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

FORM 10-Q

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

For the quarterly period ended September 30, 2015

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 001-34256

HEARTWARE INTERNATIONAL, INC.
(Exact name of registrant as specified in its charter)

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

500 Old Connecticut Path
Framingham, Massachusetts 01701
(508) 739-0950
(Address of principal executive offices)
(Registrant's telephone number, including area code)

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

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

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

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

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

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

Class	Shares Outstanding as of October 30, 2015
Common Stock, $0.001 Par Value Per Share	17,315,187

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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.

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 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 entities, planned acquisitions 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 described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed with the SEC on March 2, 2015, 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.

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	September 30, 2015 (unaudited)	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	$ 184,882	$ 102,946
Short-term investments	63,391	75,535
Accounts receivable, net	34,968	38,041
Inventories	47,245	54,046
Prepaid expenses and other current assets	6,744	5,975
Total current assets	337,230	276,543
Property, plant and equipment, net	15,711	19,036
Goodwill	61,273	61,390
In-process research and development	32,850	32,850
Other intangible assets, net	17,935	17,807
Deferred financing costs, net	4,160	1,552
Long-term investments and other assets	19,307	14,635
Total assets	$ 488,466	$ 423,813
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,731	$ 13,322
Other accrued liabilities	47,463	36,589
Total current liabilities	60,194	49,911
Convertible senior notes, net	188,790	114,803
Contingent liabilities – *See* Note 4	50,440	43,740
Other long-term liabilities	4,680	6,825
Commitments and contingencies – *See* Note 12		
Stockholders' equity:		
Preferred stock – $.001 par value; 5,000 shares authorized; no shares issued and outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock – $.001 par value; 50,000 and 25,000 shares authorized at September 30, 2015 and December 31, 2014, respectively; 17,315 and 17,156 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	17	17
Additional paid-in capital	613,204	565,609
Accumulated deficit	(420,574)	(348,719)
Accumulated other comprehensive loss:		
Cumulative translation adjustments	(8,199)	(8,112)
Unrealized loss on investments	(86)	(261)
Total accumulated other comprehensive loss	(8,285)	(8,373)
Total stockholders' equity	184,362	208,534
Total liabilities and stockholders' equity	$ 488,466	$ 423,813

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Revenue, net	$ 65,166	$68,608	$208,756	$205,211
Cost of revenue	32,990	22,977	80,258	68,846
Gross profit	32,176	45,631	128,498	136,365
Operating expenses:				
Selling, general and administrative	25,171	20,584	69,347	65,765
Research and development	30,386	29,477	93,355	88,981
Change in fair value of contingent consideration	2,360	(3,620)	6,700	(14,180)
Total operating expenses	57,917	46,441	169,402	140,566
Loss from operations	(25,741)	(810)	(40,904)	(4,201)
Other income (expense):				
Foreign exchange gain (loss)	(426)	(3,298)	(3,367)	(3,109)
Interest expense	(3,638)	(3,312)	(10,618)	(9,759)
Investment income, net	150	138	431	543
Loss on extinguishment of long-term debt	—	—	(16,588)	—
Other, net	—	—	—	(1,261)
Loss before income taxes	(29,655)	(7,282)	(71,046)	(17,787)
Provision for income taxes	272	88	809	663
Net loss	$(29,927)	$ (7,370)	$ (71,855)	$ (18,450)
Net loss per common share – basic and diluted	$ (1.73)	$ (0.43)	$ (4.16)	$ (1.09)
Weighted average shares outstanding – basic and diluted	17,303	17,007	17,256	16,977

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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net loss	$(29,927)	$(7,370)	$(71,855)	$(18,450)
Other comprehensive income (loss)				
Foreign currency translation adjustments	320	250	(87)	(318)
Unrealized (loss) gain on investments	67	(101)	175	(127)
Comprehensive loss	$(29,540)	$(7,221)	$(71,767)	$(18,895)

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, 2014	17,156	$ 17	$565,609	$ (348,719)	$ (8,373)	$208,534
Issuance of common stock in connection with an intellectual property agreement	26	—	2,000	—	—	2,000
Issuance of common stock pursuant to share-based awards	133	—	81	—	—	81
Settlement of conversion feature on convertible debt exchanged	—	—	(19,467)	—	—	(19,467)
Allocation of fair value of equity component of convertible debt	—	—	47,400	—	—	47,400
Allocation of pro-rata portion of convertible debt issuance costs to the equity component of convertible debt	—	—	(1,218)	—	—	(1,218)
Share-based compensation	—	—	18,799	—	—	18,799
Net loss	—	—	—	(71,855)	—	(71,855)
Other comprehensive loss	—	—	—	—	88	88
Balance, September 30, 2015	17,315	$ 17	$613,204	$ (420,574)	$ (8,285)	$184,362

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)

	Nine Months Ended September 30,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (71,855)	$ (18,450)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation of property, plant and equipment	5,034	4,929
Amortization of intangible assets	1,545	1,222
Impairment of fixed assets	1,118	607
Share-based compensation expense	18,799	17,291
Amortization of premium on investments	834	516
Amortization of discount on convertible senior notes	6,418	5,671
Amortization of deferred financing costs	399	304
Change in fair value of contingent consideration	6,700	(14,180)
Loss on extinguishment of long-term debt	16,588	—
Other	(10)	1,321
Change in operating assets and liabilities:		
Accounts receivable	1,912	(10,426)
Inventories	4,545	(13,083)
Prepaid expenses and other current assets	(887)	2,416
Accounts payable	(575)	(2,262)
Accrued interest on convertible senior notes	1,581	1,262
Other accrued liabilities	8,884	7,106
Other long-term liabilities	(143)	710
Net cash provided by (used in) operating activities	887	(15,046)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of investments	(17,695)	(44,290)
Maturities of investments	29,215	14,625
Additions to property, plant and equipment, net	(2,094)	(5,990)
Additions to patents	(1,673)	(1,205)
Investment in unconsolidated affiliate	(5,000)	—
Cash received from security deposits	294	—
Net cash provided by (used in) investing activities	3,047	(36,860)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of convertible debt	79,901	—
Payment of convertible debt issuance costs	(4,429)	—
Repayment of convertible debt	(12)	—
Proceeds from exercise of stock options	80	837
Net cash provided by financing activities	75,540	837
Effect of exchange rate changes on cash and cash equivalents	2,462	1,837
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	81,936	(49,232)
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD	102,946	162,880
CASH AND CASH EQUIVALENTS — END OF PERIOD	$ 184,882	$ 113,648

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

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, 2014. The accompanying condensed consolidated balance sheet as of December 31, 2014 has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2015 and cash flows for the nine months ended September 30, 2015 are not necessarily indicative of the results to be expected for any future period or for the year ending December 31, 2015.

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

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.

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 adoption of ASU No. 2015-02 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*. 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. ASU 2015-03 will be effective for us in periods beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. ASU 2015-03 should be applied on a retrospective basis,

wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. The adoption of ASU No. 2015-03 will result in the reclassification of debt issuance costs currently classified in long-term assets to be offset against the carrying value of our convertible notes. Based on the amount of debt issuance costs included in long-term assets as of September 30, 2015, the adoption of ASU 2015-03 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

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 September 30, 2015, we had approximately $249.5 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 September 30, 2015. At September 30, 2015, we had an accumulated deficit of approximately $420.6 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. At September 30, 2015, one customer had an accounts receivable balance that represented approximately 15% of total accounts receivable. At December 31, 2014, no customer had an accounts receivable balance greater than 10% of total accounts receivable.

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

The following table summarizes the change in our allowance for doubtful accounts for the nine months ended September 30, 2015 and 2014:

	2015	2014
	(in thousands)	
Beginning balance	$671	$495
Reversal of expense	(53)	—
Charge-offs	—	—
Ending balance	$618	$495

As of and for the three months ended September 30, 2015, we recorded customer sales allowances totaling $66,000. At December 31, 2014, we did not maintain a sales allowance.

Inventories

Components of inventories are as follows:

	September 30, 2015	December 31, 2014
	(in thousands)	
Raw material	$ 23,983	$ 28,688
Work-in-process	9,020	10,240
Finished goods	14,242	15,118
	$ 47,245	$ 54,046

Finished goods inventories includes inventory held on consignment at customer sites of approximately $6.3 million at September 30, 2015 and $5.8 million at December 31, 2014.

Property, Plant and Equipment, Net

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

	Estimated Useful Lives	September 30, 2015	December 31, 2014
		(in thousands)	
Machinery and equipment	1.5 to 7 years	$ 21,976	$ 21,279
Leasehold improvements	3 to 10 years	8,938	9,070
Office equipment, furniture and fixtures	5 to 7 years	2,104	2,206
Purchased software	1 to 7 years	6,674	6,474
		39,692	39,029
Less: accumulated depreciation		(23,981)	(19,993)
		$ 15,711	$ 19,036

In the first quarter of 2015, we ceased activities at our facility in Aachen, Germany. We recorded an impairment charge of $1.1 million related to leasehold improvements and equipment at the facility upon their discontinued use. This amount is included in research and development expenses in our condensed consolidated statements of operations.

In the first quarter of 2014, we ceased activities at our facility in Teaneck, New Jersey. We recorded an impairment charge of $0.6 million related to office equipment and software at the facility upon their discontinued use. This amount is included in selling, general and administrative expenses in our condensed consolidated statements of operations.

Long-Term Investment

In October 2013, we invested $10 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 in the form of a convertible promissory note with an interest rate of 6% per annum (the "2013 Note"). On October 7, 2014 (the maturity date), the note together with accrued interest was converted pursuant to its terms into shares of its Valtech's preferred stock which represented approximately 3.1% of its total equity ownership.

In July 2015, we invested an additional $5 million in Valtech in the form of a convertible promissory note (the "2015 Note"). Principal and interest at a rate equal to 6% per annum is due and payable at maturity. Maturity occurs at the earlier of two years or the occurrence of certain events defined in the 2015 Note, including an event of default or a change in control. Principal and interest on the 2015 Note are repayable, at the option of the issuer, in cash or shares of the most recently issued series of preferred stock or a comparable newly issued series of preferred stock.

On September 1, 2015 we entered into a Business Combination Agreement ("BCA") with Valtech, pursuant to which HeartWare and Valtech will both become subsidiaries of a new holding company, HW Global, Inc, ("Holdco"). HeartWare stockholders would receive one share of Holdco common stock for each share of HeartWare common stock and Valtech shareholders would receive Holdco common stock as follows:

- 5.2 million shares upon closing;

- 700,000 shares upon achievement of certain clinical milestones;
- Warrants to purchase 850,000 shares which are exercisable upon attainment of $75 million of net sales (trailing 12 months) of Valtech products; and
- An earn-out payment of $375 million (payable in cash or stock at the discretion of Holdco), upon attainment of $450 million of net sales (trailing 12 months) of Valtech products.

