June 30, 2013 and 2012.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
Dividend yield	0%	0%	0%	0%
Expected volatility	40.00%	57.00%	40.00%	57.00%
Risk-free interest rate	1.15%	1.00%	1.15%	1.00%
Estimated holding period (years)	6.25	6.25	6.25	6.25

Information related to options granted under all of our plans at June 30, 2013 and activity in the six 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, 2012	291	\$ 36.70		
Granted	7	95.05		
Exercised	(68)	24.98		
Forfeited	—	—		
Expired	—	—		
Outstanding at June 30, 2013	230	\$ 38.73	4.49	\$ 12,944
Exercisable at June 30, 2013	190	\$ 33.85	3.81	\$ 11,667

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The aggregate intrinsic values at June 30, 2013 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.

The weighted average grant date fair value per share of options issued in the six months ended June 30, 2013 and 2012 was \$38.51 and \$43.83 per share, respectively.

The total intrinsic value of options exercised in the six months ended June 30, 2013 and 2012 was approximately \$4.6 million and \$1.4 million, respectively. Cash received from options exercised in the six months ended June 30, 2013 and 2012 was approximately \$1.7 million and \$1.1 million, respectively.

At June 30, 2013, there was approximately \$0.5 million of unrecognized compensation expense, net of estimated forfeitures, related to non-vested options. This expense is expected to be recognized over a weighted average period of one year.

Restricted Stock Units

Each RSU represents a contingent right to receive one share of our common stock. RSUs generally 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 RSUs with performance-based vesting criteria vest in one or more tranches contingent upon the achievement of pre-determined milestones related to the development of our products, the achievement of certain prescribed clinical and regulatory objectives, the achievement of specific financial performance measures or similar multi-year metrics. There is no consideration payable on the vesting or exercise of RSUs issued under the plans. Upon vesting, the RSUs are exercised automatically and settled in shares of our common stock.

Information related to RSUs at June 30, 2013 and activity in the six 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, 2012	547		
Granted	96		
Vested/Exercised	(22)		
Forfeited	(14)		
Expired	—		
Outstanding at June 30, 2013	<u>607</u>	1.84	\$ 57,765
Exercisable at June 30, 2013	<u>—</u>	—	\$ —

The aggregate intrinsic value at June 30, 2013 noted in the table above represents the closing price of our common stock traded on NASDAQ multiplied by the number of RSUs outstanding.

At June 30, 2013, 16,700 of the RSUs outstanding are subject to performance-based vesting criteria as described above.

The total intrinsic value of RSUs vested in the six months ended June 30, 2013 and 2012 was approximately \$2.0 million and \$2.7 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 RSUs granted in the six months ended June 30, 2013 and 2012 was \$92.07 and \$80.67, respectively.

At June 30, 2013, we had approximately \$25.6 million of unrecognized compensation expense related to non-vested RSU awards, net of estimated forfeitures. This expense is expected to be recognized over a weighted average period of 1.6 years.

[Table of Contents](#)**Note 13. 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 the 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.

Common shares issuable upon:	Three and Six Months Ended June 30,	
	2013	2012
	(in thousands)	
Conversion of convertible senior notes	1,438	1,438
Exercise or vesting of share-based awards	837	953

Note 14. 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 and as commercial products, 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 June 30,		Six Months Ended June 30,	
	2013	2012	2013	2012
	(in thousands)			
United States	\$25,106	\$ 4,196	\$ 51,256	\$10,637
Germany	13,703	10,282	26,033	19,813
International, excluding Germany	12,027	14,575	22,786	24,948
	<u>\$50,836</u>	<u>\$29,053</u>	<u>\$100,075</u>	<u>\$55,398</u>

The percentage of our revenue generated in the U.S. increased in 2013 as compared to 2012 due to receipt in November 2012 of FDA approval to sell the HeartWare System commercially in the U.S. As a significant portion 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 six months ended June 30, 2013, no customer exceeded 10% of product sales individually.

Note 15. Commitments and Contingencies

At June 30, 2013, we had purchase order commitments of approximately \$42.9 million related to product costs, supplies, services and property, plant and equipment purchases. Many of our materials and supplies require long lead times. Our purchase order commitments reflect materials that may be received up to one year from the date of order.

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

From time to time we invest in certain development stage entities in connection with research activities. Certain contingent milestone payments in connection with these arrangements have not been accrued in the accompanying condensed consolidated financial statements as the amounts are indeterminate at this time.

