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

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2016

**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

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**HEARTWARE INTERNATIONAL, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State of Incorporation)

26-3636023  
(I.R.S. Employer  
Identification No.)

500 Old Connecticut Path  
Framingham, Massachusetts 01701  
(508) 739-0950  
(Address of principal executive offices)

(Registrant's telephone number, including area code)

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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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>

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

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

Class	Shares Outstanding as of May 2, 2016
Common Stock, \$0.001 Par Value Per Share	17,540,557

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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 direct and indirect subsidiaries.

### Currency

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

### Trademarks

HEARTWARE®, HVAD®, MVAD®, Pal™, CIRCULITE®, SYNERGY® and various company logos are the trademarks of the Company. 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 ability to implement systemic improvements necessary to satisfactorily address the observations cited in the June 2, 2014 warning letter we received from the United States Food and Drug Administration (“FDA”);
- our expectations with respect to submissions to and approvals from regulatory bodies, such as the FDA;
- our ability to operate our business in compliance with regulatory requirements and to implement appropriate corrective and preventive actions;
- our expectations with respect to our clinical trials, including enrollment in, completion of, or outcomes of our clinical trials as well as approval of new clinical trials and continued access or supplemental protocols with respect to our existing clinical trials;
- our expectations with respect to the integrity or capabilities of our intellectual property position;
- our ability and plans to commercialize our existing products;
- our ability and plans to develop and commercialize new products and the expected features, functionalities and benefits of these products;
- our ability to successfully compete against our competitors, especially as they increase in size and leverage, including our ability to respond to bundled product offerings and competitive pricing strategies;
- our estimates regarding our capital requirements and financial performance, including earnings fluctuation and cash availability; and
- our ability to manage the costs and achieve the benefits of our strategic initiatives, including acquired companies and technologies.

Our management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on our forward-looking statements because they speak only as of the date when made. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by federal securities laws and the rules and regulations of the Securities and Exchange Commission (the “SEC”). We may not actually achieve the plans, projections or expectations disclosed in our forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including without limitation those

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described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 filed with the SEC on February 26, 2016, and those described from time to time in our other filings with the SEC. Investors should read this entire Quarterly Report on Form 10-Q and consult their respective financial, legal or other professional adviser in relation to the subject matter therein, especially as it pertains to our risks and uncertainties outlined in Part I, Item 1A. "Risk Factors" of our Annual Report on Form 10-K, together with the information provided in our other public 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>March 31, 2016</u> (unaudited)	<u>December 31, 2015</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 113,256	\$ 175,047
Short-term investments	74,952	68,531
Accounts receivable, net	29,472	35,570
Inventories	43,407	39,947
Prepaid expenses and other current assets	6,905	2,868
Total current assets	267,992	321,963
Property, plant and equipment, net	14,602	15,098
Goodwill	61,282	61,233
In-process research and development	10,800	10,800
Other intangible assets, net	12,970	13,045
Long-term investments and other assets	63,668	31,464
Total assets	<u>\$ 431,314</u>	<u>\$ 453,603</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 13,709	\$ 15,249
Other accrued liabilities	35,521	45,889
Total current liabilities	49,230	61,138
Convertible senior notes, net	189,572	187,089
Contingent liabilities – See Note 4	12,910	12,330
Other long-term liabilities	4,035	4,554
Commitments and contingencies – See Note 12		
Stockholders' equity:		
Preferred stock – \$.001 par value; 5,000 shares authorized; no shares issued and outstanding at March 31, 2016 and December 31, 2015	—	—
Common stock – \$.001 par value; 50,000 shares authorized; 17,536 and 17,405 shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively	18	17
Additional paid-in capital	622,606	618,219
Accumulated deficit	(438,959)	(421,499)
Accumulated other comprehensive loss:		
Cumulative translation adjustments	(8,063)	(8,085)
Unrealized loss on investments	(35)	(160)
Total accumulated other comprehensive loss	(8,098)	(8,245)
Total stockholders' equity	175,567	188,492
Total liabilities and stockholders' equity	<u>\$ 431,314</u>	<u>\$ 453,603</u>

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

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

(In thousands, except per share data)

	Three Months Ended March 31,	
	2016	2015
Revenue, net	\$ 55,074	\$ 70,021
Cost of revenue	23,021	22,040
Gross profit	32,053	47,981
Operating expenses:		
Selling, general and administrative	21,474	21,929
Research and development	25,221	31,267
Change in fair value of contingent consideration	580	2,100
Total operating expenses	47,275	55,296
Loss from operations	(15,222)	(7,315)
Other income (expense):		
Foreign exchange (loss) gain	920	(3,697)
Interest expense	(3,740)	(3,437)
Investment income, net	725	146
Other, net	5	—
Loss before income taxes	(17,312)	(14,303)
Provision for income taxes	147	232
Net loss	<u>\$ (17,459)</u>	<u>\$ (14,535)</u>
Net loss per common share — basic and diluted	<u>\$ (1.00)</u>	<u>\$ (0.85)</u>
Weighted average shares outstanding — basic and diluted	<u>17,462</u>	<u>17,193</u>

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

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
Net loss	\$(17,459)	\$(14,535)
Other comprehensive income (loss)		
Foreign currency translation adjustments	23	(254)
Unrealized (loss) gain on investments	124	(245)
Comprehensive loss	<u>\$(17,312)</u>	<u>\$(15,034)</u>

The accompanying notes are an integral part of these unaudited condensed consolidated 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, 2015	17,405	\$ 17	\$618,219	\$ (421,499)	\$ (8,245)	\$188,492
Issuance of common stock pursuant to share-based awards	131	1	—	—	—	1
Share-based compensation	—	—	4,387	—	—	4,387
Net loss	—	—	—	(17,459)	—	(17,459)
Other comprehensive loss	—	—	—	—	147	147
Balance, March 31, 2016	<u>17,536</u>	<u>\$ 18</u>	<u>\$622,606</u>	<u>\$ (438,959)</u>	<u>\$ (8,098)</u>	<u>\$175,567</u>

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

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

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (17,459)	\$ (14,535)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	1,609	1,710
Amortization of intangible assets	467	508
Impairment of fixed assets	—	1,118
Share-based compensation expense	4,387	5,976
Amortization of premium on investments	237	300
Amortization of discount on convertible senior notes	2,321	2,068
Amortization of deferred financing costs	162	111
Change in fair value of contingent consideration	580	2,100
Other	(144)	(6)
Change in operating assets and liabilities:		
Accounts receivable	6,670	(105)
Inventories	(3,154)	(99)
Prepaid expenses and other current assets	(4,002)	(1,445)
Other non-current assets	(951)	(337)
Accounts payable	(1,565)	(2,625)
Accrued interest on convertible senior notes	1,257	1,258
Other accrued liabilities	(12,084)	(3,662)
Other long-term liabilities	(519)	(124)
Net cash used in operating activities	(22,188)	(7,789)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of investments	(9,977)	—
Maturities of investments	3,445	5,000
Additions to property, plant and equipment, net	(918)	(720)
Additions to patents	(392)	(486)
Investment in unconsolidated investee	(31,000)	—
Cash received from security deposits	178	294
Net cash provided by (used in) investing activities	(38,664)	4,088
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from exercise of stock options	—	31
Net cash provided by financing activities	—	31
Effect of exchange rate changes on cash and cash equivalents	(939)	3,249
<b>DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(61,791)</b>	<b>(421)</b>
<b>CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD</b>	<b>175,047</b>	<b>102,946</b>
<b>CASH AND CASH EQUIVALENTS — END OF PERIOD</b>	<b>\$ 113,256</b>	<b>\$ 102,525</b>

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

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

**Note 1. Basis of Presentation**

The accompanying unaudited interim condensed consolidated financial statements for HeartWare International, Inc. (“we,” “our,” “us,” “HeartWare,” the “HeartWare Group” or the “Company”) 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 (“U.S. GAAP”) have been condensed or omitted. Accordingly, these statements do not include all the disclosures normally required by U.S. GAAP 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, 2015. The accompanying condensed consolidated balance sheet as of December 31, 2015 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three months ended March 31, 2016 are not necessarily indicative of the results to be expected for any future period or for the year ending December 31, 2016.

The preparation of our unaudited interim condensed consolidated financial statements in conformity with 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.

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.

***New Accounting Standards***

***Standards Pending Implementation***

In March 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-09, *Improvements to Employee Share-Based Payment Accounting* (“ASU 2016-09”). ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2016. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-09 on its financial statements and related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases* (“ASU 2016-02”). ASU 2016-02 supersedes the lease guidance under FASB Accounting Standards Codification (“ASC”) Topic 840, *Leases*, resulting in the creation of FASB ASC Topic 842, *Leases*. ASU 2016-02 requires a lessee to recognize in the statement of financial position a liability to make lease payments and a right-of-use asset representing its right to use the underlying asset for the lease term for both finance and operating leases. This ASU is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company is currently assessing the potential impact of adopting ASU 2016-02 on its financial statements and related disclosures.

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)* (“ASU 2014-09”). The updated standard is a new comprehensive revenue recognition model that requires revenue to be recognized in a manner that depicts the transfer of goods or services to a customer at an amount that reflects the consideration expected to be received in exchange for those goods or services. In July 2015, the FASB voted to approve the deferral of the effective date of ASU 2014-09 by one year. Therefore, ASU 2014-09 will become effective for us in the first quarter of our fiscal year ending December 31, 2018. Early adoption is permitted, but not earlier than the first quarter of our fiscal year ending December 31, 2017. The ASU allows for either full retrospective or modified retrospective adoption. We have not yet selected a transition method, and we are currently evaluating the effect that ASU 2014-09 will have on our consolidated financial statements and related disclosures.