The respective boards of HeartWare and Valtech have approved the agreement. Completion of the transaction is subject to customary closing conditions, including approval of HeartWare and Valtech stockholders and regulatory approvals. The closing of the transaction is expected in late 2015 or early 2016. In the event the BCA is terminated in accordance with the termination provisions of the BCA, HeartWare would be obligated to make a loan to Valtech in a principal amount equal to $30 million pursuant to a convertible promissory note.

The preceding description of the business combination agreement is not intended to be complete and is subject to the full text of the business combination agreement and related agreements, which are incorporated herein by reference to Exhibits 2.1 and 99.1 through 99.6 of our Form 8-K filed with the Securities and Exchange Commission on September 1, 2015.

The Valtech investment is carried at cost and is included in long-term investments and other assets on our condensed consolidated balance sheets. The carrying value of this investment was $15.5 million and $10.5 million at September 30, 2015 and December 31, 2014, respectively.

Other Accrued Liabilities

Other accrued liabilities consist of the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Accrued payroll and other employee costs	$ 11,439	$ 13,404
Accrued warranty and recall costs	14,783	6,573
Accrued material purchases	3,428	4,284
Accrued research and development costs	3,725	2,663
Other accrued expenses	14,088	9,665
	$ 47,463	$ 36,589

Accrued payroll and other employee costs

Accrued payroll and other employee costs included estimated year-end employee bonuses of approximately $5.7 million and $7.9 million at September 30, 2015 and December 31, 2014, respectively.

Accrued Warranty

Certain patient accessories sold with the HVAD System are covered by a limited warranty ranging from one to two years. Estimated contractual warranty obligations are recorded as an expense when the related revenue is recognized and are included in cost of revenue in 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 nine months ended September 30, 2015 and 2014:

	2015	2014
	(in thousands)	
Beginning balance	$ 4,685	$ 2,498
Accrual for warranty expense	3,267	3,097
Warranty costs incurred during the period	(2,053)	(1,474)
Ending balance	$ 5,899	$ 4,121

The accrual for warranty expense in the nine months ended September 30, 2014 reflected an anticipated increase in battery returns as a result of a field safety corrective action in April 2014, following an observed increase in complaints related to earlier-than-expected battery depletion and routine battery handling. The Company provided information to assist patients and clinicians to monitor battery performance, recognize abnormal behaviors and reinforce proper power management of the HVAD System.

Accrued Product Recall Costs

The costs to repair or replace products associated with product recalls and voluntary service campaigns are recorded when they are determined to be probable and reasonably estimable as a cost of revenue. The following table summarizes the change in product recall liability for the nine months ended September 30, 2015 and 2014:

	2015	2014
	(in thousands)	
Beginning balance	$ 1,888	$ —
Accrual for recall costs	8,895	3,609
Recall costs incurred during the period	(1,899)	(1,012)
Ending balance	$ 8,884	$ 2,597

During the three months ended June 30, 2014, we established a $3.0 million reserve in connection with our voluntary recall of certain older batteries. Subsequently, through March 31, 2015 we increased our recall estimates by approximately $0.7 million based upon our exchange experience. The recall was implemented to mitigate the potential risks associated with premature battery depletion following our April 2014 field action, which provided information to assist patients and clinicians with monitoring battery performance, recognizing abnormal behaviors and reinforcing proper power management of the HVAD System. During the three months ended September 30, 2015 we established a reserve of $8.2 million related to our ongoing Warning Letter remediation efforts and quality system enhancements. These corrective actions include the planned replacement of certain older batteries to further mitigate residual battery reliability concerns.

In December 2014, we established a $1.3 million reserve in connection with our voluntary recall of certain older controllers which did not incorporate later design changes implemented to mitigate susceptibility to electrostatic discharge. We increased the total estimated cost of the field action by approximately $0.4 million during the three months ended March 31, 2015 based upon our exchange experience. We anticipate completing this recall by the end of 2015. The reserve for this recall was $0.4 million as of September 30, 2015.

During the three months ended September 30, 2015, we established a $0.3 million reserve in connection with our voluntary field safety corrective action of certain older AC Adapters. The recall was also part of our ongoing Warning Letter remediation efforts and quality system enhancements and was implemented to mitigate potential risks for AC Adapters designed for use outside the United States which have a higher risk of failing in case of a power surge compared to other HeartWare AC Adapters. This field action will provide clinicians instructions on how to identify and replace the affected AC Adapters.

Accrued Restructuring Costs

The following table summarizes changes in our accrued restructuring costs for the nine months ended September 30, 2015:

	Facility Leases	Severance and Related	Contract Termination	Total
		(in thousands)		
Beginning balance	$ 1,266	$ —	$ —	$ 1,266
Restructuring charges	139	598	340	1,077
Payments	(689)	(598)	(340)	(1,627)
Adjustments to estimated obligations	403	—	—	403
Change in fair value	33	—	—	33
Ending balance	$ 1,152	$ —	$ —	$ 1,152

The restructuring obligations reflected above resulted from the following actions:

Facility Closures

In the first quarter of 2015, we ceased activities at our facility in Aachen, Germany, which was subject to an operating lease that runs through October 2017. In connection with this action, we recorded a $0.1 million charge equal to the lease termination payment that was negotiated with the landlord. This amount is included in research and development expenses in our condensed consolidated statements of operations.

In the first quarter of 2014, we ceased the use of CircuLite's former headquarters in Teaneck, New Jersey, which is subject to an operating lease that runs through the end of 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. In the first quarter of 2015, this liability was increased by $0.5 million as a result of a change in our estimated sublease start date (*see* Note 4). These amounts are included in selling, general and administrative expenses in our condensed consolidated statements of operations.

In the first quarter of 2014, we also relocated our corporate headquarters and ceased activities at our former headquarters in Framingham, Massachusetts. In connection with this action, we recorded a $0.5 million liability equal to the aggregate of the remaining payments on the lease for our former headquarters as of the cease-use date. This amount is included in selling, general and administrative expenses in our condensed consolidated statements of operations.

Severance Agreements

In the first quarter of 2015, we incurred severance costs aggregating $0.6 million in connection with our decision to cease activities at our facility in Aachen, Germany. This amount is included in research and development expenses in our condensed consolidated statements of operations.

In the first quarter of 2014, we incurred various costs related to the integration of CircuLite's operations, including severance costs aggregating $0.6 million. We recorded $0.4 million in research and development expenses and the remaining $0.2 million in selling, general and administrative expenses in our condensed consolidated statements of operations.

Contract Termination

As a result of our decision to cease activities at our facility in Aachen, Germany, we terminated supply agreements with vendors for the purchase of supplies. In connection with the termination of these supply agreements, we recorded a charge of $0.3 million in the first quarter of 2015, which is included in research and development expenses in our condensed consolidated statements of operations.

As a result of design modifications to the SYNERGY System and our decision to move manufacturing of the SYNERGY System to our Miami Lakes facility, we terminated a supply agreement with a SYNERGY components supplier in Germany. As a result of this termination, we recorded a charge of $0.7 million in the first quarter of 2014, which is included in research and development expenses in our consolidated statements of operations.

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 nine months ended September 30, 2015 or 2014.

The carrying amounts reported on our condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, accounts payable and other accrued liabilities approximate their fair value based on the short-term maturity of these instruments. Investments are considered available-for-sale as of September 30, 2015 and December 31, 2014 and are carried at fair value.

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)		
As of September 30, 2015					
Assets					
Short-term investments	$ 63,391	$ 63,391	$ —	$ 63,391	$ —
Long-term investments	1,225	1,225	—	1,225	—
Liabilities					
3.5% convertible notes	35,808 (1)	46,081	—	46,081	—
1.75% convertible notes	152,981 (1)	179,853	—	179,853	—
Contingent consideration	50,440	50,440	—	—	50,440
Royalties	896	896	—	—	896
Lease exit costs	1,152	1,152	—	—	1,152

	Carrying Value	Fair Value	Fair Value Measurements at the Reporting Date Using		
			Level 1	Level 2	Level 3
			(in thousands)		
As of December 31, 2014					
Assets					
Short-term investments	$ 75,535	$ 75,535	$ —	$ 75,535	$ —
Long-term investments	1,225	1,225	—	1,225	—
Liabilities					
3.5% convertible notes	114,803 (1)	153,978	—	153,978	—
Contingent consideration	43,740	43,740	—	—	43,740
Royalties	962	962	—	—	962
Lease exit costs	1,207	1,207	—	—	1,207

(1) The carrying amount of our convertible notes is net of unamortized discount. *See* Note 7 (Debt) for more information.

Our Level 2 financial assets and liabilities include available-for-sale investments and our convertible notes. The fair value of our available-for-sale investments and our convertible notes was determined using quoted prices (including trade data) for the instruments in markets that are not active. The fair value of our convertible 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 development timelines, 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.
- **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 September 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 will be 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 nine months ended September 30, 2015:

	Contingent Consideration (in thousands)
Beginning balance	$ 43,740
Payments	—
Change in fair value	6,700
Ending balance	$ 50,440

The change in the fair value of the contingent consideration in the nine months ended September 30, 2015 was due to 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 in 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 SYNERGY 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. During the fourth quarter of 2015 we will evaluate internal timelines and development plans for the SYNERGY System. Our evaluation will take into consideration, among other things, progress with respect to underlying MVAD pump technology and resources dedicated to SYNERGY System development. This evaluation may have an impact on overall development timelines and/or cash flows of the SYNERGY System, the effect of which may result in an adjustment to estimated fair value.

The following table summarizes the change in fair value, as determined by Level 3 inputs, of the royalties for the nine months ended September 30, 2015:

	Royalties (in thousands)
Beginning balance	$ 962
Payments	(110)
Change in fair value	44
Ending balance	$ 896

The expense associated with the change in fair value of the royalty payment obligations is included in research and development expenses in 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 nine months ended September 30, 2015:

	Lease Exit Costs (in thousands)
Beginning balance	$ 1,207
Adjustments	431
Payments	(519)
Change in fair value	33
Ending balance	$ 1,152

The expense associated with changes in the fair value of the lease exit costs is included in selling, general and administrative expenses in our consolidated statements of operations. The change in the fair value of the lease exit costs in the nine months ended September 30, 2015 was primarily due to a change in our estimated sublease start date, which was deferred by eight months. 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 September 30, 2015:

	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent consideration	Probability weighted income approach	Milestone dates	2019 to 2022
		Discount rate	17.0% to 24.0%
		Probability of occurrence	0% to 100%
Royalties	Discounted cash flow	Discount rate	4.8% to 7.8%
Lease exit costs	Discounted cash flow	Sublease start date	July 1, 2016
		Sublease rate	$26.50/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 first quarters of 2015 and 2014, we recorded impairment charges of $1.1 million and $0.6 million, respectively, related to certain property, plant, and equipment in connection with the facility closures discussed in Note 3. 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.