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The taxation and customs requirements, together with other applicable laws and regulations of certain foreign jurisdictions, can be inherently complex and subject to differing interpretation by local authorities. We are subject to the risk that either we have misinterpreted applicable laws and regulations, or that foreign authorities may take inconsistent, unclear or changing positions on local law, customs practices or rules. In the event that we have misinterpreted any of the above, or that foreign authorities take positions contrary to ours, we may incur liabilities that may differ materially from the amounts accrued in the accompanying condensed consolidated financial statements.

Litigation

From time to time we may be involved in litigation or other contingencies arising in the ordinary course of business. Based on the information presently available, management believes 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.

In accordance with FASB 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.

Milestone Payment

In connection with the purchase of assets from Kriton Medical in 2003, we entered into a settlement and release agreement pursuant to which we were required to make a milestone payment of \$1.25 million six months after our first circulatory assist device was approved for sale in the United States. The payment was accrued in November 2012 when the HeartWare System was approved for sale in the United States and made in July 2013 and was included in other accrued liabilities on our condensed consolidated balance sheets.

Note 16. Subsequent Events

We have evaluated events and transactions that occurred subsequent to June 30, 2013 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® 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-output 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 November 2012, we received approval from the FDA for the HeartWare System as a bridge to heart transplantation in patients with end-stage heart failure. The HeartWare System has been available in the European Union since receiving CE marking in 2009. 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. The HeartWare System has been implanted in patients at over 200 health care sites and in over 30 countries.

We also intend to seek an expanded indication for the HeartWare System in the United States. In May 2012, we completed enrollment in our ENDURANCE clinical trial. Designed to enroll up to 450 patients at 50 U.S. hospitals, the non-inferiority study is a randomized, controlled, unblinded, multi-center clinical trial to evaluate the use of the HeartWare System as a destination therapy in advanced heart failure patients. The study population was selected from patients with end-stage heart failure who have not responded to standard medical management and who are ineligible for heart transplantation. Patients in the study were randomly selected to receive either the HeartWare System or, as part of a control group, an alternative VAD approved by the FDA for destination therapy, in a 2:1 ratio. Each patient who received the HeartWare System or control VAD will be followed to the primary endpoint of two years, with a subsequent follow-up period extending to five years post-implant.

In June 2013, the FDA granted conditional approval to a protocol designed to confirm observations from ENDURANCE that sites adhering to more regular monitoring and management of patient blood pressure witnessed a notably lower incidence of neurological events. In this supplemental cohort, we currently expect to enroll up to an additional 240 HeartWare HVAD patients, as well as up to an additional 120 control patients using a randomization scheme consistent with the ENDURANCE protocol. Patients will be followed for 12 months after implant. We intend to incorporate the data from this new cohort into an anticipated Pre-Market Approval application seeking approval of the HeartWare System for the Destination Therapy indication. Patient enrollment in this supplemental cohort can commence at the 50 centers participating in the ENDURANCE clinical trial, following edits to the protocol as prescribed by FDA and Institutional Review Board approvals at each of the centers. We expect patient enrollment will commence in the second half of 2013.

Beyond the HeartWare System, we are also evaluating our new miniaturized device, known as the MVAD® System. The MVAD System utilizes the same technology platform as the HeartWare System but adopts an axial flow, rather than a centrifugal flow, configuration. The MVAD Pump is less than one-half the size of the HVAD Pump and can provide partial or full support. The MVAD platform has been designed to allow for multiple configurations and surgical placements in order to reduce surgical invasiveness while improving clinical outcomes. We currently expect to enroll our first patient in an MVAD international study in early 2014.

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 System, and related accessories and support on-going and new clinical trial activity.

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We have financed our operations primarily through the issuance of shares of our common stock and the issuance of convertible notes. Most recently, in March 2013, we completed a public offering of 1,725,000 shares of our common stock, including the underwriters' exercise of their over-allotment option to purchase 225,000 shares, at an offering price of \$86.45 per share for aggregate gross proceeds of approximately \$149.1 million. After fees and related expenses, net proceeds from the offering were approximately \$141.0 million.

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

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, 2012 ("2012 Annual Report on Form 10-K") filed with the Securities and Exchange Commission on February 27, 2013. During the six months ended June 30, 2013, 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 2012 Annual Report on Form 10-K.