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

*Implemented Standards*

In April 2015, the FASB issued ASU 2015-03, *Interest — Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. In June 2015, the FASB amended ASU 2015-03 with ASU 2015-15. The updated standard requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. This guidance is effective for periods beginning after December 15, 2015, and interim periods within those annual periods applied retrospectively. The Company adopted this guidance in the first quarter of 2016. Debt issuance costs associated with debt were \$3.8 and \$4.0 million as of March 31, 2016 and December 31, 2015, respectively.

In February 2015, the FASB issued ASU No. 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis*, which is intended to improve targeted areas of consolidation guidance for legal entities such as limited partnerships, limited liability corporations and securitization structures (collateralized debt obligations, collateralized loan obligations and mortgage-backed security transactions). This ASU focuses on the consolidation evaluation for reporting organizations (public and private companies and not-for-profit organizations) that are required to evaluate whether they should consolidate certain legal entities. In addition to reducing the number of consolidation models from four to two, the new standard simplifies the FASB Accounting Standards Codification by: i) placing more emphasis on risk of loss when determining a controlling financial interest; ii) reducing the frequency of the application of related-party guidance when determining a controlling financial interest in a variable interest entity (“VIE”); and iii) changing consolidation conclusions for public and private companies in several industries that typically make use of limited partnerships or VIEs. ASU No. 2015-02 will be effective for us in periods beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. The Company adopted this guidance in the first quarter of 2016 and it did not have an effect on our consolidated financial position, results of operations or cash flows.

In January 2015, the FASB issued ASU No. 2015-01, *Income Statement—Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items*. The FASB issued this ASU as part of its initiative to reduce complexity in accounting standards. This ASU eliminates from U.S. GAAP the concept of extraordinary items. Subtopic 225-20 required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. If an event or transaction meets the criteria for extraordinary classification, an entity is required to segregate the extraordinary item from the results of ordinary operations and show the item separately in the income statement, net of tax, after income from continuing operations. The entity also is required to disclose applicable income taxes and either present or disclose earnings-per-share data applicable to the extraordinary item. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the amendments prospectively. A reporting entity also may apply the amendments retrospectively to all prior periods presented in the financial statements. The Company adopted this guidance in the first quarter of 2016 and it did not have an effect on our consolidated financial position, results of operations or cash flows.

***Reclassification of Prior Year Presentation***

Certain prior year amounts have been reclassified for consistency with the current period presentation. These reclassifications had no effect on the reported results of operations. In the period ended March 31, 2016, management reassessed certain inventory policies based on recent trends, including sales, usage and forecasted usage of specific inventory items. As a result, we now expect that certain inventory could be held beyond one year. As of March 31, 2016, approximately \$7.4 million of inventory was classified as non-current inventory and included within other assets on the accompanying consolidated balance sheet. To reflect the result of this change, for consistency we reclassified approximately \$7.7 million of inventory as of December 31, 2015 from current assets to non-current and included within other assets on the consolidated balance sheet. Corresponding reclassifications have also been made to the Consolidated Condensed Statement of Cash Flows for the periods ended March 31, 2015 and 2016, to reflect the gross purchases and sales of these assets as a component of other non-current assets. This change in classification does not affect previously reported cash flows from operations or from financing activities in the Consolidated Condensed Statement of Cash Flows, and had no effect on the previously reported Consolidated Condensed Statement of Operations for any period.

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

**Note 2. Liquidity**

We have funded our operations primarily through product revenue, the issuance of shares of our common stock and the issuance of convertible notes. At March 31, 2016, we had approximately \$189.2 million of cash, cash equivalents and available-for-sale investments. Our cash, cash equivalents and available-for-sale investments are expected to be used primarily to fund our ongoing operations including expanding our sales and marketing capabilities on a global basis; research and development (including clinical trials) of new and existing products, components and accessories; regulatory and other compliance functions; acquisition of, and investment in, third-party technologies; as well as for general working capital. We believe our cash, cash equivalents and available-for-sale investment balances are sufficient to support our planned operations for at least the next twelve months.

The accompanying unaudited interim 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 March 31, 2016. At March 31, 2016, we had an accumulated deficit of approximately \$439.0 million.

**Note 3. Balance Sheet Information***Accounts Receivable*

Accounts receivable consists of amounts due from the sale of our HeartWare Ventricular Assist System (the "HVAD 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. We had one customer with an accounts receivable balance representing approximately 25% and 17% of our total accounts receivable at March 31, 2016 and December 31, 2015, respectively. A portion of this account receivable was classified as long-term as of March 31, 2016 and December 31, 2015 in accordance with our payment terms with this customer.

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.

The following table summarizes the change in our allowance for doubtful accounts for the three months ended March 31, 2016 and 2015:

	<u>2016</u>	<u>2015</u>
	<u>(in thousands)</u>	
Beginning balance	\$ 676	\$671
Reversal of expense	(154)	(26)
Charge-offs	—	—
Ending balance	<u>\$ 522</u>	<u>\$645</u>

As of March 31, 2016 and December 31, 2015, we recorded customer sales allowances of \$92,000 and \$81,000, respectively.

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

***Inventories, net***

Components of inventories are as follows:

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
	<b>(in thousands)</b>	
Raw material	\$ 15,090	\$ 17,940
Work-in-process	9,243	8,858
Finished goods	19,074	13,149
	<u>\$ 43,407</u>	<u>\$ 39,947</u>

Finished goods inventories includes inventory held on consignment at customer sites of approximately \$9.1 million at March 31, 2016 and \$6.2 million at December 31, 2015. The increase in consignment inventory as of March 31, 2016 is due to pre-shipment of batteries to execute a field action announced in September 2015 (see *Accrued Field Action Costs for more information*). We review our inventory for excess or obsolete items and write-down obsolete or otherwise unmarketable inventory to its net realizable value.

***Property, Plant and Equipment, Net***

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

	<b>Estimated Useful Lives</b>	<b>March 31, 2016</b>	<b>December 31, 2015</b>
		<b>(in thousands)</b>	
Machinery and equipment	1.5 to 7 years	\$ 22,557	\$ 21,785
Leasehold improvements	3 to 10 years	8,901	8,891
Office equipment, furniture and fixtures	5 to 7 years	2,105	2,105
Purchased software	1 to 7 years	7,796	7,575
		41,359	40,356
Less: accumulated depreciation		(26,757)	(25,258)
		<u>\$ 14,602</u>	<u>\$ 15,098</u>

***Long-Term Investment and Other Assets***

Long-term investments consist of the following:

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
	<b>(in thousands)</b>	
Investment in Valtech Cardio, Ltd.	\$ 48,960	\$ 17,620
Long-term inventory	7,367	7,739
Long-term receivables	3,953	2,539
Security deposits	2,408	2,586
Other assets	980	980
	<u>\$ 63,668</u>	<u>\$ 31,464</u>

***Valtech Cardio, Ltd.***

As of March 31, 2016, we have invested approximately \$48.0 million in Valtech Cardio, Ltd (“Valtech”), an early-stage, privately held company headquartered in Or Yehuda, Israel specializing in the development of devices for mitral and tricuspid valve repair and replacement. Our investment is carried in long-term investments and other assets and consists of the following:

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

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
	(in thousands)	
Preferred Stock	\$ 10,495	\$ 10,495
Convertible Promissory Notes Receivable, due July 10, 2017	8,222	7,125
Convertible Promissory Notes Receivable, due February 1, 2019	30,243	—
	<u>\$ 48,960</u>	<u>\$ 17,620</u>

In October 2013, we invested \$10 million in Valtech in the form of a convertible promissory note with an interest rate of 6% per annum (the “2013 Note”), which, along with net accrued interest, has since been converted to Valtech equity pursuant to the terms of the 2013 Note.

In July 2015, we invested an additional \$5 million in Valtech in the form of a convertible promissory note with an interest rate of 6% per annum.

On September 1, 2015, we entered into a Business Combination Agreement (the “BCA”) by and among the Company, Valtech, HW Global, Inc. (“Holdco”), HW Merger Sub, Inc., Valor Merger Sub Ltd. and Valor Shareholder Representative, LLC, pursuant to which we and Valtech proposed to effect a strategic combination of our respective businesses under Holdco, subject to certain closing conditions. Effective January 28, 2016, we terminated the BCA pursuant to the terms of the BCA by delivering written notice to the other parties. After entering into the BCA and pursuant to the terms of the BCA, we loaned Valtech an aggregate principal amount of \$3 million in interim funding at an interest rate of 6% per annum in \$1 million increments in each of November 2015, December 2015 and January 2016. In connection with the termination provisions of the BCA, we loaned Valtech an additional \$30 million on February 1, 2016 also in the form of a convertible promissory note with an interest rate of 6% per annum. We have no current contractual obligations to further fund Valtech.

Upon maturity, each of the convertible promissory notes become due and payable in cash or Valtech preferred stock, at the option of Valtech, pursuant to terms of the convertible promissory notes. If the convertible promissory notes become due and payable upon an event of default (as defined in the notes), we determine whether the notes are paid in cash or Valtech preferred stock.

Our investment in Valtech was deemed to be realizable as of March 31, 2016. The fair value of this investment has not been estimated as of March 31, 2016 and December 31, 2015 as no impairment indicators were identified.