Note 5. Investments

We have cash investment policies that limit investments to investment grade rated securities. At September 30, 2015 and December 31, 2014, all of our investments were classified as available-for-sale and carried at fair value. At September 30, 2015 and December 31, 2014, 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)		
At September 30, 2015				
Short-term investments:				
Corporate debt	$ 32,906	$ —	$ (85)	$ 32,821
U.S. government agency debt	20,000	1	(1)	20,000
Certificates of deposit	10,570	—	—	10,570
Total short-term investments	$ 63,476	$ 1	$ (86)	$ 63,391
Long-term investments:				
Certificates of deposit	$ 1,225	$ —	$ —	$ 1,225
Total long-term investments	$ 1,225	$ —	$ —	$ 1,225

	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Aggregate Fair Value
		(in thousands)		
At December 31, 2014				
Short-term investments:				
Corporate debt	$ 51,241	$ 8	$ (244)	$ 51,005
U.S. government agency debt	15,000	—	(25)	14,975
Certificates of deposit	9,555	—	—	9,555
Total short-term investments	$ 75,796	$ 8	$ (269)	$ 75,535
Long-term investments:				
Certificates of deposit	$ 1,225	$ —	$ —	$ 1,225
Total long-term investments	$ 1,225	$ —	$ —	$ 1,225

For the three and nine months ended September 30, 2015 and 2014, we did not have any realized gains or losses on our investments. At September 30, 2015, 13 of our available-for-sale investments with an aggregate fair value of $34.7 million had been in a continuous loss position for more than twelve months. At September 30, 2015, the gross unrealized loss on these 13 available-for-sale investments was $79,000 and was deemed to be temporary. At September 30, 2015, 4 individual securities had been in an unrealized loss position for twelve months or less. At December 31, 2014, none of our available-for-sale investments had been in a continuous loss position for more than twelve months, while 22 individual securities had been in an unrealized loss position for twelve months or less.

The unrealized losses noted above were deemed 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.

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 nine months ended September 30, 2015 and 2014 is as follows:

	2015	2014
	(in thousands)	
Beginning balance	$61,390	$61,596
Additions	—	—
Impairment	—	—
Foreign currency translation impact	(117)	(138)
Ending balance	$61,273	$61,458

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 technologies acquired during our acquisition of CircuLite in December 2013, consisted of the following at September 30, 2015 and December 31, 2014:

	September 30, 2015	December 31, 2014
	(in thousands)	
SYNERGY System technology	$ 32,850	$ 32,850

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.

We evaluate the carrying value of intangible assets (not subject to amortization) related to in-process research and development ("IPR&D") assets which are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. Accordingly, amortization of the IPR&D assets does not occur until the product reaches commercialization. During the period the assets are considered indefinite-lived, they are tested for impairment on an annual basis in the fourth quarter of each year, as well as between annual tests if we become aware of any events occurring or changes in circumstances that indicate that the fair values of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs when regulatory approval to market the product is obtained, the associated IPR&D assets are deemed definite-lived and are then amortized based on their estimated useful lives at that point in time. If the related project is terminated or abandoned, we may have a full or partial impairment related to the IPR&D assets, calculated as the excess of their carrying value over fair value. During the fourth quarter of 2015 we will evaluate internal timelines and development plans for the SYNERGY System. Our evaluation will take into consideration, among other things, progress with respect to underlying MVAD pump technology and resources dedicated to SYNERGY System development. This evaluation may have an impact on overall development timelines and/or cash flows of the SYNERGY System, the effect of which may result in an impairment of related intangible assets.

Other Intangible Assets

Other intangible assets, net consisted of the following:

	September 30, 2015	December 31, 2014
	(in thousands)	
Patents	$ 6,983	$ 5,310
Purchased intangible assets		
Tradenames	3,700	3,700
Customer relationships	1,800	1,800
Acquired technology rights	9,925	9,925
	22,408	20,735
Less: Accumulated amortization – Patents	(1,430)	(1,118)
Less: Accumulated amortization – Purchased intangible assets	(3,043)	(1,810)
	$ 17,935	$ 17,807

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

Patents	15 years
Purchased intangible assets	
Tradenames	15 years
Customer relationships	20 years
Acquired technology rights	6 to 16 years

Amortization expense for the three months ended September 30, 2015 and 2014 was $0.5 million and $0.4 million, respectively. Amortization expense for the nine months ended September 30, 2015 and 2014 was $1.5 million and $1.2 million, respectively.

We also evaluate the carrying value of our long-lived assets, including purchased intangible assets, whenever events, changes in business circumstances or our planned use of long-lived assets indicate that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. If these facts and circumstances exist, we assess for recovery by comparing the carrying values of long-lived assets with their future undiscounted net cash flows. If the comparison indicates that impairment exists, impairment losses are recorded for the excess of the carrying value over the fair value of the long-lived assets based on discounted cash flows. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected undiscounted cash flows. During the fourth quarter of 2015 we will evaluate internal timelines and development plans for the SYNERGY System. Our evaluation will take into consideration, among other things, progress with respect to underlying MVAD pump technology and resources dedicated to SYNERGY System development. This evaluation may have an impact on overall development timelines and/or cash flows of the SYNERGY System, the effect of which may result in an impairment of related purchased intangible assets.

Note 7. Debt

At September 30, 2015 and December 31, 2014, we had outstanding convertible debt as follows:

	September 30, 2015	December 31, 2014
	(in thousands)	
Principal amount of the 3.5% convertible senior notes, due 2017	$ 42,471	$ 143,750
Unamortized discount	(6,663)	(28,947)
	$ 35,808	$ 114,803
Equity component	$ 7,629	$ 55,038
Principal amount of the 1.75% convertible senior notes, due 2021	$ 202,366	$ —
Unamortized discount	(49,385)	—
	$ 152,981	$ —
Equity component	$ 47,400	$ —

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 and nine months ended September 30, 2015 and 2014, interest expense related to our convertible debt was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
Coupon rate	$ 1,257	$ 1,258	$ 3,799	$3,774
Amortization of discount	2,225	1,948	6,418	5,671
Amortization of deferred financing costs	156	103	399	304
	$ 3,638	$ 3,309	$10,616	$9,749

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"). The 2017 Notes are the 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. 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.

The 2017 Notes offering was completed pursuant to a prospectus supplement, dated December 9, 2010, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on December 9, 2010.

The 2017 Notes will be 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.

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. As of the date of this report on Form 10-Q, none of the events that would allow holders to convert their 2017 Notes have occurred. 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.

We may not redeem the 2017 Notes prior to maturity. Holders of the 2017 Notes may require us to purchase for cash all or a part of their 2017 Notes at a repurchase price equal to 100% of the principal amount of the 2017 Notes to be repurchased, plus accrued and unpaid interest, upon the occurrence of certain fundamental changes (as defined in the Indenture) involving the Company. The Indenture does not contain any financial or operating covenants or restrictions on the payment of dividends, the incurrence of indebtedness or the issuance or repurchase of securities by us or any of our subsidiaries.

The Indenture contains customary terms and nonfinancial covenants and defines events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization) involving the Company occurs and is continuing, the Trustee (by notice to the Company) or the holders of at least 25% in principal amount of the outstanding 2017 Notes (by notice to the Company and the Trustee) may declare 100% of the principal of and accrued and unpaid interest, if any, on all the 2017 Notes to be due and payable. In case of certain events of bankruptcy, insolvency or reorganization, involving the Company, 100% of the principal of and accrued and unpaid interest on the 2017 Notes will automatically become due and payable. Notwithstanding the foregoing, the Indenture provides that, to the extent we elect, the sole remedy for an event of default relating to certain failures by us to comply with certain reporting covenants in the Indenture consists exclusively of the right to receive additional interest on the 2017 Notes.

In accordance with FASB ASC 470-20, *Debt with Conversion and Other Options*, which applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion, we recorded the long-term debt and equity components on our 2017 Notes separately on the issuance date. The amount recorded for long-term debt was determined by measuring the fair value of a similar liability that does not have an associated equity component. The equity component of $55.0 million was recorded in additional paid-in-capital. The measurement of fair value required the Company to make estimates and assumptions to determine the present value of the cash flows of the 2017 Notes, absent the conversion feature. This treatment increased interest expense associated with our 2017 Notes by adding a non-cash component to interest expense in the form of amortization of a debt discount calculated based on the difference between the 3.5% cash coupon rate and the effective interest rate on debt borrowing of approximately 12.5%. The discount is being amortized to interest expense through the December 15, 2017 maturity date of the 2017 Notes using the effective interest method. Additionally, we allocated the costs related to issuance of the 2017 Notes on the same percentage as the long-term debt and equity components, such that a portion of the costs is allocated to the long-term debt component and the equity component included in additional paid-in capital. The portion of the costs allocated to the long-term debt component is presented as deferred financing costs, net on our condensed consolidated balance sheets. These deferred financing costs are also being amortized to interest expense through the December 15, 2017 maturity date of the 2017 Notes using the effective interest method.

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 September 30, 2015 of $52.31 per share, was approximately $22.2 million. The fair value of our 2017 Notes as presented in Note 4 was $46.1 million at September 30, 2015.

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. 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.

Interest on the 2021 Notes is payable semiannually in arrears on June 15 and December 15, at a rate of 1.75% per annum, beginning on December 15, 2015.

The 2021 Notes will 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: (1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2015 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period after any five consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on such trading day; (3) upon the occurrence of specified corporate events, or (4) if we call the 2021 Notes for redemption, until the close of business on the business day immediately preceding the redemption date. As of the date of this report on Form 10-Q, none of the events that would allow holders to convert their 2021 Notes have occurred. 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. Upon conversion, we will satisfy our conversion obligation by paying or delivering, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election.

Both the 2017 and 2021 Notes offer noteholders the right to convert during the period beginning 35 trading days prior to the anticipated closing date of certain merger transactions, include the Valtech transaction, and ending 35 trading days following the actual closing date.