Results of Operations

Three and six months ended June 30, 2013 and 2012

Revenue, net

In November 2012, we received approval from the FDA for the HeartWare System as a bridge to heart transplantation in patients with end-stage heart failure. This approval resulted in substantially increased year-to-date sales in the United States compared to year-to-date fiscal 2012 sales which were derived from a mix of clinical trial activities in the United States and ongoing commercial sales of our HVAD system internationally.

During the three and six months ended June 30, 2013, domestic revenues comprised approximately 49% and 51%, respectively, of our product sales compared to approximately 14% and 19% in the three and six months ended June 30, 2012, respectively.

	Three Months Ended June 30,		Change	Six Months Ended June 30,		Change
	2013	2012		2013	2012	
	(in thousands)			(in thousands)		
Revenue, net	\$50,836	\$29,053	75%	\$100,075	\$55,398	81%

During the three months ended June 30, 2013, our U.S. revenues increased approximately \$20.9 million, or 498%, to \$25.1 million compared to U.S. revenues of approximately \$4.2 million in the three months ended June 30, 2012. A total of 235 HVAD pumps were sold in the U.S. during the quarter compared to 42 pumps sold in the same period in 2012. International sales increased during the quarter by approximately \$0.8 million, or 4%, to \$25.7 million compared to international revenues of approximately \$24.9 million in the three months ended June 30, 2012. A total of 288 HVAD pumps were sold internationally during the quarter compared to 276 pumps sold internationally in the same period in 2012.

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During the six months ended June 30, 2013, our U.S. revenues increased approximately \$40.7 million, or 382%, to \$51.3 million compared to U.S. revenues of approximately \$10.6 million in the six months ended June 30, 2012. A total of 473 HVAD pumps were sold in the U.S. during the six month period compared to 116 pumps sold in the same period in 2012. International sales increased during the six month period by approximately \$4.0 million, or 9%, to \$48.8 million compared to international revenues of approximately \$44.8 million in the six months ended June 30, 2012. A total of 532 HVAD pumps were sold internationally year-to-date compared to 500 pumps sold internationally in the year-to-date period in 2012.

Changes in foreign currency exchange rates favorably impacted net revenue by approximately \$0.2 million and \$0.1 million, or less than 1%, in the three and six months ended June 30, 2013, respectively, compared to the three and six months ended June 30, 2012. During the three and six month ended June 30, 2013, approximately 43% and 42% of our sales were denominated in foreign currencies including principally the Euro and British pound. Movements in foreign currency exchange rates have had an effect on our reported revenue amounts in the past and could have a significant favorable or unfavorable impact on our reported revenue amounts in the future.

We expect to continue to generate and grow commercial revenue from product sales as we further expand our sales and marketing efforts on a global basis, including commercial sales in the U.S. following our recent FDA approval of the HeartWare System for bridge-to-transplant. Future product sales are dependent on many factors, including perception of product performance and market acceptance among physicians, patients, health care payers and the medical community as well as our capacity to meet customer demand by manufacturing sufficient quantities of our products.

Cost of Revenue

Cost of revenue includes costs associated with manufacturing and distributing our products and consists of direct materials, labor and overhead expenses allocated to the manufacturing process, provisions for excess or obsolete inventory, and shipping costs. Cost of revenue totaled approximately \$18.9 million and \$12.7 million in the three months ended June 30, 2013 and 2012, respectively. Cost of revenue totaled approximately \$37.6 million and \$23.5 million in the six months ended June 30, 2013 and 2012, respectively.

Gross profit and gross margin percentage are as follows:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2013	2012	2013	2012
	(in thousands)		(in thousands)	
Gross profit	\$31,970	\$16,388	\$62,429	\$31,905
Gross margin %	62.9%	56.4%	62.4%	57.6%

Gross margin percentage for the three and six months ended June 30, 2013 increased compared to the same periods in 2012 by 6.5% and 4.8% respectively. The increase was primarily a result of decreased cost per unit due to production efficiencies associated with increased sales and higher per unit sales prices in 2013, which are attributable to the introduction of commercial product in the United States during the fourth quarter of 2012. Compared to the same periods in the prior year higher unit sales prices contributed 1.4% and 2.4% of the gross margin increase for the three and six months ended June 30, 2013, respectively, with the balance of the increase related to the described production efficiencies.

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, marketing, 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.