***Other Accrued Liabilities***

Other accrued liabilities consist of the following:

	<b>March 31, 2016</b>	<b>December 31, 2015</b>
	(in thousands)	
Accrued payroll and other employee costs	\$ 7,589	\$ 14,068
Accrued field action	7,552	8,503
Accrued warranty	5,893	6,116
Accrued material purchases	2,486	4,107
Accrued professional fees	2,002	2,685
Accrued research and development costs	1,744	2,191
Accrued restructuring costs	1,796	1,955
Accrued VAT	1,144	1,238
Other accrued expenses	5,315	5,026
	<u>\$ 35,521</u>	<u>\$ 45,889</u>

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*Accrued payroll and other employee costs*

Accrued payroll and other employee costs included estimated year-end employee bonuses of approximately \$2.2 million and \$8.0 million at March 31, 2016 and December 31, 2015, respectively.

*Accrued Warranty*

Certain patient accessories sold with the HVAD System are covered by a limited warranty ranging from one to two years. Estimated 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 the 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.

The following table summarizes the change in our warranty liability for the three months ended March 31, 2016 and 2015:

	<u>2016</u>	<u>2015</u>
	<u>(in thousands)</u>	
Beginning balance	\$6,116	\$4,685
Accrual for warranty expense	371	785
Warranty costs incurred during the period	<u>(594)</u>	<u>(655)</u>
Ending balance	<u>\$5,893</u>	<u>\$4,815</u>

*Accrued Field Action Costs*

The costs to repair or replace products associated with field actions and voluntary service campaigns are recorded when they are determined to be probable and reasonably estimable as a cost of revenue. Costs associated with field actions are not included in our warranty liability. The following table summarizes the change in field action liability for the three months ended March 31, 2016 and 2015:

	<u>2016</u>	<u>2015</u>
	<u>(in thousands)</u>	
Beginning balance	\$ 8,503	\$ 1,888
Accrual for field action costs	3,492	505
Field action costs incurred during the period	<u>(4,443)</u>	<u>(1,305)</u>
Ending balance	<u>\$ 7,552</u>	<u>\$ 1,088</u>

In February 2015, we expanded a 2013 voluntary field safety corrective action, by initiating a voluntary medical device recall of certain older controllers distributed in the U.S. during the ADVANCE and ENDURANCE clinical trial periods. The action had been initiated in certain foreign markets around the end of 2014. The affected controllers exhibit a higher susceptibility to electrostatic discharge than newer, commercial controllers. This recall was ongoing as of March 31, 2016.

In September 2015, we announced planned field actions to replace certain older AC adapters in use outside the United States and older batteries with new, more reliably designed product improvements. We also announced plans to implement a controller software update intended to improve controller performance reliability. These actions began on January 7, 2016 following requisite regulatory approvals. Recall costs incurred during the three months ended March 31, 2016 were associated with these actions.

The accrued field action liability as of March 31, 2016 includes an allowance of \$2.3 million related to the anticipated replacement of certain controllers based upon the potential for the power or driveline connectors to become loose. The Company's estimated liability for replacements is based upon assumptions which it considers reasonable in light of known circumstances.

During the quarter ended March 31, 2016, the Company recorded charges of \$3.5 million related to the above mentioned field actions.

**HEARTWARE INTERNATIONAL, INC.**  
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*Accrued Restructuring Costs*

The following table summarizes changes in our accrued restructuring costs for the three months ended March 31, 2016:

	<u>Facility Leases</u> <u>(in thousands)</u>
Beginning balance	\$ 1,955
Restructuring charges	—
Payments	(179)
Adjustments to estimated obligations	—
Change in fair value	<u>20</u>
Ending balance	<u>\$ 1,796</u>

The restructuring obligations reflected above resulted from the closure of CircuLite's former headquarters in Teaneck, New Jersey, which we ceased to occupy in 2014. The Teaneck operating lease runs September 2020. In connection with this action, we recorded a \$1.7 million liability equal to the estimated fair value of the remaining lease obligation as of the cease-use date. The fair value of the remaining liability is remeasured at the estimated fair value at each reporting period. In the three months ended March 31, 2015, this liability was increased by \$0.5 million as a result of a change in our estimated sublease start date (see Note 4 for significant inputs in determining estimate). These amounts are included in selling, general and administrative expenses on our condensed consolidated statements of operations.

In the three months ended March 31, 2016 the change in fair value is associated with accretion of the liability due to the effect of the passage of time on the fair value measurement.

**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.

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. There were no transfers between Level 1, Level 2 and Level 3 during the three months ended March 31, 2016 or 2015.

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 March 31, 2016 and December 31, 2015 and are carried at fair value.

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The following tables represent 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 the respective dates.

	Carrying Value	Fair Value	Fair Value Measurements at the Reporting Date Using		
			Level 1	Level 2	Level 3
(in thousands)					
<b>As of March 31, 2016</b>					
<b>Assets</b>					
Short-term investments	\$ 74,952	\$ 74,952	\$ —	\$ 74,952	\$ —
Long-term investments	980	980	—	980	—
<b>Liabilities</b>					
Convertible senior notes	189,572(1)	175,438	—	175,438	—
Contingent consideration	12,910	12,910	—	—	12,910
Royalties	934	934	—	—	934
Lease exit costs	1,796	1,796	—	—	1,796

	Carrying Value	Fair Value	Fair Value Measurements at the Reporting Date Using		
			Level 1	Level 2	Level 3
(in thousands)					
<b>As of December 31, 2015</b>					
<b>Assets</b>					
Short-term investments	\$ 68,531	\$ 68,531	\$ —	\$ 68,531	\$ —
Long-term investments	980	980	—	980	—
<b>Liabilities</b>					
Convertible senior notes	187,089(1)	200,351	—	200,351	—
Contingent consideration	12,330	12,330	—	—	12,330
Royalties	918	918	—	—	918
Lease exit costs	1,955	1,955	—	—	1,955

(1) The carrying amount of our convertible senior notes is net of unamortized discount and deferred financing costs. See Note 7 (Debt) for more information.

Our Level 2 financial assets and liabilities include available-for-sale investments and our convertible senior notes. The fair value of our available-for-sale investments and our 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. Our Level 3 financial liabilities include the following:

- **Contingent consideration** – Determining the fair value of the contingent consideration related to our acquisition of CircuLite in December 2013 requires significant management judgment or estimation. The estimated fair value is calculated using the income approach, with significant inputs that include various revenue assumptions, discount rates and applying a probability to each outcome. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement. The fair value of the contingent consideration is remeasured at the estimated fair value at each reporting period. Actual amounts paid may differ from the obligations recorded.

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- **Royalties** – Royalties represent future royalty payments to be made over the next 14 years pursuant to agreements related to intellectual property licensed or acquired by World Heart Corporation, which we acquired in August 2012. Determination of fair value requires 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.
- **Lease exit costs** – In the first quarter of 2014, we ceased the use of CircuLite’s former headquarters in Teaneck, New Jersey, which was subject to an operating lease that runs through the end of 2020, and we recorded a liability equal to the estimated fair value of the remaining lease payments as of the cease-use date. The fair value was estimated based upon the discounted present value of the remaining lease payments, considering future estimated sublease income, estimated broker fees and required tenant improvements. This estimated fair value requires management judgment. The fair value of this liability is remeasured at estimated fair value at each reporting period. Actual amounts paid may differ from the obligation recorded.

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the contingent consideration for the three months ended March 31, 2016:

	<u>Contingent Consideration (in thousands)</u>
Beginning balance	\$ 12,330
Payments	—
Change in fair value	<u>580</u>
Ending balance	<u>\$ 12,910</u>

The change in the fair value of the contingent consideration in the three months ended March 31, 2016 resulting from accretion of the liability due to the effect of the passage of time on the fair value measurement. Adjustments associated with the change in fair value of contingent consideration are presented on a separate line item on our condensed consolidated statements of operations. Potential valuation adjustments will be made in future accounting periods as additional information becomes available, including, among other items, progress toward developing the CircuLite System, as well as revenue and milestone targets as compared to our current projections, with the impact of these adjustments being recorded in our condensed consolidated statements of operations.

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the royalties for the three months ended March 31, 2016:

	<u>Royalties (in thousands)</u>
Beginning balance	\$ 918
Payments	(0)
Change in fair value	<u>16</u>
Ending balance	<u>\$ 934</u>

The expense associated with the change in fair value of the royalty payment obligations is included in research and development expenses on our condensed consolidated statements of operations.

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the lease exit costs for the three months ended March 31, 2016:

	<u>Lease Exit Costs (in thousands)</u>
Beginning balance	\$ 1,955

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Adjustments	0
Payments	(179)
Change in fair value	<u>20</u>
Ending balance	<u>\$1,796</u>

The expense associated with changes in the fair value of the lease exit costs is included in selling, general and administrative expenses on our consolidated statements of operations. The change in the fair value of the lease exit costs in the three months ended March 31, 2016 resulting from accretion of the liability due to the effect of the passage of time on the fair value measurement. Potential valuation adjustments will be made in future accounting periods as additional information becomes available, including our ability to sublease the facility in a timely manner and obtain a rate equivalent to our estimated sublease rate, with the impact of these adjustments being recorded in our condensed consolidated statements of operations.

The following table presents quantitative information about the inputs and valuation methodologies used for our fair value measurements classified in Level 3 of the fair value hierarchy as of March 31, 2016:

	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent consideration	Probability weighted income approach	Milestone dates	2020 to 2023
		Discount rate	17.0% to 24.0%
		Probability of occurrence	50%
Royalties	Discounted cash flow	Discount rate	4.8% to 7.8%
Lease exit costs	Discounted cash flow	Sublease start date	March 1, 2017
		Sublease rate	\$22.00/square foot
		Discount rate	3.5%

*Assets That Are Measured at Fair Value on a Nonrecurring Basis*

Non-marketable equity investments and non-financial assets such as intangible assets, goodwill and property, plant, and equipment, are evaluated for impairment annually or when indicators of impairment exist and are measured at fair value only if an impairment charge is recorded. In the three months ended March 31, 2016 and 2015, we recorded impairment charges of zero and \$1.1 million related to certain property, plant, and equipment. See Note 3 for more information. Non-financial assets such as identified intangible assets acquired in connection with our acquisitions 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 March 31, 2016 and December 31, 2015, all of our investments were classified as available-for-sale and carried at fair value. At March 31, 2016 and December 31, 2015, our short-term and long-term investments had maturity dates of less than twenty-four months.