We may not redeem the 2021 Notes prior to June 19, 2019. On or after June 19, 2019, we may redeem for cash all or part of the 2021 Notes if the last reported sale price per share of our common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the trading day immediately preceding the date on which we provide the notice of redemption exceeds 130% of the applicable conversion price for the 2021 Notes on each applicable trading day. The redemption price will equal 100% of the principal amount of the 2021 Notes being redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. No sinking fund is provided for the 2021 Notes.

If we undergo a fundamental change, as defined in the Indenture among the Company and Wilmington Trust, N.A., holders may require us to repurchase for cash all or part of their 2021 Notes at a fundamental change repurchase price equal to 100% of the principal amount of the 2021 Notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date. The fundamental change is primarily triggered by a change of control, liquidation, dissolution or delisting from NASDAQ.

The 2021 Notes are senior unsecured obligations and rank senior in right of payment to our future indebtedness that is expressly subordinated in right of payment to the 2021 Notes; equal in right of payment to our existing and future unsecured indebtedness that is not subordinated; effectively subordinated in right of payment to any of our secured indebtedness to the extent of the value of the assets securing such indebtedness; and structurally subordinated to all existing and future indebtedness and other liabilities of our subsidiaries.

The 2021 Notes will be 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.

In accordance with FASB ASC 470-20, *Debt with Conversion and Other Options*, which applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion, we recorded the long-term debt and equity components on our 2021 Notes separately on the issuance date. The amount recorded for long-term debt was determined by measuring the fair value of a similar liability that does not have an associated equity component. The equity component of $47.4 million was recorded in additional paid-in-capital. The measurement of fair value required the Company to make estimates and assumptions to determine the present value of the cash flows of the 2021 Notes, absent the conversion feature. This treatment increased interest expense associated with our 2021 Notes by adding a non-cash component to interest expense in the form of amortization of a debt discount calculated based on the difference between the 1.75% cash coupon rate and the effective interest rate on debt borrowing of approximately 7.2%. The discount is being amortized to interest expense through the December 15, 2021 maturity date of the 2021 Notes using the effective interest method. Additionally, we allocated the costs related to issuance of the 2021 Notes on the same percentage as the long-term debt and equity components, such that a portion of the costs is allocated to the long-term debt component and the equity component included in additional paid-in capital. The portion of the costs allocated to the long-term debt component is presented as deferred financing costs, net on our condensed consolidated balance sheets. These deferred financing costs are also being amortized to interest expense through the December 15, 2021 maturity date of the 2021 Notes using the effective interest method.

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 September 30, 2015 of $52.31 per share, was approximately $105.9 million. The fair value of our 2021 Notes as presented in Note 4 was $179.9 million at September 30, 2015.

Note 8. Stockholders' Equity

At our 2015 Annual Meeting of Stockholders held on June 4, 2015, our stockholders approved an amendment to our Certificate of Incorporation to increase the number of our authorized shares of common stock from 25 million to 50 million. The amendment became effective upon filing with the Secretary of State of the State of Delaware on June 25, 2015.

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 September 30, 2015, 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 CircuLite merger agreement.

Following satisfaction of a pre-specified milestone in the fourth quarter of 2014, we were obligated to pay $2.0 million under a certain patent assignment and license agreement. The $2.0 million, which was payable in cash or shares of our common stock, was accrued at December 31, 2014 in other long term liabilities on our condensed consolidated balance sheets. We issued an aggregate of 26,042 shares of our common stock in the second quarter of 2015 to settle this liability.

Following satisfaction of a pre-specified milestone in December 2013, we were obligated to pay an additional $5.0 million under a certain patent assignment and license agreement. The $5.0 million, which was payable in cash or shares of our common stock, was settled through the issuance of 50,330 shares of our common stock in the first quarter of 2014.

In the nine months ended September 30, 2015, we issued an aggregate of 2,866 shares of our common stock upon the exercise of stock options and an aggregate of 129,896 shares of our common stock upon the vesting of restricted stock units.

In the nine months ended September 30, 2014, we issued an aggregate of 28,250 shares of our common stock upon the exercise of stock options and an aggregate of 58,000 shares of our common stock upon the vesting of restricted stock units.

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 and nine months ended September 30, 2015 and 2014, we recorded share-based compensation expense as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)			
Cost of revenues	$ 514	$ 611	$ 1,499	$ 1,720
Selling, general and administrative	3,426	3,561	10,558	9,958
Research and development	2,138	2,205	6,742	5,613
	$ 6,078	$ 6,377	$18,799	$17,291

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, SARs or other Awards for which the holder pays the intrinsic value existing as of the date of grant whether directly or by forgoing a right to receive a payment from the Company) is 2,375,000. As of September 30, 2015, 239,857 shares have been issued upon vesting of Awards issued under the 2012 Plan and Awards with respect to 693,351 shares were issued and outstanding under the 2012 Plan. Subsequent to adoption of the 2012 Plan, no new Awards will be granted under our prior plans. Any outstanding Awards under the prior plans will continue to be subject to the terms and conditions of the plan under which they were granted.

Stock Options

Each option allows the holder to subscribe for and be issued one share of our common stock at a specified price, which is generally the quoted market price of our common stock on the date the option is issued. Options generally vest on a pro-rata basis on each anniversary of the issuance date within four years of the date the option is issued. Options may be exercised after they have vested and prior to the specified expiry date provided applicable exercise conditions are met, if any. The expiry date can be for periods of up to ten years from the date the option is issued.

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions established at that time. The following table includes the weighted average assumptions used for options issued in the three and nine months ended September 30, 2015 and 2014.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Dividend yield	0%	0%	0%	0%
Expected volatility	37.50%	39.00%	37.50%	39.00%
Risk-free interest rate	1.69%	1.65%	1.69%	1.65%
Estimated holding period (years)	5.00	5.00	5.00	5.00

Information related to options granted under all of our plans at September 30, 2015 and activity in the nine months then ended is as follows (certain amounts in U.S.$ were converted from AU$ at the then period-end spot rate):

	Number of Options (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	107	$ 48.32		
Granted	7	76.60		
Exercised	(3)	27.95		
Forfeited	—	—		
Expired	—	—		
Outstanding at September 30, 2015	111	$ 48.66	4.03	$ 1,727
Exercisable at September 30, 2015	99	$ 44.48	3.46	$ 1,727

The aggregate intrinsic values at September 30, 2015 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 weighted average grant date fair value per share of options issued in the nine months ended September 30, 2015 and 2014 was $27.10 and $32.41 per share, respectively.

The total intrinsic value of options exercised in the nine months ended September 30, 2015 and 2014 was approximately $0.2 million and $1.8 million, respectively. Cash received from options exercised in the nine months ended September 30, 2015 and 2014 was approximately $0.1 million and $0.8 million, respectively.

At September 30, 2015, there was approximately $0.2 million of unrecognized compensation expense, net of estimated forfeitures, related to non-vested options. This expense is expected to be recognized over a weighted average period of one year.

Restricted Stock Units

Each 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 pre-determined milestones related to the development of our products, the achievement of certain prescribed clinical and regulatory objectives, the achievement of specific financial performance measures or similar 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 September 30, 2015 and activity in the nine months then ended is as follows:

	Number of Units (in thousands)	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2014	589		
Granted	306		
Vested/Exercised	(130)		
Forfeited	(36)		
Expired	—		
Outstanding at September 30, 2015	729	1.48	$ 38,114

The aggregate intrinsic value at September 30, 2015 noted in the table above represents the closing price of our common stock traded on NASDAQ multiplied by the number of RSUs outstanding.

At September 30, 2015, 71,705 of the RSUs outstanding were subject to performance-based vesting criteria as described above.

The total intrinsic value of RSUs vested in the nine months ended September 30, 2015 and 2014 was approximately $10.9 million and $5.3 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 nine months ended September 30, 2015 and 2014 was $88.47 and $98.40, respectively.

At September 30, 2015, we had approximately $29.5 million of unrecognized compensation expense related to non-vested RSU awards, net of estimated forfeitures. This expense is expected to be recognized over a weighted average period of 1.5 years.

Note 10. Net Loss Per Share

Basic earnings per share was computed by dividing net (loss) income for the period by the weighted-average number of common shares outstanding for each respective period. Diluted earnings per share adjusts basic earnings per share for the dilutive effects of share-based awards as determined under the "treasury stock" method, our convertible 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 were excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(In thousands)			
Common shares issuable upon:				
Conversion of 3.5% convertible senior notes	425	1,438	425	1,438
Conversion of 1.75% convertible senior notes	2,024	—	2,024	—
Exercise or vesting of share-based awards	840	837	840	837

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 under special access in other countries. Product sales attributed to a country or region are based on the location of the customer to whom the products are sold. Long-lived assets are primarily held in the United States.

Product sales by geographic location were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)			
United States	$35,578	$39,068	$120,689	$109,801
Germany	14,870	15,105	40,683	47,187
International, excluding Germany	14,718	14,435	47,384	48,223
	$65,166	$68,608	$208,756	$205,211

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 and nine months ended September 30, 2015 and 2014, no customer exceeded 10% of product sales individually.

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. During 2014 and 2015, we commenced implementing systemic changes and organizational enhancements to address the four warning letter items and related quality systems. We established teams to review and address the items cited by the FDA and engaged external subject matter experts to assist in assessment and remediation efforts. We have developed an overall corporate quality plan and individual quality plans which govern our quality improvement efforts.

As more fully explained in Note 3, we have entered into a business combination agreement with Valtech. Following the consummation of the Transactions, as defined in the BCA, both HeartWare and Valtech will be subsidiaries of Holdco. Immediately following Closing, based on the number of HeartWare and Valtech shares outstanding as of the record date, the former stockholders of HeartWare are expected to own approximately 77% of the outstanding shares of Holdco common stock and the former Valtech security holders, together with minority shareholders of a subsidiary of Valtech, are expected to own approximately 23% of the outstanding shares of Holdco common stock.

In the event the BCA is terminated in accordance with the termination provisions of the BCA, HeartWare would be obligated to make a loan to Valtech in a principal amount equal to $30 million pursuant to a convertible promissory note.

At September 30, 2015, we had purchase order commitments of approximately $45.5 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 payable over periods ranging from 8-10 years subsequent to the acquisition date. As of September 30, 2015, the maximum future milestone and royalty payment amounted to $300 million, reduced from the original agreement maximum of $320 million, since certain milestones are no longer achievable. As of September 30, 2015, the fair value of the contingent consideration was estimated to be $50.4 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 pay 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.

Litigation

From time to time we may be involved in litigation or other contingencies arising in the ordinary course of business. Based on the information presently available, management believes there are no contingencies, claims or actions, pending or threatened, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or results of operations.

In accordance with FASB ASC 450*, Contingencies*, we accrue loss contingencies including costs of settlement, damages and defense related to litigation to the extent they are probable and reasonably estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range.