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	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	Change	2013	2012	Change
	(in thousands)			(in thousands)		
Total selling, general and administrative expenses	\$17,217	\$14,204	21%	\$33,704	\$26,920	25%
% of operating expenses	42%	42%		42%	40%	

The increase of \$3.0 million for the three months ended June 30, 2013 as compared to the three months ended June 30, 2012 was primarily a result of an increase in employee costs, including salaries and related costs, of approximately \$1.7 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 expenses related to our commercial launch of the HeartWare System in the United States, including travel, conferences and trade shows and marketing expenditures, aggregating \$1.1 million. These expense increases were partially offset by a reduction in non-cash share-based compensation expense of \$0.8 million, primarily due to the reduction in our estimated forfeiture rate in the second quarter of 2012, which resulted in an expense catch-up on historical grants in the three months ended June 30, 2012. Selling, general and administrative expenses for the three months ended June 30, 2012 were partially offset by an insurance recovery of \$0.8 million related to the settlement of litigation.

The increase of \$6.8 million for the six months ended June 30, 2013 as compared to the six months ended June 30, 2012 was primarily a result of an increase in employee costs, including salaries and related costs, of approximately \$3.5 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 expenses related to our commercial launch of the HeartWare System in the United States, including travel, conferences and trade shows and marketing expenditures, aggregating \$2.2 million. Selling, general and administrative expenses for the six months ended June 30, 2012 were partially offset by an insurance recovery of \$0.8 million related to the settlement of litigation. Expense increases were partially offset by a reduction in non-cash share-based compensation expense of \$0.3 million, primarily due to the reduction in our estimated forfeiture rate in the second quarter of 2012, which resulted in an expense catch-up on historical grants in the three months ended June 30, 2012.

In 2010, the Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education Reconciliation Act of 2010 (the "Reconciliation Act") were signed into law. Among other things, the PPACA and the Reconciliation Act, when taken together, impose a 2.3% excise tax on the U.S. sales of certain medical devices, including our devices, which became effective January 1, 2013. We have included this tax expense in selling, general and administrative expenses on our condensed consolidated statements of operations. We have not invoiced our customers for this tax as a separate charge, and the tax is not included as an element of revenue. The statutory rate of the medical device excise tax is 2.3% of revenues on initial sales of finished medical products sold in the United States. The amount of excise tax recognized in the three and six months ended June 30, 2013 was approximately \$0.5 million and \$1.1 million, respectively.

We expect our selling, general and administrative expenses to continue to increase in 2013 compared to 2012 as we continue to expand our sales and distribution capabilities in an effort to increase market penetration on a global basis as well as enhance 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 staffs, external research and development costs, and materials and expenses associated with clinical trials. Additional costs include travel, facilities and overhead allocations.

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	Three Months Ended June 30,			Six Months Ended June 30,		
	2013	2012	Change	2013	2012	Change
	(in thousands)			(in thousands)		
Total research and development expenses	\$24,188	\$20,005	21%	\$46,330	\$40,012	16%
% of operating expenses	58%	58%		58%	60%	

The increase in research and development expenses for the three and six months ended June 30, 2013 as compared to the same periods in 2012 was primarily due to an increase in spending associated with product development initiatives, namely development of the PAL controller and the MVAD Pump.

The \$4.2 million increase for the three months ended June 30, 2013 was primarily due to an increase in costs associated with development projects, including consumables, outside engineering, consultants and contractors, of \$3.5 million and additional employee costs, including salaries and wages and related costs, of approximately \$1.9 million associated with increased headcount. These increases were partially offset by a decrease in costs related to clinical trials of \$1.7 million.

The \$6.3 million increase for the six months ended June 30, 2013 was primarily due to an increase in costs associated with development projects, including consumables, outside engineering, consultants and contractors, of \$3.6 million and additional employee costs, including salaries and wages and related costs, of approximately \$3.2 million associated with increased headcount. These increases were partially offset by a decrease in costs related to clinical trials of \$2.1 million.

We expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future as we continue to incur substantial development costs related to our next generation products, including PAL and MVAD, and certain early research initiatives, new clinical trial expenses related to clinical trials for HVAD in new markets and MVAD both in Europe and the United States, as well as ongoing clinical trial expenses associated with bridge-to-transplant post-approval study requirements and ongoing patient follow-up related to the ENDURANCE clinical trial.