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

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
(in thousands)				
<b>At March 31, 2016</b>				
Short-term investments:				
Corporate debt	\$ 32,492	\$ 0	\$ (31)	\$ 32,461
U.S. government agency debt	30,000	2	(6)	29,996
Certificates of deposit	12,495	—	—	12,495
Total short-term investments	<u>\$ 74,987</u>	<u>\$ 2</u>	<u>\$ (37)</u>	<u>\$ 74,952</u>
Long-term investments:				
Certificates of deposit	\$ 980	\$ —	\$ —	\$ 980
Total long-term investments	<u>\$ 980</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 980</u>
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
(in thousands)				
<b>At December 31, 2015</b>				
Short-term investments:				
Corporate debt	\$ 32,666	\$ —	\$ (100)	\$ 32,566
U.S. government agency debt	25,000	—	(60)	24,940
Certificates of deposit	11,025	—	—	11,025
Total short-term investments	<u>\$ 68,691</u>	<u>\$ —</u>	<u>\$ (160)</u>	<u>\$ 68,531</u>
Long-term investments:				
Certificates of deposit	\$ 980	\$ —	\$ —	\$ 980
Total long-term investments	<u>\$ 980</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 980</u>

For the three months ended March 31, 2016 and 2015, we did not have any realized gains or losses on our investments. At March 31, 2016 and December 31, 2015, the number of available-for-sale investments that had been in a continuous loss position for more than twelve months was twelve and thirteen, respectively. As of March 31, 2016, a total of six individual securities had been in an unrealized loss position for twelve months or less and the losses were determined to be temporary. We regularly review our investment portfolio to determine if any security is other-than-temporarily impaired, which would require us to record an impairment charge in the period any such determination is made. In making this judgment, we evaluate, among other things, the duration and extent to which the fair value of a security has been less than its amortized cost, the financial condition of the issuer, the time to maturity of the investment and our intent to sell the security prior to maturity where we would not be able to recover its amortized cost basis.

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**Note 6. Goodwill, In-Process Research and Development and Other Intangible Assets, Net**

*Goodwill*

The carrying amount of goodwill and the change in the balance for the three months ended March 31, 2016 and 2015 is as follows:

	2016	2015
	(in thousands)	
Beginning balance	\$61,233	\$61,390
Additions	—	—
Impairment	—	—
Foreign currency translation impact	49	(167)
Ending balance	<u>\$61,282</u>	<u>\$61,223</u>

*In-Process Research and Development*

The carrying value of our in-process research and development assets, which relate to the development and potential commercialization of certain acquired technologies, consisted of the following at March 31, 2016 and December 31, 2015:

	March 31, 2016	December 31, 2015
	(in thousands)	
CircuLite System technology	<u>\$ 10,800</u>	<u>\$ 10,800</u>

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.

*Other Intangible Assets*

Other intangible assets, net consisted of the following:

	March 31, 2016	December 31, 2015
	(in thousands)	
Patents	\$ 7,816	\$ 7,424
Purchased intangible assets		
Acquired technology rights	9,925	9,925
	17,741	17,349
Less: Accumulated amortization – Patents	(1,691)	(1,551)
Less: Accumulated amortization – Purchased intangible assets	(3,080)	(2,753)
	<u>\$ 12,970</u>	<u>\$ 13,045</u>

Our other intangible assets are amortized using the straight-line method over their estimated useful lives as follows:

Patents	15 years
Purchased intangible assets Acquired technology rights	6 to 16 years

Amortization expense was \$0.5 million for each of the three months ended March 31, 2016 and 2015.

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**Note 7. Debt**

At March 31, 2016 and December 31, 2015, we had outstanding convertible debt as follows:

	<u>March 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
(in thousands)		
Principal amount of the 3.5% convertible senior notes, due 2017	\$ 42,471	\$ 42,471
Deferred financing costs	(3,527)	(3,652)
Unamortized discount	(5,305)	(5,994)
	<u>\$ 33,639</u>	<u>\$ 32,825</u>
Equity component	<u>\$ 7,629</u>	<u>\$ 7,629</u>
Principal amount of the 1.75% convertible senior notes, due 2021	\$202,366	\$ 202,366
Deferred financing costs	(285)	(321)
Unamortized discount	(46,149)	(47,781)
	<u>\$155,932</u>	<u>\$ 154,264</u>
Equity component	<u>\$ 47,400</u>	<u>\$ 47,400</u>

Interest expense related to our convertible debt consisted of contractual 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 and was included in interest expense in our condensed consolidated statements of operations. For the three months ended March 31, 2016 and 2015, interest expense related to our convertible debt was as follows:

	<u>Three Months Ended</u> <u>March 31,</u>	
	<u>2016</u>	<u>2015</u>
(in thousands)		
Coupon rate	\$ 1,257	\$ 1,258
Amortization of discount	2,321	2,068
Amortization of deferred financing costs	162	111
	<u>\$ 3,740</u>	<u>\$ 3,437</u>

*3.5% Convertible Senior Notes*

On December 15, 2010, we completed the sale of 3.5% convertible senior notes due December 15, 2017, unless earlier repurchased by us or converted (the “2017 Notes”) for an aggregate principal amount of \$143.75 million, pursuant to the terms of an indenture dated December 15, 2010 (the “Indenture”) and a supplemental indenture (the “First Supplemental Indenture”), both filed with the SEC as exhibits to our Current Report on Form 8-K on December 15, 2010. The 2017 Notes are senior unsecured obligations of the Company. The 2017 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.

In May 2015, we entered into separate, privately negotiated, exchange agreements (the “Exchange”) with certain holders of our outstanding 2017 Notes. The general terms of exchange agreements were filed with the SEC on May 7, 2015 as an exhibit to our Current Report on Form 8-K. Pursuant to these agreements, we exchanged \$101.3 million aggregate principal amount of the 2017 Notes for \$118.2 million principal amount of 1.75% convertible senior notes due 2021 (see further discussion below). We did not receive any proceeds related to the Exchange.

Pursuant to the terms of the Indenture and First Supplemental Indenture, the 2017 Notes are convertible at an initial conversion rate of 10 shares of our common stock per \$1,000 principal amount of 2017 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.

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The 2017 Notes mature on December 15, 2017, unless earlier repurchased by us or converted. Prior to June 15, 2017, holders may convert their 2017 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 2017 Notes or (iii) specified corporate events. On or after June 15, 2017, until the close of business of the business day immediately preceding the date the 2017 Notes mature, holders may convert their 2017 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.

Based on the initial conversion rate of 10 shares of our common stock per \$1,000 principal amount of 2017 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 2017 Notes is 424,710. The value of these shares, based on the closing price of our common stock on March 31, 2016 of \$31.42 per share, was approximately \$13.3 million. The fair value of our 2017 Notes as presented in Note 4 was \$38.2 million at March 31, 2016.

*1.75% Convertible Senior Notes*

In May 2015, we issued \$84.2 million principal amount of 1.75% convertible senior notes due December 15, 2021 (the “2021 Notes”), unless earlier repurchased, redeemed or converted (the “2021 Notes”) pursuant to the terms of the Indenture and a second supplemental indenture (the “Second Supplemental Indenture”), which was filed with the SEC on May 19, 2015 as an exhibit to our Current Report on Form 8-K. Combined with the 2021 Notes issued in connection with the Exchange described above, the aggregate principal amount issued under the 2021 Notes was \$202.4 million. The Exchange resulted in the retirement of outstanding 2017 Notes with a carrying value of \$83.1 million, the write-off of unamortized debt issuance costs of \$1.0 million and settlement of \$10.7 million related to the conversion feature embedded in the 2017 Notes. The 2021 Notes offered in the Exchange had a fair value of \$88.0 million, which resulted in a loss on extinguishment of debt of \$16.6 million in the three months ended June 30, 2015.

The net proceeds from the issuance of the 2021 Notes amounted to \$75.5 million, net of deferred issuance costs paid as of September 30, 2015. In connection with the issuance of the 2021 Notes, we incurred costs of approximately \$5.2 million. The 2021 Notes are senior unsecured obligations of the Company and bear interest at a rate of 1.75% per annum, payable semi-annually in arrears on June 15 and December 15 of each year.

Pursuant to the terms of the Indenture and the Second Supplemental Indenture, the 2021 Notes are convertible at an initial conversion rate of 10 shares of our common stock per \$1,000 principal amount of 2021 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.

The 2021 Notes mature on December 15, 2021 unless earlier repurchased, redeemed or converted. Prior to the close of business on the business day immediately preceding June 15, 2021, holders may convert their 2021 Notes at their option only under the following circumstances: (i) sale price of our common stock, (ii) the trading price per \$1,000 principal amount of 2017 Notes or (iii) specified corporate events, or (iv) if we call the 2021 Notes for redemption, until the close of business on the business day immediately preceding the redemption date. On or after June 15, 2021 until the close of business on the scheduled trading day immediately preceding the maturity date, holders may convert their 2021 Notes at any time, regardless of whether any of the foregoing conditions has been met.