Note 13. Subsequent Events

We have evaluated events and transactions that occurred subsequent to September 30, 2015 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.

The HeartWare® Ventricular Assist System (the "HVAD® System"), which includes a ventricular assist device ("VAD"), or blood pump, patient accessories and surgical tools, is designed to provide circulatory support for patients in the advanced stage of heart failure. The core of the 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, which is generally required to implant similar devices.

In November 2012, we received approval from the United States Food and Drug Administration ("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 September 30, 2015, there have been approximately 9,000 implants of the HVAD System in patients at over 290 health care sites in 47 countries.

We also intend to seek an expanded indication for the HVAD System in the U.S. to include destination therapy. In May 2012, we completed enrollment in our ENDURANCE destination therapy clinical trial. Each trial patient has now been followed to the primary endpoint of two years, and will be followed for a subsequent five-year period post-implant. On August 27, 2013, the FDA approved a supplemental Investigational Device Exemption trial ("ENDURANCE2") allowing us to commence enrollment in an additional patient cohort for the ENDURANCE clinical trial. ENDURANCE2 studies the benefits of blood pressure management to reduce neurological events. Enrollment commenced in October 2013 and was completed in August 2015. Patients have been, or will be, followed for 12 months after implant. In 2016, we intend to incorporate the data from both ENDURANCE2 and ENDURANCE into an anticipated pre-market approval application seeking approval of the HVAD System for the destination therapy indication.

In April 2015, we presented results from our ENDURANCE clinical trial during the Opening Plenary Session at the 35th International Society for Heart and Lung Transplantation (ISHLT) Annual Meeting in Nice, France, which demonstrated that the trial achieved the primary endpoint. Although neurological events in the treatment arm were higher than in the control arm, the data suggested that blood pressure management appears to reduce neurological events, a hypothesis being tested in the ENDURANCE2 trial. The data presented also showed that sintering of the inflow cannula, a system modification which occurred during the trial, reduced the overall rate of suspected thrombus and that pump exchanges for thrombus were less frequent in patients with the currently available HVAD system as compared to the control.

MVAD System

We continue to expand our pipeline through research and development into next-generation products and peripherals and through ongoing and new clinical trials and to expand our presence in commercial markets outside of the United States. The MVAD Pump is a heart pump that supports a wide range of flows to enable circulatory support for patients with advanced heart failure. The MVAD Pump was designed with a low shear stress impeller and optimal blood flow paths, which together are expected to result in improved hemodynamic performance. In addition, the MVAD System incorporates a pulsatility algorithm called the qPulse™ Cycle that allows physicians to customize the device for each patient, providing four pulse settings designed to enhance aortic valve function and reduce chronic bleeding events. The MVAD Pump, which is less than one-half the size of the HVAD Pump, weighs only 78 grams and displaces 22 cc of volume, and has a steerable

sewing ring, which enables clinicians to position the inflow cannula to facilitate optimal blood flow into the pump. The integrated Pal controller and battery system includes a touch-screen display and two sizes of small, light-weight, snap-on batteries.

In July 2015, we commenced our MVAD System CE Mark international clinical trial. The MVAD System CE Mark trial is a multicenter, prospective, non-randomized, single-arm trial that evaluates the clinical safety and performance of the MVAD System for the treatment of advanced heart failure. The trial will enroll 70 patients at 11 sites in the United Kingdom, Austria, Australia, France and Germany. In the trial, patients will be implanted with the MVAD Pump via sternotomy or thoracotomy, and the device will be evaluated for short- and long-term use. The primary endpoint is survival at six months.

On September 9, 2015, we announced a voluntary pause of enrollment in our MVAD CE Mark clinical trial to address an MVAD controller manufacturing process issue. We are in the process of implementing manufacturing improvements as well as software updates, which were also described on September 9, 2015. Subsequently on October 13, 2015, and following discussions with the trial investigators, we began investigating causes of reported adverse events in certain clinical trial patients. The events being analyzed are typical of those seen in other clinical trials for ventricular assist devices. We took similar actions successfully during our initial human study for the HVAD System during the HVAD CE Mark clinical trial in 2007, and HeartWare remains confident in its MVAD System and the potential for the MVAD design to meaningfully improve outcomes for ventricular assist patients. A date for re-initiation of the MVAD clinical trial has yet to be established.

We have submitted to the FDA an Investigational Device Exemption seeking approval to commence an MVAD System clinical trial in the United States. Health Canada is also reviewing a submission for a 15-patient, three-center study, which is expected to commence around the time the MVAD CE Mark trial is re-initiated.

Valtech

On September 1, 2015 we entered into a Business Combination Agreement ("BCA") with 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, pursuant to which HeartWare and Valtech will both become subsidiaries of a new holding company, HW Global, Inc, ("Holdco"). HeartWare stockholders would receive one share of Holdco common stock for each share of HeartWare common stock and Valtech shareholders would receive 5.2 million shares of Holdco common stock, 700,000 shares of Holdco common stock upon achievement of certain milestones, warrants to purchase 850,000 shares of Holdco common stock which are exercisable upon attainment of $75 million of net sales (trailing 12 months) of Valtech products and an earn-out payment of $375 million (payable in cash or stock at the discretion of Holdco), upon attainment of $450 million of net sales (trailing 12 months) of Valtech products. The respective boards of HeartWare and Valtech have approved the agreement. Completion of the transaction is subject to customary closing conditions, including approval of HeartWare and Valtech stockholders and regulatory approvals. The closing of the transaction is expected in late 2015 or early 2016. In the event the BCA is terminated in accordance with the termination provisions of the BCA, HeartWare would be obligated to make a loan to Valtech in a principal amount equal to $30 million pursuant to a convertible promissory note.

The preceding description of the business combination agreement is not intended to be complete and is subject to the full text of the business combination agreement and related agreements, which are incorporated herein by reference to Exhibits 2.1 and 99.1 through 99.6 of our Form 8-K filed with the Securities and Exchange Commission on September 1, 2015.

CircuLite

On December 1, 2013, we acquired CircuLite, Inc. CircuLite is the developer of the SYNERGY Circulatory Support System, a partial support system designed to treat less sick, ambulatory, chronic heart failure patients who are not yet inotrope-dependent. The SYNERGY Surgical System is designed for long-term partial support and is intended to reduce the heart's workload while improving blood flow to vital organs. The system is currently undergoing an upgrade to resolve 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 prior micropump and have focused our efforts on a version of our MVAD pump for our SYNERGY partial-assist program. Following the necessary clinical trials and regulatory approvals, we plan to re-launch the system in Europe and will focus on building experience at a small number of centers of excellence, refining training techniques and implementing additional system upgrades. The next-generation endovascular system,

which will be implanted collaboratively by cardiologists and surgeons in a hybrid catheterization ("cath") lab setting, offers an interventional approach to circulatory support. While our HVAD and MVAD Systems offer minimally invasive treatment to end-stage heart failure patients, the SYNERGY Circulatory Support System offers even less invasive and ultimately interventional options to earlier-stage heart failure patients.

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. During 2014 and 2015, we commenced implementing systemic changes and organizational enhancements to address the four warning letter items and related quality systems. We established teams to review and address the items cited by the FDA and engaged external subject matter experts to assist in assessment and remediation efforts. We have developed an overall corporate quality plan and individual quality plans which govern our quality improvement efforts. As we complete this comprehensive review of 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.

Field Actions

On September 9, 2015, we announced plans to implement voluntary corrective actions as part of HeartWare's ongoing Warning Letter remediation efforts and quality system enhancements. These corrective actions include the planned replacement of certain older batteries in the field as a further action to previous field actions targeted to address battery performance issues including complaints related to earlier-than-expected battery depletion and routine battery handling. These plans also include a field safety corrective action to identify and replace certain HeartWare AC Adapters designed for use outside of the United States which have a higher risk of failing in case of a power surge compared to other HeartWare AC Adapters. The combination of these field actions resulted in a charge of approximately $8.5 million during the third quarter of 2015.

During the first quarter of 2015, we recorded charges aggregating to $0.5 million for previous field actions addressing different types of complaints reviewed as part of our ongoing product performance monitoring. These previous actions were related to performance improvements or corrections affecting the HVAD System for issues such as continuous power supply, worn alignment guides, planned software improvements, driveline care, and susceptibility to electrostatic discharge.

As we continue to make quality systems improvements, there may be additional field safety corrections identified in the future which could have an impact on our financial position, liquidity or results of operations.

Summary of Recent Financial Performance

Total revenue decreased 5%, to $65.2 million for the quarter ended September 30, 2015 compared to $68.6 million during the third quarter of 2014. Currency changes negatively impacted total revenue growth by approximately $4.9 million, or 7%, during the third quarter of 2015 compared to the third quarter of 2014. International unit sales increased by 18% compared to the third quarter of 2014, while U.S. unit sales decreased by 9% compared to the same period, the latter resulting primarily from the completion of patient enrollment of the ENDURANCE2 clinical trial. We added six new U.S. customer sites and five new international customer sites during the third quarter of 2015, modestly contributing to our results. A total of 697 HVAD Systems were sold during the third quarter of 2015, including 327 U.S. units and 370 international units.

With several HeartWare and competitive product clinical trials either ongoing, or expected to be ongoing throughout 2015 and 2016, we anticipate that our quarterly revenue and market share may be subject to greater volatility. As of September 30, 2015, the Company had 126 customers in the United States and 180 customers internationally.

We realized a decrease in gross margin percentage, to 49.4% in the third quarter compared to 65.7% in second quarter of 2015 and 66.5% in the third quarter of 2014. This decrease was primarily a result of the expanded battery recall explained above and in Note 3 under the heading Accrued Product Recall Costs. Other factors include unfavorable foreign exchange rates, customer and geographic mix, and to a lesser extent limited competitive pricing pressures.

Combined selling, general, administrative, research and development expenses were $55.6 million in the third quarter of 2015, an increase of $1.7 million from $53.9 million in the second 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, 2014 ("2014 Annual Report on Form 10-K") filed with the Securities and Exchange Commission on March 2, 2015. During the nine months ended September 30, 2015, 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 2014 Annual Report on Form 10-K.