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 affect our financial results. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter.

In the three and six months ended June 30, 2013, our net foreign exchange losses totaled approximately \$0.6 million and \$2.5 million, respectively, compared to net losses of approximately \$2.2 million and \$1.1 million in the same periods of 2012. In 2013 and 2012, 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 a significant portion of our sales is denominated in foreign currencies. We do not currently utilize foreign currency contracts to manage foreign exchange risks.

Interest Expense

Interest expense in 2013 and 2012 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 June 30, 2013, interest expense was approximately \$3.0 million, which included \$1.3 million of interest incurred on the principal amount of the convertible notes at the 3.5% coupon rate and \$1.7 million of non-cash amortization of the discount and deferred financing costs. In the three months ended June 30, 2012, interest expense was approximately \$2.8 million, which included \$1.3 million of interest incurred on the principal amount of the convertible notes at the 3.5% coupon rate and \$1.5 million of non-cash amortization of the discount and deferred financing costs.

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In the six months ended June 30, 2013, interest expense was approximately \$6.0 million, which included \$2.5 million of interest incurred on the principal amount of the convertible notes at the 3.5% coupon rate and \$3.5 million of non-cash amortization of the discount and deferred financing costs. In the six months ended June 30, 2012, interest expense was approximately \$5.6 million, which included \$2.5 million of interest incurred on the principal amount of the convertible notes at the 3.5% coupon rate and \$3.1 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 \$0.1 million in both the three and six months ended June 30, 2013, compared to \$0.1 million and \$0.2 million in the same periods in the prior year. We ended the second quarter of 2013 with approximately \$222.4 million in cash, cash equivalents and available-for-sale investments, primarily due to our public offering of our common stock completed in March 2013. While we had higher average balances during the second quarter of 2013 and first half of 2013 compared to 2012, we continue to experience low interest rates.

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. Foreign earnings are considered to be permanently reinvested in operations outside the U.S. and therefore we have not provided for U.S. income taxes on these unrepatriated foreign earnings. We have incurred significant U.S. losses since inception, however, 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 therefore a 100% valuation allowance has been recorded against our net deferred tax assets. As of June 30, 2013, 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 June 30, 2013, our cash and cash equivalents were approximately \$190.0 million as compared to \$85.9 million at December 31, 2012.

Following is a summary of our cash flow activities:

	Six Months Ended	
	June 30,	
	2013	2012
	(in thousands)	
Net cash used in operating activities	\$ (22,410)	\$(29,270)
Net cash (used in) provided by investing activities	(17,782)	71,058
Net cash provided by financing activities	142,699	1,065
Effect of exchange rate changes on cash and cash equivalents	1,596	391
Net increase in cash and cash equivalents	<u>\$104,103</u>	<u>\$ 43,244</u>

Cash Used in Operating Activities

For the six months ended June 30, 2013, cash used in operating activities included a net loss of approximately \$25.9 million and non-cash adjustments to net loss totaling approximately \$16.6 million which primarily consisted of \$9.4 million of share-based compensation, \$3.3 million for the amortization of the discount on our convertible notes and \$3.5 million of depreciation and amortization on long-lived assets. Also included in cash used in operating activities in the six months ended June 30, 2013 was approximately \$8.7 million in increased trade accounts receivable, \$2.6 million for the payment of accrued liabilities, \$1.2 million for the payment of trade payables and \$1.2 million for prepaid expenses and other current assets.

For the six months ended June 30, 2012, cash used in operating activities included a net loss of approximately \$41.6 million and non-cash adjustments to net loss totaling approximately \$16.2 million, which primarily consisted of \$10.1 million of share-based compensation, \$2.9 million for the amortization of the discount on our convertible senior notes and \$2.1 million of depreciation and amortization on long-lived assets. Also included in cash used in operating activities in the six months ended June 30, 2012 is approximately \$6.8 million related to an increase in accounts receivable, \$3.2 million for the purchase and manufacture of inventories and \$1.3 million for prepaid expenses and other current assets. These amounts were partially offset by increases in trade accounts payable of \$6.0 million and other current liabilities of \$0.8 million.

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Cash Used in Investing Activities

In the six months ended June 30, 2013, net cash used by investing activities included \$15.8 million for the purchase (net of maturities) of available-for-sale securities. Other investing activities in the six months ended June 30, 2013 used cash of approximately \$2.0 million, primarily to acquire property, plant and equipment.