Based on the initial conversion rate of 10 shares of our common stock per \$1,000 principal amount of 2021 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 2021 Notes is 2,023,660. The value of these shares, based on the closing price of our common stock on March 31, 2016 of \$31.42 per share, was approximately \$63.6 million. The fair value of our 2021 Notes as presented in Note 4 was \$137.2 million at March 31, 2016.

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**(unaudited)**

*Accounting for Debt Transactions*

In accordance with accounting guidance for debt with conversion and other options, we separately account for the liability and equity components of the Convertible Notes by allocating the proceeds between the liability component and the embedded conversion option, or equity component, due to our ability to settle the Convertible Notes in cash, common stock or a combination of cash and common stock, at our option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the Convertible Notes and the fair value of the liability of the Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount, or debt discount, is amortized to interest expense using the effective interest method over the life of the Convertible Notes. The equity component is not remeasured as long as it continues to meet the conditions for equity classification. Additionally, we allocated the costs related to the 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 component and the equity component included in additional paid-in-capital. These deferred financing costs are being amortized to interest expense over the life of the Convertible Notes using the effective interest method.

**Note 8. Stockholders' Equity**

On January 30, 2014, we filed a shelf registration statement with the SEC on Form S-3. 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 will determine at the time of the offering any combination and amount of the securities described in the prospectus contained in the registration statement or in the prospectus supplement filed with respect to a particular offering. An aggregate of 530,816 shares of our common stock were registered for issuance pursuant to various prospectus filings on January 30, 2014 in connection with our acquisition of CircuLite. As of March 31, 2016, there remained 248,872 shares of our common stock reserved for potential issuance in connection with future contingent milestone payments under the terms of the merger agreement.

In the three months ended March 31, 2016, we issued 131,031 shares of our common stock upon the vesting of restricted stock units pursuant to stockholder approved equity plans. There were no options exercised during this period.

In the three months ended March 31, 2015, we issued an aggregate of 1,429 shares of our common stock upon the exercise of stock options and an aggregate of 88,184 shares of our common stock upon the vesting of restricted stock units.

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

**Note 9. Share-Based Compensation**

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 months ended March 31, 2016 and 2015, we recorded share-based compensation expense as follows:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Cost of revenue	\$ 495	\$ 438
Selling, general and administrative	2,653	3,449
Research and development	1,239	2,089
	<u>\$ 4,387</u>	<u>\$ 5,976</u>

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 for the excess of the fair market value of our shares of common stock over the exercise price of the stock options at the date of exercise. For restricted stock units, the amount of the tax deduction is generally for the fair market value of our shares of common stock at the vesting date. Excess tax benefits are not included in the accompanying condensed consolidated financial statements because we are in a net operating loss position and a full valuation allowance is maintained for all net deferred tax assets.

**Equity Plans**

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

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. At our 2015 Annual Meeting of Stockholders held on June 4, 2015, our stockholders approved an amendment to the 2012 Plan to increase the number of shares of our common stock available for issuance by 1.1 million shares. Under the terms of the 2012 Plan, as amended, the total number of shares of our common stock reserved for issuance under Awards is 2,475,000, provided that the total number of shares of our common stock that may be issued pursuant to "Full Value Awards" (Awards other than options, stock appreciation rights 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 2,375,000. As of March 31, 2016, 407,969 shares have been issued upon vesting of Awards issued under the 2012 Plan and Awards with respect to 911,349 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 three or 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. In the three months ended March 31, 2016 and 2015, we issued 149,940 and zero stock options, respectively.

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

Information related to options granted under all of our plans at March 31, 2016 and activity in the three 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, 2015	111	\$ 49.20		
Granted	150	33.49		
Exercised	—	—		
Forfeited	(10)	51.28		
Expired	—	—		
Outstanding at March 31, 2016	<u>251</u>	39.63	7.21	\$ 332
Exercisable at March 31, 2016	<u>92</u>	43.75	2.77	\$ 332

The aggregate intrinsic values at March 31, 2016 noted in the table above represent the number of in-the-money options outstanding or exercisable multiplied by the closing price of our common stock traded on NASDAQ less the weighted-average exercise price at period end.

The total intrinsic value of options exercised in the three months ended March 31, 2016 and 2015 was zero and approximately \$0.1 million, respectively. Cash received from options exercised in the three months ended March 31, 2016 and 2015 was zero and \$31,000, respectively.

At March 31, 2016, there was approximately \$2.1 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 1.8 years.

**Restricted Stock Units**

Each restricted stock unit (“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 predetermined 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 metrics. There is no consideration payable on the vesting 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 March 31, 2016 and activity in the three 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, 2015	623		
Granted	296		
Vested/Exercised	(131)		
Forfeited	(42)		
Expired	—		
Outstanding at March 31, 2016	<u>746</u>	1.93	\$ 23,426

The aggregate intrinsic value at March 31, 2016 noted in the table above represents the closing price of our common stock traded on NASDAQ multiplied by the number of RSUs outstanding.

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

At March 31, 2016, 112,522 of the RSUs outstanding were subject to performance-based vesting criteria as described above.

The total intrinsic value of RSUs vested in the three months ended March 31, 2016 and 2015 was approximately \$4.4 million and \$7.9 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 three months ended March 31, 2016 and 2015 was \$33.47 and \$89.53, respectively.

At March 31, 2016, 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 2.0 years.

**Note 10. Net Loss Per 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 for each respective period. Diluted net loss per common share adjusts basic net loss per common share for the dilutive effects of share-based awards as determined under the treasury stock method, our convertible senior notes as determined under the if-converted method, 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 Months Ended March 31,	
	2016	2015
	(in thousands)	
Conversion of convertible senior notes	2,448	1,438
Exercise or vesting of share-based awards	997	879

**Note 11. 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 distributed to customers located in the United States through our clinical trials and as commercial products, as commercial products to customers in Europe and other countries and under special access in certain 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 March 31,	
	2016	2015
	(in thousands)	
United States	\$33,348	\$42,189
Germany	10,673	12,741
International, excluding Germany	11,053	15,091
	\$55,074	\$70,021

As a significant portion of our revenue is generated outside of the United States, we are dependent on favorable economic and regulatory environments for our products in Europe and other countries outside of the United States. For the three months ended March 31, 2016 and 2015, no customer exceeded 10% of product sales individually.

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

**Note 12. Commitments and Contingencies**

We received a warning letter from the FDA, dated June 2, 2014, following an inspection of our Miami Lakes, Florida facility conducted in January 2014. The FDA letter cited four categories for us to address: (1) procedures for validating device design, including device labeling; (2) procedures for implementing corrective and preventive action (“CAPA”); (3) maintaining records related to investigations; and (4) validation of computer software used as part of production or quality systems. The warning letter did not require any action by physicians or patients and did not restrict use of our devices.

We sent the FDA our initial response to the warning letter within the required fifteen business days of receipt and committed to undertaking certain quality system improvements and providing the FDA with periodic updates. Since 2014 and continuing in 2016, we implemented systemic changes and organizational enhancements to address the four warning letter items and related quality systems. We have established teams to review and address the items cited by the FDA and have engaged external subject matter experts to assist in assessment and remediation efforts. As we continue to evaluate our quality systems, it is possible that we may need to take additional actions including the possibility of voluntary product recalls when necessary to ensure patient safety and effective performance of the HVAD System.

At March 31, 2016, we had purchase order commitments of approximately \$46.6 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, 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.

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.

***Contingent Consideration and Milestone Payments***

In December 2013, we acquired CircuLite using a combination of cash, stock and post-acquisition milestone and royalty payments. The post-acquisition payments are payable based upon the achievement of CircuLite related revenue and certain specified performance milestones over periods ranging from 8-10 years subsequent to the acquisition date. The maximum amount of the aggregate post-acquisition payments could be \$300 million. As of March 31, 2016, the fair value of the contingent consideration was estimated to be \$12.9 million (*see* Note 4).

***License and Development Agreements***

From time to time, we license rights to technology or intellectual property from third parties. These licenses may require us to make upfront payments as well as development or other payments upon successful completion of preclinical, clinical, regulatory or revenue milestones. In addition, these agreements may require us to pay royalties on sales of products arising from the licensed technology or intellectual property. Because the achievement of these milestones is not reasonably estimable, we have not recorded a liability in the accompanying consolidated financial statements for any of these contingencies.

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

***Litigation***

From time to time we may be involved in litigation or other contingencies arising in the ordinary course of business. Except as set forth below, 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 results of operations.

On January 22, 2016, the St. Paul Teachers' Retirement Fund Association filed a putative class action complaint (the "Complaint") in the United States District Court for the Southern District of New York on behalf of all persons and entities who purchased or otherwise acquired shares of the Company from June 10, 2014 through January 11, 2016 (the "Class Period"). The Complaint claims that the Company and two of our executives violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements about, among other things, the Company's response to the June 2014 FDA warning letter, the development of the MVAD System and the acquisition of Valtech. The Complaint claims that the disclosure of the purportedly false and misleading statements caused the price of the Company's stock to drop, and seeks to recover damages on behalf of all purchasers or acquirers of the Company's stock during the Class Period. The Company intends to vigorously defend itself against these claims. Because of the many questions of fact and law that may arise, the outcome of this legal proceeding is uncertain at this point. As a result we cannot reasonably estimate a range of loss for this action and accordingly have not accrued any liability associated with this action.

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.

**Note 13. Subsequent Events**

We have evaluated events and transactions that occurred subsequent to March 31, 2016 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 and manufactures miniaturized implantable heart pumps, or ventricular assist devices, to treat patients suffering from advanced heart failure. We have one operating segment, which designs, manufactures and markets our medical devices. We are headquartered in Framingham, Massachusetts and have facilities in Miami Lakes, Florida, Arden Hills, Minnesota and Hannover, Germany.