Results of Operations

Three and nine months ended September 30, 2015 and 2014

Revenue, net

In the three and nine months ended September 30, 2015 and 2014, we generated revenue through commercial sales and clinical trials.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
	(in thousands)			(in thousands)		
United States	$35,578	$39,068	-9%	$120,689	$109,801	10%
International	29,588	29,540	0%	88,067	95,410	-8%
Total	$65,166	$68,608	-5%	$208,756	$205,211	2%

The following table presents our HVAD pump unit sales by geography for the three and nine months ended September 30, 2015 and 2014:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
United States	327	361	-9%	1,099	1,012	9%
International	370	314	18%	1,084	1,002	8%
Total	697	675	3%	2,183	2,014	8%

Revenue in the United States, where our HVAD System is labeled for bridge-to-transplantation, reflects the completion of enrollment in the Company's ENDURANCE2 clinical trial. U.S. revenue included 15 and 108 HVAD Systems sold under the Company's ENDURANCE2 clinical trial in the three and nine months ended September 30, 2015, respectively. International revenue decreased due to the impact of currency fluctuations, which negated the potential benefit from the increased unit sales. The international unit sales expansion was attributable to further adoption of the HVAD System in less penetrated markets.

Currency changes negatively impacted total revenue growth by approximately $4.9 million and $16.0 million, or 7% and 8%, in the three and nine months ended September 30, 2015, respectively, compared to the same periods in 2014. In the three and nine months ended September 30, 2015, approximately 40% and 38% of our net revenue was denominated in foreign currencies including principally the Euro and British pound compared to 40% and 44% in the same periods of 2014. This geographic mix shift results in a partial offset of the impact of foreign currency declines. Movements in foreign currency exchange rates have had an effect on our reported revenue amounts in the past and could have a significant favorable or unfavorable impact on our reported revenue amounts in the future.

We expect to continue to generate and grow commercial revenue from product sales as we further expand our sales and marketing efforts on a global basis. Future product sales are dependent on many factors, including perception of product performance and market acceptance among physicians, patients, health care payers and the medical community as well as our capacity to meet customer demand by manufacturing sufficient quantities of our products. Our quarterly revenue and market share may be subject to greater volatility in future periods due to several HeartWare and competitive product clinical trials either ongoing, or expected to be ongoing, in the course of 2015 and 2016, expected commercial launch of competitive products, enrollment completion of ENDURANCE2, increased mix of international sales resulting in lower average selling prices due to currency fluctuations and growing unrest in the middle east, which is an important market for us, as we anticipate that the current state of affairs in that region of the world could dampen international sales.

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 $33.0 million and $23.0 million in the three months ended September 30, 2015 and 2014, respectively. Cost of revenue totaled approximately $80.3 million and $68.8 million in the nine months ended September 30, 2015 and 2014, respectively.

Gross profit and gross margin percentage are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
	(in thousands)		(in thousands)	
Gross profit	$32,176	$45,631	$128,498	$136,365
Gross margin %	49.4%	66.5%	61.6%	66.5%

The decrease in gross margin percentage during the three months ended September 30, 2015 compared to the same period in 2014 was primarily a result of charges associated with field actions (11.3%), unfavorable foreign exchange rates (3.5%), European customs duties charge (1.3%), customer and geographic mix (0.5%), and to a lesser extent limited competitive pricing pressures in a handful of indirect markets.

The decrease in gross margin percentage during the nine months ended September 30, 2015 compared to the same period in 2014 was primarily a result of unfavorable foreign exchange rates (2.7%), charges associated with field actions (2.4%), and to a lesser extent customer and geographic mix, European customs duties charge and limited competitive pricing pressures in a handful of indirect markets.

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 September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
	(in thousands)			(in thousands)		
Selling, general and administrative expenses	$ 25,171	$ 20,584	22%	$ 69,347	$ 65,765	5%
% of operating expenses, excluding changes in fair value of contingent consideration	45%	41%		43%	42%	

The increase of $4.6 million for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014 reflects Valtech-related transaction fees of $3.6 million, an increase in salaries and related costs associated with headcount growth of $0.8 million, and professional fees of $0.9 million. All other expenses decreased by $0.7 million.

The increase of $3.6 million for the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014 reflects an increase in salaries and related costs associated with headcount growth of $2.7 million, legal and advisory fees related to the Valtech acquisition of $3.0 million and non-cash share-based compensation expense of $0.6 million. Offsetting decreases include approximately $2.5 million of restructuring charges in 2014 resulting from lease exit costs associated with facilities we vacated in Massachusetts and New Jersey, severance costs and asset impairment charges. Aside from the Massachusetts facility item, these charges related to our acquisition of CircuLite.

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 costs associated with our compliance with FDA regulations. Additional costs include travel, facilities and overhead allocations.

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
	(in thousands)			(in thousands)		
Research and development expenses	$ 30,386	$ 29,477	3%	$ 93,355	$ 88,981	5%
% of operating expenses, excluding changes in fair value of contingent consideration	55%	59%		57%	58%	

The net increase of $0.9 million for the three months ended September 30, 2015 as compared to the three months ended September 30, 2014 resulted primarily from increases in clinical and regulatory expenses of $2.1 million, including outside costs associated with FDA warning letter remediation efforts, salaries and related costs associated with headcount growth of $0.5 million and infrastructure-related costs of $0.3 million. Overall research and development project expenses decreased by $1.7 million. All other expenses resulted in a net decrease of approximately $0.3 million.

The net increase of $4.4 million for the nine months ended September 30, 2015 as compared to the nine months ended September 30, 2014 resulted primarily from increases in salaries and related costs associated with headcount growth of $1.7 million, non-cash share-based compensation expense of $1.1 million, infrastructure-related costs of $1.9 million and restructuring costs of $1.2 million. All other expenses resulted in a decrease of $1.5 million and were primarily due to lower research and development project costs. The restructuring charges associated with the CircuLite acquisition were approximately $2.2 million and $1.1 million in the nine months ended September 30, 2015 and 2014, respectively. The charges recorded in 2015 included fixed asset impairment, contract termination fees and severance costs in connection with our decision to cease activities at our facility in Aachen, Germany. The charges recorded in 2014 included contract termination fees and severance costs.

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 SYNERGY 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 ENDURANCE2 clinical trials. In addition, we continue to incur substantial costs to remediate warning letter-related observations as well as make improvements to our quality systems.

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 five 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 September 30, 2015, we recorded a $2.4 million adjustment for the increase in the estimated fair value of the contingent consideration since June 30, 2015. In the nine months ended September 30, 2015, we recorded a $6.7 million adjustment for the increase in the estimated fair value of the contingent consideration since December 31, 2014. The change in the fair value of the contingent consideration in the three and nine months ended September 30, 2015 was due to accretion of the liability due to the passage of time.

In the three months ended September 30, 2014, we recorded a $3.6 million adjustment for the decrease in the estimated fair value of the contingent consideration since June 30, 2014. The decrease in the estimated fair value of the contingent consideration was primarily due to a $6.1 million reduction due to the likelihood of not achieving the performance milestone conditions related to the re-launch of the acquired form of the SYNERGY Surgical System following its loss of CE marking in the European Union in March 2014. In addition, we have discontinued development of the SYNERGY micropump and have focused our efforts on a version of our MVAD pump for our partial-assist program. The $6.1 million reduction in fair value was partially offset by an increase of $2.5 million due to accretion of the liability due to the passage of time.

In the nine months ended September 30, 2014, we recorded a $14.2 million adjustment for the decrease in the estimated fair value of the contingent consideration. The decrease in the estimated fair value of the contingent consideration was primarily due to a $22.7 million reduction due to the likelihood of not achieving the performance milestone conditions related to the re-launch of the acquired form of the SYNERGY Surgical System as noted above. The $22.7 million reduction in fair value was partially offset by an increase of $8.5 million due to accretion of the liability due to the passage of time.

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 development timelines, 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. During the fourth quarter of 2015 we will evaluate internal timelines and development plans for the SYNERGY System. Our evaluation will take into consideration, among other things, progress with respect to underlying MVAD pump technology and resources dedicated to SYNERGY System development. This evaluation may have an impact on overall development timelines and/or cash flows of the SYNERGY System, the effect of which may result in an adjustment to estimated fair value.

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 September 30, 2015, our net foreign exchange loss totaled approximately $0.4 million, primarily due to a modest rebound in the U.S. dollar. This compared to a net foreign exchange loss of approximately $3.3 million in the same period of 2014. In the nine months ended September 30, 2015, our net foreign exchange loss totaled approximately $3.4 million, primarily due to a significant weakening of the Euro during the first quarter of 2015. This loss compared to net foreign exchange losses of approximately $3.1 million in the same period of 2014. In 2015 and 2014, 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 in 2015 and 2014 primarily consists of interest incurred on the principal amount of our convertible notes, amortization of the related discount and amortization of the portion of the deferred financing costs allocated to the debt component. The discount on the 3.5% convertible notes and the deferred financing costs are being amortized to interest expense through the December 15, 2017 maturity date of the convertible notes using the effective interest method. The discount on the 1.75% convertible notes and the deferred financing costs are being amortized to interest expense through the December 15, 2021 maturity date of the convertible notes using the effective interest method.

In the three months ended September 30, 2015, interest expense was approximately $3.6 million, which included $1.3 million of interest incurred on the principal amount of the convertible notes at the stated coupon rates and $2.3 million of non-cash amortization of the discount and deferred financing costs. In the three months ended September 30, 2014, interest expense was approximately $3.3 million, which included $1.3 million of interest incurred on the principal amount of the convertible notes at the stated coupon rate and $2.0 million of non-cash amortization of the discount and deferred financing costs.

In the nine months ended September 30, 2015, interest expense was approximately $10.6 million, which included $3.8 million of interest incurred on the principal amount of the convertible notes at the stated coupon rates and $6.8 million of non-cash amortization of the discount and deferred financing costs. In the nine months ended September 30, 2014, interest expense was approximately $9.8 million, which included $3.8 million of interest incurred on the principal amount of the convertible notes at the stated coupon rate and $6.0 million of non-cash amortization of the discount and deferred financing costs.

Investment Income, net

Investment income is primarily derived from investments and cash and short-term deposit accounts held in the U.S. The amortization of premium on our investments is also included in investment income, net. Investment income, net was approximately $0.2 million and $0.4 million, respectively, in the three and nine months ended September 30, 2015, compared to $0.1 million and $0.5 million, respectively, in the same periods in the prior year. 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 we have not provided for U.S. income taxes on these unrepatriated foreign earnings. We have incurred significant U.S. losses since inception, however, changes in issued capital and share ownership, as well as other factors, may limit our ability to utilize any net operating loss carry-forwards, and therefore a 100% valuation allowance has been recorded against our net deferred tax assets. For the three and nine months ended September 30, 2015, our tax provision includes estimated foreign taxes in jurisdictions where wholly-owned subsidiaries may be subject to current taxes.

Liquidity and Capital Resources

As of September 30, 2015, our cash and cash equivalents combined with short term available-for-sale investments were approximately $248.3 million as compared to $178.5 million at December 31, 2014.