In the six months ended June 30, 2012, net cash provided by investing activities included \$75.0 million received upon maturity (net of purchases) of available-for-sale securities, \$2.9 million used to acquire property, plant and equipment and \$0.8 million paid for a security deposit on a facility lease.

Cash Provided by Financing Activities

On March 12, 2013, we entered into an Underwriting Agreement (the "Underwriting Agreement") with J.P. Morgan Securities LLC, as representative of the several underwriters named in the Underwriting Agreement (the "Underwriters"), pursuant to which we agreed to sell and the Underwriters agreed to purchase, subject to and upon terms and conditions set forth therein, an aggregate of 1,500,000 shares of our common stock at a net sales price of \$81.9114 per share (the public offering price of \$86.45 per share minus the underwriting discount). We also granted the Underwriters an option to purchase 225,000 additional shares of our common stock at the public offering price less the underwriting discount, which the Underwriters exercised in full on March 13, 2013. The closing of the offering occurred on March 18, 2013. After fees and related expenses, net proceeds from the offering were approximately \$141.0 million. The offering was completed pursuant to a prospectus supplement, dated March 12, 2013, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010. This shelf registration statement allows us to offer and sell from time to time, in one or more series or issuances and on terms that we determine at the time of the offering, any combination and amount of the securities described in the prospectus contained in the registration statement.

The exercise of stock options in the six months ended June 30, 2013 and 2012 resulted in cash proceeds of approximately \$1.7 million and \$1.1 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, develop new products and seek regulatory approvals for expanded indications of the HeartWare System in the U.S. For the remainder of 2013, cash on hand is expected to primarily be used to fund our ongoing operations, including:

- expanding our sales and marketing capabilities on a global basis;
- growing market penetration particularly in the U.S. following FDA approval of the HeartWare System;
- continued product development, including development of the MVAD Pump and PAL controller, and clinical trials related to expanded indications of the HeartWare System;
- pre-clinical costs relating to prospective first human implants of the MVAD Pump;
- regulatory and other compliance functions;
- planned investments in infrastructure to support our growth; 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, 2013, we paid the \$2.5 million interest payment that was due on June 15, 2013. To date, all interest payments have been paid on a timely basis. Based on the outstanding principal amount of our convertible senior notes at June 30, 2013, the semi-annual interest payment due on December 15, 2013 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 June 30, 2013 are sufficient to support our planned operations for at least the next twelve months. At June 30, 2013, approximately \$8.3 million of our cash on hand was held in foreign

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locations, including Australia, Germany and the United Kingdom. To date, the Company has not had unremitted foreign earnings and has not incurred U.S. federal and state income taxes related to repatriated earnings. As our operations in our foreign subsidiaries grow, we may generate foreign earnings and repatriation of those earnings to the U.S. could result in the levy of U.S. federal and state income taxes.

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;
- reimbursement of our products by governmental agencies and third party payers;
- 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;
- 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;
- payment of the 2.3% excise tax on gross revenue from the sale of our medical devices in the U.S. imposed by the PPACA;
- payment of our convertible notes on maturity if not converted or repurchased; and
- complying with the requirements related to being a public company in both the United States and Australia.

Contractual Obligations

In the six months ended June 30, 2013, there were no material changes outside the ordinary course of business 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 2012 Annual Report on Form 10-K filed with the SEC on February 27, 2013.

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 June 30, 2013. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2013, 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 June 30, 2013, 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.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company is not a party to any material legal proceedings at the date of filing of this 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, 2012 filed with the SEC on February 27, 2013.

ITEM 6. EXHIBITS

- 3.1 Certificate of Incorporation of HeartWare International, Inc. (1)
- 3.2 Bylaws of HeartWare International, Inc. (1)
- 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 June 30, 2013, 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.

*** 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: August 8, 2013

/s/ Douglas Godshall

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

Date: August 8, 2013

/s/ Peter F. McAree

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

EXHIBIT INDEX

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**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: August 8, 2013

/s/ Douglas Godshall

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

**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: August 8, 2013

/s/ Peter F. McAree

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

**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 June 30, 2013 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: August 8, 2013

/s/ Douglas Godshall

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

**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 June 30, 2013 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: August 8, 2013

/s/ Peter F. McAree

Peter F. McAree

Senior Vice President and Chief Financial Officer
(Principal Financial Officer)