#### *About Heart Failure*

Heart failure is a chronic disease that results in the heart's pumping power being weaker than normal. In a healthy person, the left ventricle of the heart pumps oxygenated blood into the aorta and the blood is then circulated throughout the body until it returns through the venous system to the right side of the heart, which then pumps the blood into the lungs where it is re-oxygenated. If the left ventricle is not working properly, the oxygenated blood is not fully cleared from the lungs and the blood is not circulated effectively. If the muscle of the left ventricle is damaged or is not working efficiently, the ventricle will tend to compensate by working harder in an effort to supply adequate blood flow into the aorta. The increased effort generally results in dilation or enlargement of the ventricle, rather than increased blood flow. This dilation then makes it harder for the heart to contract effectively, which results in even lower blood flow and increased effort and further dilation of the ventricle. This progressive, degenerative process generally continues until the patient becomes debilitated and eventually dies from inadequate clearing of the lungs and inadequate flow of oxygenated blood throughout the body. The inadequate lung clearance or lung congestion is why the advanced stages of heart failure are called congestive heart failure, or CHF.

#### *The HeartWare Ventricular Assist System*

HeartWare currently manufactures and sells the HeartWare Ventricular Assist System (the "HVAD System"), which includes a ventricular assist device ("VAD") or blood pump, patient accessories and surgical tools, and is designed to provide circulatory support for patients in the advanced stage of heart failure. The core of the HVAD 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 HVAD System is designed to be implanted adjacent to the heart, avoiding abdominal surgery.

In November 2012, we received approval from the FDA for the HVAD System as a bridge-to-heart-transplantation in patients with end-stage heart failure. The HVAD 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 HVAD System in all patients at risk of death from refractory, end-stage heart failure. As of March 31, 2016, there have been over 10,000 implants of the HVAD System in patients at over 330 health care sites in 47 countries.

#### *Bridge-to-Transplant*

FDA approval for a bridge-to-transplant ("BTT") indication was based on the results of our pivotal ADVANCE clinical trial, an FDA-approved Investigational Device Exemption ("IDE") study designed to evaluate the HVAD System as a bridge-to-heart-transplantation for patients with end-stage heart failure, as well as a Continued Access Protocol ("CAP"). Under ADVANCE, 140 patients at 30 hospitals in the U.S. received the HeartWare investigational device between August 2008 and February 2010. The ADVANCE study achieved 94% survival at six months and successfully met its primary endpoint of establishing non-inferiority between the investigational device and comparator arm of the study, which was derived from contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support ("INTERMACS") ( $p < 0.0001$ ). Four supplemental allotments of patients were granted by the FDA under a CAP, encompassing more than 250 additional patients.

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To help assure the continued safety and effectiveness of an approved device, FDA requires a post-approval study (“PAS”) as a condition of approval to assess device performance in a real-world setting. HeartWare’s PAS is a two-year registry study consisting of 600 patients who received an HVAD post approval and an additional 600 control patients derived from a contemporaneous group of patients entered into the INTERMACS database, receiving a continuous flow, intracorporeal left VAD (“LVAD”). The data for both arms of the study will be entered into the INTERMACS registry by the implanting centers. Other post-approval commitments include the transfer of patients from the ADVANCE IDE study into a post-approval trial as well as an obligation to continue training sites in accordance with an approved training program.

### *Destination Therapy*

In May 2012, we completed enrollment in our clinical trial named “ENDURANCE” for a destination therapy indication for the HVAD System. Designed to enroll up to 450 patients at 50 U.S. hospitals, this non-inferiority study is a randomized, controlled, unblinded, multicenter clinical trial to evaluate the use of the HVAD 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 HVAD System or, as part of a control group, an alternative ventricular assist device approved by the FDA for destination therapy, in a 2:1 ratio. Each patient receiving the HVAD System or control VAD was followed to the primary endpoint at two years and will undergo subsequent follow-up for a five-year period post implant. In April 2015, we announced that ENDURANCE had achieved its primary endpoint.

In August 2015, we completed enrollment of ENDURANCE2, a supplemental trial to study the clinical benefits of close management of mean arterial pressure in HVAD patient. In ENDURANCE2, HeartWare enrolled 310 patients receiving the HVAD System, as well as 155 control patients using a 2:1 randomization consistent with the original ENDURANCE protocol. HeartWare intends to incorporate the data from both ENDURANCE and ENDURANCE2 into an anticipated Premarket Approval Supplement Application seeking approval of the HVAD System for a destination therapy indication.

### *Other Clinical Activities*

In the fourth quarter of 2013, HeartWare received approval from the Japanese Pharmaceuticals and Medical Devices Agency to commence a clinical study in Japan for market authorization for a BTT indication for the HVAD System. Enrollment was completed in August 2014 with six patients at five clinical sites. All patients reached the primary endpoint and we are currently preparing the submission for market authorization for a BTT indication in Japan.

In addition, in the fourth quarter of 2013, HeartWare received conditional approval from the FDA for a prospective, controlled, unblinded, multicenter clinical trial to evaluate the thoracotomy implant technique for the HVAD System. We began enrollment in this study in January 2015 and completed enrollment in April 2016.

### *MVAD System*

Beyond the HVAD System, we are developing our next-generation miniaturized device, known as the MVAD System. The MVAD System is based on the same technology platform as the HVAD 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 System is designed to allow for a variety of configurations and surgical placements with the goal of further reducing surgical invasiveness while producing superior clinical results.

In July 2015, we initiated a multicenter, prospective, non-randomized, single-arm CE Mark trial to evaluate the clinical safety and performance of the MVAD System for the treatment of advanced heart failure. In September 2015, we voluntarily paused the MVAD CE Mark clinical trial to address an MVAD controller manufacturing issue. Subsequent to that action, during the fourth quarter of 2015 and in consultation with study investigators, we began evaluating MVAD System performance and reported adverse events in certain clinical trial patients, including events that showed evidence of pump thrombus. We are currently evaluating various aspects of the MVAD System design to determine whether changes should be made. Should design changes be implemented, initiation of a new trial would likely be required. The timetable for updating affected regulatory filings and restarting clinical implants cannot be reliably projected at this time.

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### *CircuLite*

On December 1, 2013, we acquired CircuLite, Inc., the developer of the CircuLite Circulatory Support System, a partial-support system designed to treat less-sick, ambulatory, patients with chronic heart failure who are not yet inotrope-dependent. The CircuLite Surgical System is designed for long-term support and is intended to reduce the heart's workload while improving blood flow to vital organs. The CircuLite System experienced issues that arose after its commercial release and caused the loss of its CE marking in the European Union in March 2014. In January 2015, we discontinued development of the CircuLite micro pump and have focused our efforts on a version of our MVAD pump for our partial-assist program. Thus, delays to the development and regulatory approval of the MVAD System will affect the timing of the development and regulatory approval of the CircuLite System. The next-generation endovascular system, which is expected to be implanted collaboratively by cardiologists and surgeons in a hybrid catheterization ("cath") lab setting, offers an interventional approach to circulatory support. The CircuLite Circulatory Support System would offer less-invasive, and ultimately interventional, options to patients with earlier-stage heart failure.

### *FDA Warning Letter*

We received a warning letter from the FDA, dated June 2, 2014, following an inspection of our Miami Lakes, Florida facility conducted in January 2014. The FDA letter cited four categories for us to address: (1) procedures for validating device design, including device labeling; (2) procedures for implementing corrective and preventive action (CAPA); (3) maintaining records related to investigations; and (4) validation of computer software used as part of production or quality systems. The warning letter did not require any action by physicians or patients and did not restrict the use of our devices.

We sent the FDA our initial response to the warning letter within the required fifteen business days of receipt and committed to undertaking certain quality system improvements and providing the FDA with periodic updates. Since 2014 and continuing in 2016, we implemented systemic changes and organizational enhancements to address the four warning letter items and related quality systems. We have established teams to review and address the items cited by the FDA and have engaged external subject matter experts to assist in assessment and remediation efforts. As we continue to evaluate our quality systems, it is possible that we may need to take additional actions including the possibility of voluntary product recalls when necessary to ensure patient safety and effective performance of the HVAD System.

### *Termination of Valtech Business Combination Agreement*

On September 1, 2015, we entered into a Business Combination Agreement (the "BCA") by and among the Company, Valtech, HW Global, Inc. ("Holdco"), HW Merger Sub, Inc., Valor Merger Sub Ltd. and Valor Shareholder Representative, LLC, pursuant to which we and Valtech proposed to effect a strategic combination of our respective businesses under Holdco, subject to certain closing conditions. Effective January 28, 2016, we terminated the BCA pursuant to the terms of the BCA by delivering written notice to the other parties. After entering into the BCA and pursuant to the terms of the BCA, we loaned Valtech an aggregate principal amount of \$3 million in interim funding at an interest rate of 6% per annum in \$1 million increments in each of November 2015, December 2015 and January 2016. In connection with the termination provisions of the BCA, we loaned Valtech an additional \$30 million on February 1, 2016 also in the form of a convertible promissory note with an interest rate of 6% per annum. We have no current contractual obligations to further fund Valtech.

### *Summary of Recent Financial Performance*

Total revenue decreased 21% to \$55.1 million for the quarter ended March 31, 2016 compared to \$70.0 million during the first quarter of 2015. U.S. revenue decreased by 21% on unit sales decline of 23%, while international revenue decreased by 22% corresponding to a decrease in international unit sales of 15%. Comparative first quarter revenue was impacted by completion of enrollment in our ENDURANCE2 clinical trial in August 2015, increased competition from a competitor's launch of a new device and continuing enrollment of a competitor's U.S. IDE study for its new device. Currency changes negatively impacted total revenue by \$0.6 million, or approximately 1%, during the first quarter of 2016.