Following is a summary of our cash flow activities for the nine months ended September 30, 2015 and 2014:

	Nine Months Ended September 30,	
	2015	2014
	(in thousands)	
Net cash provided by (used in) operating activities	$ 887	$ (15,046)
Net cash provided by (used in) investing activities	3,047	(36,860)
Net cash provided by financing activities	75,540	837
Effect of exchange rate changes on cash and cash equivalents	2,462	1,837
Net increase (decrease) in cash and cash equivalents	$ 81,936	$ (49,232)

Cash Provided By (Used in) Operating Activities

For the nine months ended September 30, 2015, cash used in operating activities included a net loss of approximately $71.9 million, adjustments for non-cash items totaling $57.4 million and cash from changes in working capital of $15.3 million. The net loss was driven by normal operating activities including the sale of the HVAD System in the United States and abroad, the loss on extinguishment of long-term debt, planned field actions, 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 $18.8 million of share-based compensation, $6.6 million of depreciation and amortization on long-lived assets,

$6.4 million of amortization of the discount on our convertible notes, $6.7 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 increase in cash from changes in working capital included $8.9 million for the decrease in accrued liabilities, $4.5 million for the decrease in inventory, $1.9 million for the decrease in accounts receivable and $1.6 million for the decrease in accrued interest on convertible notes. These amounts were partially offset by increases in accounts payable and prepaid expenses totaling $1.6 million.

For the nine months ended September 30, 2014, cash used in operating activities consisted of net loss of $18.5 million, adjustments for non-cash items of $17.7 million and cash used in working capital of $14.3 million. Adjustments for non-cash items primarily consisted of $17.3 million of share-based compensation, $6.2 million of depreciation and amortization of long-lived assets, $5.7 million for the amortization of the discount on our convertible notes, $1.0 million loss on an equity investment and $0.6 million for the impairment of fixed assets, which were partially offset by an adjustment of $14.2 million from the decrease in fair value of contingent consideration. The decrease in cash from changes in working capital included $10.4 million in increased trade accounts receivable, $13.1 million for the purchase and manufacture of inventories and $2.3 million for the payment of trade accounts payable. These amounts were partially offset by a decrease in prepaid expenses and other assets of $2.4 million and an increase in accrued liabilities of $7.1 million.

Cash Provided By (Used in) Investing Activities

In the nine months ended September 30, 2015, net cash provided by investing activities included maturities of available-for-sale securities (net of purchases) aggregating $11.5 million. This amount was partially offset by cash usages of $2.1 million to acquire property, plant and equipment, $1.7 million for intellectual property as well as a $5 million investment in Valtech in the form of a convertible promissory note (the "2015 Note"). Pursuant to the terms of the 2015 Note, principal and interest at a rate equal to 6% per annum is due and payable at maturity. Maturity occurs at the earlier of two years or the occurrence of certain events defined in the 2015 Note, including an event of default or a change in control. Principal and interest on the 2015 Note are repayable, at the option of the issuer, in cash or shares of the most recently issued series of preferred stock or a comparable newly issued series of preferred stock.

In the nine months ended September 30, 2014, net cash used in investing activities included $29.7 million for the purchase (net of maturities) of available-for-sale securities, $6.0 million to acquire property, plant and equipment and $1.2 million for intellectual property.

Cash Provided by Financing Activities

In the nine months ended September 30, 2015, cash provided by financing activities was primarily the result of the net cash proceeds from the issuance of our 1.75%, 2021 Notes. In May 2015, we issued our 1.75%, 2021 Notes with an aggregate principal amount of $202.4 million in exchange for a portion of our outstanding 3.5%, 2017 Notes with an aggregate principal amount $101.3 million and net cash proceeds of approximately $75.5 million, after paying offering costs. Interest on the 2021 Notes is payable semiannually in arrears on June 15 and December 15 of each year, beginning on December 15, 2015. The 2021 Notes will mature on December 15, 2021, unless earlier repurchased by the Company or converted.

The exercise of stock options in the nine months ended September 30, 2015 and 2014 resulted in cash proceeds of approximately $0.1 million and $0.8 million, 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 2015, 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 United States;
- continued product development, including refinement 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;

- development of the SYNERGY System, including the next generation endovascular 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;
- expand work in process and finished goods inventory to support ongoing operations;
- planned investments in infrastructure to support our growth;
- transaction and integrations costs related to proposed acquisition of Valtech;
- acquisition of and investment in third party technologies; and
- general working capital.

Interest on our convertible notes is 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 notes at September 30, 2015, the semi-annual interest payment due on December 15, 2015 will be approximately $2.8 million. This amount is expected to be paid from cash on hand.

We believe cash on hand and investment balances as of September 30, 2015 are sufficient to support our planned operations for at least the next twelve months, including the acquisition of Valtech. At September 30, 2015, approximately $9.9 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;
- closing of the Valtech acquisition
- commercial acceptance of our products;
- 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;
- expenses related to funding and integrating strategic investments, acquisitions and collaborative arrangements;
- payment of the 2.3% excise tax on gross revenue from the sale of our medical devices in the United States imposed by the Patient Protection and Affordable Care Act;
- payment of our convertible notes on maturity if not converted or repurchased; and
- complying with the requirements related to being a public company in the United States.

Contractual Obligations

On September 1, 2015 we entered into a BCA with 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, pursuant to which HeartWare and Valtech will both become subsidiaries of a new holding company, HW Global, Inc, ("Holdco"). HeartWare stockholders would receive one share of Holdco common stock for each share of HeartWare common stock and Valtech shareholders would receive 5.2 million shares of Holdco common stock, 700,000 shares of Holdco common stock upon achievement of certain milestones, warrants to purchase 850,000 shares of Holdco common stock which are exercisable upon attainment of $75 million of net sales (trailing 12 months) of Valtech products and an earn-out payment of $375 million (payable in cash or stock at the discretion of Holdco), upon attainment of $450 million of net sales (trailing 12 months) of Valtech products. The respective boards of HeartWare and Valtech have approved the agreement. Completion of the transaction is subject to customary closing conditions, including approval of HeartWare and Valtech stockholders and regulatory approvals. The closing of the transaction is expected in late 2015 or early 2016.

In May 2015, we amended the lease for our corporate headquarters in Framingham, Massachusetts to include approximately 12,500 square feet of additional office space. This lease is scheduled to expire in March 2021. Annual base rent for the additional space will be approximately $0.3 million, payable monthly starting in March 2016. Annual base rent is subject to periodic increases beginning in 2018.

In May 2015, we issued $202.4 million principal amount of 1.75% convertible senior notes due December 15, 2021 (the "2021 Notes"), unless earlier repurchased, redeemed or converted. This included $118.2 million of 2021 Notes that were issued in exchange for $101.3 million aggregate principal amount of our 3.5% convertible senior notes due December 15, 2017 (the "2017 Notes"). Subsequent to the exchange, the outstanding balance of 2017 Notes is $42.5 million, which is due December 15, 2017, unless the 2017 Notes are earlier repurchased or converted. Interest on the 2021 Notes and 2017 Notes is payable semi-annually in arrears on June 15 and December 15 of each year. Based on the outstanding principal amounts of our 2021 Notes and 2017 Notes at September 30, 2015, annual interest payments will be approximately $5.0 million.

Except as disclosed above, in the nine months ended September 30, 2015, there were no material changes outside the ordinary course of business to our contractual obligations provided in Part II, Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, included in our 2014 Annual Report on Form 10-K filed with the SEC on March 2, 2015.

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 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 in our condensed consolidated statements of operations. Continued fluctuation of these exchange rates could result in financial results that are not comparable from quarter to quarter. We do not currently utilize foreign currency contracts to mitigate the gains and losses generated by the re-measurement of non-functional currency assets and liabilities but do hold cash reserves in currencies in which those reserves are anticipated to be expended.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, carried out an evaluation required by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of September 30, 2015. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2015, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the fiscal quarter ended September 30, 2015, 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

The Company is not a party to any material legal proceedings at the date of filing of this Quarterly Report on Form 10-Q.

ITEM 1A. RISK FACTORS

In addition to the information set forth in this report you should carefully consider the risk factors described in Part I, Item 1A. "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 filed with the SEC on March 2, 2015 and the risk factors described in the Registration Statement on Form S-4 filed by HW Global, Inc. as of October 15, 2015 included in Exhibit 99.1 hereto.

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

On May 15, 2015, following the satisfaction of a pre-specified milestone under the terms of a 2012 patent assignment and license agreement, we issued an aggregate of 26,042 unregistered shares of our common stock to the inventor of certain intellectual property in partial consideration of the assignment and license to us of the intellectual property pursuant to the 2012 agreement. The issuance of the shares was exempt from registration under Section 4(a)(2) of the Securities Act of 1933, as amended. Shortly following the issuance of the shares to the assignor, the shares were registered for resale on Form S-3 pursuant to a Prospectus Supplement filed with the SEC on May 15, 2015 in accordance with Rule 424(b)(7). HeartWare did not engage in, nor has engaged in, a general solicitation with respect to the issuance and sale of the shares, and HeartWare did not receive, nor will receive, any proceeds from the sale of the shares.

ITEM 6. EXHIBITS

2.1	Business Combination Agreement, dated as of September 1, 2015, by and among HeartWare International, Inc., Valtech Cardio, Ltd., HW Global, Inc., HW Merger Sub, Inc., Valor Merger Sub Ltd. and Valor Shareholder Representative, LLC. (4)
3.1	Certificate of Incorporation of HeartWare International, Inc. (1)
3.2	Amendment dated June 25, 2015, to Certificate of Incorporation of HeartWare International, Inc. (1)
3.3	Bylaws of HeartWare International, Inc. (1)
31.1	Certification by the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *
31.2	Certification by the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 *
32.1	Certification by the Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 **
32.2	Certification by the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 **
99.1	Risk factors described in the Registration Statement on Form S-4 filed by HW Global, Inc as of October 15, 2015*
99.2	Form of Escrow Agreement, by and among U.S. Bank N.A., HW Global, Inc. and Valor Shareholder Representative, LLC. (4)
99.3	Form of Warrant between HW Global, Inc. and holders of shares and other equity interests of Valtech Cardio, Ltd. (4)
99.4	Form of Interim Funding Convertible Promissory Note between HeartWare International, Inc. and Valtech Cardio, Ltd. (4)

99.5	Form of HeartWare Termination Note between HeartWare International, Inc. and Valtech Cardio, Ltd. (4)
99.6	Form of Shareholder Support Agreement, by and among HW Global, Inc., certain officers and directors and holders of shares and other equity interests of Valtech Cardio, Ltd. and Valor Shareholder Representative, LLC. (4)
99.7	Form of Stockholders Voting Agreement, by and among HW Global, Inc. and certain officers and directors and holders of shares and other equity interests of Valtech Cardio, Ltd. (4)
101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in eXtensible Business Reporting Language (XBRL): (i) Unaudited Condensed Consolidated Balance Sheets as of September 30, 2015 and December 31, 2014, (ii) Unaudited Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2015 and 2014, (iii) Unaudited Condensed Consolidated Statements of Comprehensive (Loss) Income for the three and nine months ended September 30, 2015 and 2014, (iv) Unaudited Condensed Consolidated Statement of Stockholders' Equity for the nine months ended September 30, 2015, (v) Unaudited Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2015 and 2014, and (vi) Notes to Unaudited Condensed Consolidated Financial Statements.