A total of 578 HVAD Systems were sold during the first quarter of 2016, compared to 720 units sold during the fourth quarter of 2015 and 713 units sold in the first quarter of 2015, reflecting the ongoing commercial launch of competitive products internationally and clinical trials in the U.S. Due to these activities we anticipate that our quarterly revenue and market share may be subject to greater volatility in the near-term. As of March 31, 2016, we had 134 customers in the United States and 196 customers internationally.

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We realized a decrease in gross margin percentage, to 58.2% in the first quarter of 2016 compared to 66.2% in the fourth quarter of 2015 and 68.5% in the first quarter of 2015. This decrease was primarily a result of lower sales volume and a \$2.3 million field action charge related to the anticipated replacement of certain controllers.

Combined selling, general, administrative, research and development expenses in the first quarter of 2016 decreased to \$46.7 million, compared to \$52.3 million in the fourth quarter of 2015 and \$53.2 million in the first quarter of 2015. This decrease was primarily due to \$2.6 million of restructuring charges associated with the closure of our facility in Aachen, Germany in first quarter of 2015, a reduction in expense of \$1.6 million in estimated change in fair value of contingent consideration related to our acquisition of CircuLite compared to first quarter of 2015, and reduced stock based compensation expense of \$1.6 million.

First quarter operating expenses included \$0.6 million of expense associated with a change in the estimated fair value of contingent consideration obligations related to our acquisition of CircuLite, and \$0.3 million of acquired intangible asset amortization compared to \$2.1 million and \$0.5 million, respectively in the first quarter of 2015.

These summary results are more fully described in *Results of Operations* below.

### **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, 2015 ("2015 Annual Report on Form 10-K") filed with the Securities and Exchange Commission on February 26, 2015. During the three months ended March 31, 2016, 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, valuation of tax assets and liabilities, reserves, long-lived assets, intangible assets and goodwill, and contingent consideration. 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 2015 Annual Report on Form 10-K.

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**Results of Operations**

**Three months ended March 31, 2016 and 2015**

***Revenue, net***

In the three months ended March 31, 2016 and 2015, we generated revenue through commercial sales and clinical trials.

	<b>Three Months Ended</b>		<b>Change</b>
	<b>March 31,</b>		
	<b>2016</b>	<b>2015</b>	
	<b>(in thousands)</b>		
Revenue, net	\$55,074	\$70,021	-21%

Total revenue was \$55.1 million for the quarter ended March 31, 2016, reflecting a 21% decrease in revenue in the United States due to completion of the Company's ENDURANCE2 clinical trial in third quarter of 2015 and increased competition from a competitor's clinical trial, as well as a 22% decrease in our international revenue due, in part, to increased competition from a competitor's launch of a new device. Currency changes negatively impacted total revenue growth by approximately \$0.6 million, or 1%, during the first quarter of 2016.

Our U.S. revenue was \$33.3 million for the quarter ended March 31, 2016 compared to \$42.2 million during the quarter ended March 31, 2015. A total of 295 pumps were sold in the U.S. during the first quarter of 2016 compared to 381 pumps sold in the same period of 2015. The U.S. revenue in the period ended March 31, 2015 included 48 HVAD Systems sold under the Company's ENDURANCE2 clinical trial.

Our international revenue was \$21.7 million for the quarter ended March 31, 2016 compared to \$27.8 million during the quarter ended March 31, 2015. A total of 283 pumps were sold internationally during the first quarter of 2016 compared to 332 pumps sold in the same period of 2015. The first quarter of 2016 was a particularly challenging quarter due to increased competition as international centers began reallocating a portion of their implant volumes to a new competitive device.

In the first quarter ended March 31, 2016, approximately 36% of our net revenue was denominated in foreign currencies including principally the Euro and British pound, which was unchanged compared to the same period in 2015. 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 hope to generate and grow commercial revenue from product sales as we further expand our sales and marketing efforts on a global basis. Future product sales are dependent on many factors, including perception of product performance, competition 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.

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**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 \$23.0 million and \$22.0 million in the three months ended March 31, 2016 and 2015, respectively.

Gross profit and gross margin percentage are as follows:

	Three Months Ended March 31,	
	2016	2015
	(in thousands)	
Gross profit	\$32,053	\$47,981
Gross margin %	58%	69%

The decrease in gross margin percentage was primarily a result of field action costs of \$3.5 million, or 6.3% and decreased sales volume.

**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.

	Three Months Ended March 31,		Change
	2016	2015	
	(in thousands)		
Selling, general and administrative expenses	\$21,474	\$21,929	-2%
% of operating expenses, excluding changes in fair value of contingent consideration	46%	41%	

The decrease of \$0.5 million for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 is primarily due to a \$0.9 million reduction in expenses associated with the suspension of the medical device excise tax, \$0.8 million reduction in stock-based compensation expense, \$0.4 million decrease in restructuring charges and all other expenses of \$0.8 million. These reductions were partially offset by increased professional fees of \$1.4 million and personnel related costs of \$1.0 million.

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**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. Research and development expenses also include most costs associated with our compliance with FDA regulations. Additional costs include travel, facilities and overhead allocations.

	Three Months Ended March 31,		Change
	2016	2015	
	(in thousands)		
Total research and development expenses	\$25,221	\$31,267	(19)%
% of operating expenses, excluding changes in fair value of contingent consideration	54%	59%	

The net decrease of \$6.0 million for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015 resulted from a decrease in overall research and development project expenses of \$2.8 million, restructuring charges of \$2.2 million related to closure of our facility in Aachen, Germany in Q1 2015, stock based compensation of \$0.8 million and other net expenses of 0.2 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 the Pal controller, the MVAD System, the CircuLite System and certain early research initiatives. We also expect to incur substantial costs for clinical trials for the HVAD System in new markets and expanded indications and for the MVAD System 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 and LATERAL clinical trials. We expect our warning letter-related expenses to begin to decrease in the second half of 2016 as we complete some of the resource-intensive activities for which we have contracted external consultants and advisors.

**Change in Fair Value of Contingent Consideration**

On December 1, 2013, we acquired CircuLite, Inc. using a combination of cash and stock. In addition to initial consideration paid at closing, the former CircuLite securityholders may be entitled to receive additional shares of HeartWare common stock (or cash, in certain cases, at our discretion) upon the achievement of certain specified performance milestones and royalty payments. We calculate the estimated fair value of the contingent consideration on a quarterly basis. In the three months ended March 31, 2016, we recorded a \$0.6 million charge for the increase in the estimated fair value of the contingent consideration from December 31, 2015 to March 31, 2016. The change in the fair value of the contingent consideration in the three months ended March 31, 2016 was due to the effect of the passage of time on the fair value measurement. In the three months ended March 31, 2015, we recorded a \$2.1 million charge for the increase in the estimated fair value of the contingent consideration from December 31, 2014 to March 31, 2015. The change in the fair value of the contingent consideration in the three months ended March 31, 2015 was due to the effect of the passage of time on the fair value measurement.

Determining the estimated fair value of the contingent consideration requires significant management judgment or estimation. The estimated fair value is calculated using the income approach, with significant inputs that include various revenue assumptions, discount rates and applying a probability to each outcome. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement. Potential valuation adjustments will be made in future accounting periods as additional information becomes available, including, among other items, progress toward developing the CircuLite System, as well as revenue and milestone targets as compared to our current projections. Adjustments associated with changes in the estimated fair value of the contingent consideration are presented on a separate line item on our consolidated statements of operations.

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***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 months ended March 31, 2016, our net foreign exchange gain totaled approximately \$0.9 million, compared to a net loss of approximately \$3.7 million in the same period of 2015. In 2016 and 2015, the majority of our realized and unrealized foreign exchange gains and losses resulted from the settlement of certain balance sheet accounts, primarily accounts receivable that were denominated in foreign currencies, and the remeasurement 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 primarily consists of interest incurred on the principal amount of our convertible senior notes issued in December 2010 and May 2015, amortization of the related discount and amortization of the portion of the deferred financing costs allocated to the debt component. The discount on the convertible senior notes and the deferred financing costs are being amortized to interest expense through the maturity dates of the convertible senior notes using the effective interest method.

In the three months ended March 31, 2016, interest expense was approximately \$3.7 million, which included \$1.2 million of interest incurred on the principal amount of the convertible notes and \$2.5 million of non-cash amortization of the discount and deferred financing costs. In the three months ended March 31, 2015, interest expense was approximately \$3.4 million, which included \$1.3 million of interest incurred on the principal amount of the convertible notes and \$2.1 million of non-cash amortization of the discount and deferred financing costs.

***Investment Income, net***

Investment income is primarily derived from the outstanding Valtech Convertible Notes, financial investments and cash and short-term deposit accounts held in the U.S. The amortization of premium on our financial investments is also included in investment income, net. Investment income, net was approximately \$0.7 million in the three months ended March 31, 2016, compared to \$0.1 million in the same period in the prior year, the increase of which is primarily due to net interest related to the outstanding Valtech Convertible Notes. We continue to experience low interest rates on our deposits and available-for-sale investments.

***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 are not subject to U.S. income taxes until repatriated. As of December 31, 2015, we had no 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 in the United States and Australia. For the three months ended March 31, 2016, our tax provision includes estimated foreign taxes in jurisdictions where wholly owned subsidiaries may be subject to current taxes.

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**Liquidity and Capital Resources**

As of March 31, 2016, our cash and cash equivalents combined with short-term available-for-sale investments were approximately \$189.2 million as compared to \$243.6 million at December 31, 2015.

Following is a summary of our cash flow activities for the three months ended March 31, 2016 and 2015:

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
	<b>(in thousands)</b>	
Net cash used in operating activities	\$ (22,188)	\$ (7,789)
Net cash provided by (used in) investing activities	(38,664)	4,088
Net cash provided by financing activities	0	31
Effect of exchange rate changes on cash and cash equivalents	(939)	3,249
Net decrease in cash and cash equivalents	<u>\$ (61,791)</u>	<u>\$ (421)</u>

***Cash Used in Operating Activities***

For the three months ended March 31, 2016, cash used in operating activities included a net loss of approximately \$17.5 million, adjustments for non-cash items totaling \$9.6 million and cash used in working capital of \$14.3 million. The net loss was driven by normal operating activities including the sale of the HVAD System in the United States and abroad, a charge for the increase in the fair value of contingent consideration and interest expense which were partially offset by foreign exchange gains. Adjustments for non-cash items primarily consisted of \$4.4 million of share-based compensation, \$2.1 million of depreciation and amortization on long-lived assets, \$2.3 million of amortization of the discount on our convertible notes and \$0.6 million for the increase in the fair value of contingent consideration related to the CircuLite acquisition. The decrease in cash from changes in working capital primarily included \$12.1 million for the decrease in accrued liabilities, an increase in inventories of \$3.2 million, \$1.6 million for the payment of trade accounts payable, and an increase in prepaid expenses and other assets of \$4.0 million. These amounts were partially offset by a decrease in accounts receivable of \$6.7 million and an increase in accrued interest on our convertible senior notes of \$1.3 million.

For the three months ended March 31, 2015, cash used in operating activities included a net loss of approximately \$14.5 million, adjustments for non-cash items totaling \$13.9 million and cash used in working capital of \$7.1 million. The net loss was driven by normal operating activities including the sale of the HVAD System in the United States and abroad, a charge for the increase in the fair value of contingent consideration, interest expense and foreign exchanges losses. Adjustments for non-cash items primarily consisted of \$6.0 million of share-based compensation, \$2.2 million of depreciation and amortization on long-lived assets, \$2.1 million of amortization of the discount on our convertible notes, \$2.1 million for the increase in the fair value of contingent consideration related to the CircuLite acquisition and \$1.1 million for the impairment of fixed assets. The decrease in cash from changes in working capital included \$3.7 million for the decrease in accrued liabilities, \$2.6 million for the payment of trade accounts payable, and an increase in prepaid expenses and other assets of \$1.4 million. These amounts were partially offset by an increase in accrued interest on our convertible senior notes of \$1.3 million.

***Cash Used in Investing Activities***

In the three months ended March 31, 2016, net cash used in investing activities included loans to Valtech aggregating \$31.0 million, net purchases of available-for-sale securities aggregating \$6.5 million, \$0.9 million to acquire property, plant and equipment and \$0.4 million for intellectual property.

In the three months ended March 31, 2015, net cash provided by investing activities included maturities of available-for-sale securities aggregating \$5.0 million. This amount was partially offset by cash usage of \$0.7 million to acquire property, plant and equipment and \$0.5 million for intellectual property.

***Cash Provided by Financing Activities***

The exercise of stock options in the three months ended March 31, 2016 and 2015 resulted in cash proceeds of approximately \$0 and \$31,000, respectively.

### ***Operating Capital and Capital Expenditure Requirements***

We have incurred operating losses to date and anticipate that we will continue to consume cash and incur substantial net losses as we expand our sales and marketing capabilities, develop new products and seek regulatory approvals for expanded indications of the HVAD System in the United States. For the remainder of 2016, cash on hand is expected to be used primarily to fund our ongoing operations, including:

- expanding our sales and marketing capabilities on a global basis;
- growing market penetration, particularly in the U.S.;
- continued product development, including development of the MVAD pump and Pal controller;
- preclinical and clinical costs relating to the MVAD pump, and clinical trials related to expanded indications of the HVAD System;
- post-approval monitoring related to the HVAD System;
- regulatory and other compliance functions, including activities to enhance our quality systems in response to the warning letter we received from the FDA in June 2014;
- replacement of product in the field as a result of ongoing and potential future field actions;
- responding to litigation claims;
- expand work-in-process and finished goods inventory to support ongoing operations;
- strategic activities intended to expand our access to new technologies;
- planned investments in infrastructure to support our growth; and
- general working capital.

Our convertible notes bear interest at a rate of 1.75% or 3.5% per annum, payable semi-annually in arrears on June 15 and December 15 of each year. To date, all interest payments have been paid on a timely basis. Based on the outstanding principal amount of our convertible senior notes at December 31, 2015, the semi-annual interest payments due on June 15 and December 15, 2016 will be approximately \$2.5 million each. These amounts are expected to be paid from cash on hand.

We believe cash on hand and investment balances as of March 31, 2016 are sufficient to support our planned operations for at least the next twelve months. At March 31, 2016, approximately \$2.0 million of our cash on hand was held in foreign 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. Any repatriation of those earnings to the United States would likely result in us incurring federal and state income taxes. We currently plan to permanently reinvest any earnings of our foreign subsidiaries.

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:

- implementation of systemic improvements necessary to satisfactorily address the observations cited in the June 2, 2014 warning letter we received from the FDA;
- commercial acceptance of our products and our response to competitive pressures;
- reimbursement of our products by governmental agencies and third-party payers;
- costs to manufacture and ensure regulatory compliance of our products;
- expenses required to operate multiple clinical trials;
- further product research and development for next-generation products 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, including regulatory compliance;
- replacement of product in the field as a result of ongoing and potential future field actions;
- expenses related to funding and integrating strategic investments, acquisitions and collaborative arrangements;
- payment, if the moratorium is lifted, of the 2.3% excise tax on gross revenue from the sale of our medical devices in the United States imposed by the Patient Protection and Affordable Care Act;
- payment of our convertible notes upon maturity, if not converted or refinanced; and
- complying with the requirements related to being a public company in the U.S.

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**Contractual Obligations**

During the three months ended March 31, 2016, there were no material changes outside the ordinary course of business to material contractual obligations provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, and included in our 2015 Annual Report on Form 10-K filed with the SEC on February 26, 2016.

### **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% and 1.75% 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 March 31, 2016. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2016, 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 March 31, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Inherent Limitations on Controls and Procedures**

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

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

Except for the matter discussed below, the Company is not a party to any material pending legal proceedings at the date of filing of this Quarterly Report on Form 10-Q.

On January 22, 2016, the St. Paul Teachers' Retirement Fund Association filed a putative class action complaint (the "Complaint") in the United States District Court for the Southern District of New York on behalf of all persons and entities who purchased or otherwise acquired shares of the Company from June 10, 2014 through January 11, 2016 (the "Class Period"). The Complaint claims that the Company and two of our executives violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by making false and misleading statements about, among other things, the Company's response to the June 2014 FDA warning letter, the development of the MVAD System and the acquisition of Valtech. The Complaint claims that the disclosure of the purportedly false and misleading statements caused the price of the company's stock to drop, and seeks to recover damages on behalf of all purchasers or acquirers of the Company's stock during the Class Period. The Company intends to vigorously defend itself against these claims. Because of the many questions of fact and law that may arise, the outcome of this legal proceeding is uncertain at this point.

On January 28, 2016, we entered into a Cooperation Agreement with Engaged Capital, LLC and certain affiliates (collectively, "Engaged Capital") pursuant to which, subject to the terms of the Cooperation Agreement, we agreed, among other things, to jointly select an additional independent director to be appointed to the Company's board of directors and form a business strategy committee of the company's board of directors. In addition, Engaged Capital agreed to withdraw its previously nominated slate of directors for election at the company's 2016 annual meeting of stockholders and to certain customary standstill provisions. A copy of the Cooperation Agreement is attached as [Exhibit 10.1](#) to the company's Current Report on Form 8-K filed with the SEC on January 28, 2016. In February 2016, our board of directors formally established a business strategy committee. In addition, on March 14, 2016 we announced the appointment of Chadwick M. Cornell to Company's board of directors as an independent director jointly selected with Engaged Capital in satisfaction of our obligation under the Cooperation Agreement.

### **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, 2015 filed with the SEC on February 26, 2016.

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

There were no unregistered sales of our equity securities during the three months ended March 31, 2016.

### **ITEM 6. EXHIBITS**

- 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 March 31, 2016, formatted in eXtensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015, (ii) Unaudited Condensed Consolidated Statements of Operations for the three months ended March 31, 2016 and 2015, (iii) Unaudited Condensed Consolidated Statements of Comprehensive Loss for the three months ended March 31, 2016 and 2015, (iv) Unaudited

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Condensed Consolidated Statement of Stockholders' Equity for the three months ended March 31, 2016, (v) Unaudited Condensed Consolidated Statements of Cash Flows for the three months ended March 31, 2016 and 2015, and (vi) Notes to Unaudited Condensed Consolidated Financial Statements.

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- \* Filed herewith
  - \*\* Furnished herewith
  - + Management contract or compensatory plan or arrangement

**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: May 5, 2016

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

Date: May 5, 2016

/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: May 5, 2016

/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: May 5, 2016

/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 March 31, 2016 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: May 5, 2016

/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 March 31, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned Senior 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: May 5, 2016

/s/ Peter F. McAree

Peter F. McAree

Senior Vice President and Chief Financial Officer

(Principal Financial Officer)