(1) Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 13, 2008.
(2) Incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2012.
(3) Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2015.
(4) Incorporated by reference to the relevant exhibit to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 1, 2015.
* Filed herewith
** Furnished herewith

SIGNATURES

In accordance with the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HEARTWARE INTERNATIONAL, INC.

Date: November 2, 2015

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

Date: November 2, 2015

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

EXHIBIT INDEX

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Exhibit 31.1

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

I, Douglas Godshall, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2015

/s/ Douglas Godshall

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

Exhibit 31.2

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

I, Peter F. McAree, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2015

/s/ Peter F. McAree

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

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of HeartWare International, Inc. (the "Company") for the quarterly period ended September 30, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned President and Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

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

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

Date: November 2, 2015

/s/ Douglas Godshall

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

Exhibit 32.2

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

In connection with the Quarterly Report on Form 10-Q of HeartWare International, Inc. (the "Company") for the quarterly period ended September 30, 2015 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: November 2, 2015

/s/ Peter F. McAree

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

Exhibit 99.1

RISK FACTORS DESCRIBED IN THE REGISTRATION STATEMENT ON FORM S-4 FILED BY HW GLOBAL, INC. ("HOLDCO")

Risks Relating to the Transactions

The number of shares of Holdco common stock that Valtech and Mitraltech shareholders will receive as a result of the Transactions is fixed, subject to certain adjustments. The value of the shares of Holdco common stock that Valtech shareholders receive is different than at the date the Business Combination Agreement was signed and could be different than at the time Valtech shareholders vote to approve the ISR Merger.

Upon the effective time of the ISR Merger, the Recipient Parties will receive, as set forth in a Valtech notice delivered to its shareholders prior to Closing regarding its special meeting, a pro rata portion of: (a) 4,400,000 shares of Holdco common stock to be issued at closing, less escrowed shares of Holdco common stock and less adjustments, including with respect to certain Valtech indebtedness and transaction expenses; (b) an additional 800,000 shares of Holdco common stock to be issued at closing, less escrowed shares of Holdco common stock, because Valtech successfully obtained CE Mark approval for Valtech's Cardioband product; (c) the right to receive escrowed shares of Holdco common stock, if any are ultimately distributed; (d) the right to receive 700,000 shares of Holdco common stock contingent upon a first-in-man implant of Valtech's Cardioband Tricuspid Product or Valtech's Cardiovalve Product; (e) warrants to purchase 850,000 shares of Holdco common stock at an exercise price of $83.73 per share which become exercisable upon achieving $75 million in net sales (trailing 12 months) of Valtech products; and (f) the right to receive a payment of $375 million (payable in cash or Holdco common stock, at the discretion of Holdco) upon achieving $450 million in net sales (trailing 12 months) of Valtech products. The number of shares of Holdco common stock that Valtech shareholders will be entitled to receive will not be adjusted in the event of any increase or decrease in the share price of HeartWare common stock.

Each share of Holdco common stock will be issued in accordance with, and subject to the rights and obligations of, the Holdco Certificate of Incorporation and Bylaws substantially in the forms attached hereto as Annex B. For a comparison of the rights and privileges of a holder of shares of Holdco common stock as compared to a holder of Valtech shares, please see "*Comparison of the Rights of Holders of Valtech Shares and Holdco Common Stock*" beginning on page 146 of this proxy statement/prospectus.

The market value of the shares of Holdco common stock that Valtech shareholders and HeartWare stockholders will be entitled to receive at Closing could vary significantly from the market value of HeartWare common stock on the date of this proxy statement/prospectus. Because the number of shares of Holdco common stock issued to the Recipient Parties will not be adjusted to reflect any changes in the market value of HeartWare common stock, such market price fluctuations may affect the value that Valtech shareholders will receive at Closing. Share price changes may result from a variety of factors, including changes in the business, operations or prospects of HeartWare or Valtech, market assessments of the likelihood that the Transactions will be completed, the timing of the Transactions, regulatory considerations, general market and economic conditions and other factors. Shareholders are urged to obtain current market quotations for HeartWare common stock. See "*Comparative Per Share Data*" beginning on page 132 for additional information on the market value of HeartWare common stock.

HeartWare and Valtech must obtain required approvals and governmental and regulatory consents to consummate the Transactions, which, if delayed, not granted or granted with unacceptable conditions, may jeopardize or delay the consummation of the Transactions, result in additional expenditures of money and resources and/or reduce the anticipated benefits of the Transactions.

The Transactions are subject to customary closing conditions. These closing conditions include, among others, the receipt of required approvals of HeartWare stockholders and Valtech shareholders, the effectiveness of the registration statement, the expiration or termination of applicable waiting periods under the HSR Act and certain other approvals.

The governmental agencies from which the parties will seek certain of these approvals and consents have broad discretion in administering the governing regulations. HeartWare and Valtech can provide no assurance that all required approvals and consents will be obtained. Moreover, as a condition to their approval of the Transactions, agencies may impose requirements, limitations or costs or require divestitures or place restrictions on the conduct of Holdco's business after Closing. These requirements, limitations, costs, divestitures or restrictions could jeopardize or delay the consummation of the Transactions or reduce the anticipated benefits of the Transactions. Further, no assurance can be given that the required shareholder approvals will be obtained or that the required closing conditions will be satisfied, and, if all required consents and approvals are obtained and the closing conditions are satisfied, no assurance can be given as to the terms, conditions and timing of the approvals. If HeartWare and Valtech agree to any material requirements, limitations, costs, divestitures or restrictions in order to obtain any approvals required to consummate the Transactions, these requirements, limitations, costs, divestitures or restrictions could adversely affect Holdco's ability to integrate HeartWare andValtech's operations and/or reduce the anticipated benefits of the Transactions. This could result in a failure to consummate the Transactions or have a material adverse effect on Holdco's business and results of operations.

The Business Combination Agreement contains provisions that require HeartWare to pay to Valtech a termination fee in the form of a loan if the Business Combination Agreement is terminated.

If the Business Combination Agreement is terminated in accordance with the Business Combination Agreement, HeartWare will be required to make a loan to Valtech in the amount of $30 million. Neither party is entitled to terminate the Business Combination Agreement if the Closing has not occurred by the specified termination date if the failure of the Closing to occur by such date principally arises out of or is related to such party's failure to fulfill any obligation under the Business Combination Agreement.

Failure to consummate the Transactions could negatively impact the value and the future business and financial results of HeartWare and/or Valtech.

If the Transactions are not consummated, the ongoing businesses of HeartWare and/or Valtech may be adversely affected and, without realizing any of the benefits of having consummated the Transactions, HeartWare and/or Valtech will be subject to a number of risks, including the following:

- HeartWare and/or Valtech will be required to pay costs and expenses relating to the proposed Transactions;
- if the Business Combination Agreement is terminated for any reason, HeartWare will be required to make a loan to Valtech in the amount of $30 million;
- matters relating to the Transactions (including integration planning) may require substantial commitments of time and resources by HeartWare management and Valtech management, which could otherwise have been devoted to other opportunities that may have been beneficial to HeartWare or Valtech, as the case may be;
- the Business Combination Agreement restricts HeartWare and Valtech, without the other party's consent and subject to certain exceptions, from making certain acquisitions and taking other specified

actions until the Transactions occur or the Business Combination Agreement is terminated. These restrictions may prevent or increase the costs to, as applicable, HeartWare and Valtech from pursuing otherwise attractive business opportunities and making other changes to their businesses that may arise prior to completion of the Transactions or termination of the Business Combination Agreement; and

- HeartWare and/or Valtech also could be subject to litigation related to any failure to consummate the Transactions or related to any enforcement proceeding commenced against HeartWare and/or Valtech to perform their respective obligations under the Business Combination Agreement.

If the Transactions are not consummated, these risks may materialize and may adversely affect HeartWare and/or Valtech's business, financial results and share price.

While the Transactions are pending, HeartWare and Valtech will be subject to business uncertainties that could adversely affect their businesses.

Uncertainty about the effect of the Transactions on employees, customers and suppliers may have an adverse effect on HeartWare and Valtech and, consequently, on Holdco. These uncertainties may impair HeartWare's and Valtech's ability to attract, retain and motivate key personnel until the Transactions are consummated and for a period of time thereafter. Employee retention may be particularly challenging during the pendency of the Transactions because employees may experience uncertainty about their future roles with Holdco. If, despite HeartWare's and Valtech's retention efforts, key employees depart because of issues relating to the uncertainty and difficulty of integration or a desire not to remain with Holdco, Holdco's business could be seriously harmed.

The Opinion of HeartWare's financial advisor does not reflect changes in circumstances that may occur between the execution of the Business Combination Agreement and the consummation of the Transactions.

The HeartWare Board has not obtained an updated opinion from Canaccord Genuity as of the date of this proxy statement/prospectus and does not expect to receive an updated, revised or reaffirmed opinion prior to the consummation of the Transactions. Changes in the operations and prospects of HeartWare, Valtech or Holdco, general market and economic conditions and other factors that may be beyond the control of HeartWare, Valtech or Holdco, and on which Canaccord Genuity's Opinion was based, may significantly alter the value of Valtech or the price of HeartWare common stock or shares of Holdco common stock by the time the Transactions are completed. The Opinion does not speak as of the time the Transactions will be consummated or as of any date other than the date of such Opinion. Because Canaccord will not be updating its Opinion, the Opinion will not address the fairness to HeartWare of the Valtech Merger Consideration from a financial point of view at the time the Transactions are consummated. The HeartWare Board's recommendation that HeartWare stockholders vote "**FOR**" the proposal described herein is made as of the date of this proxy statement/prospectus. For a description of the Opinion the HeartWare Board received from Canaccord Genuity, please refer to the section entitled "*The Transactions – Opinion of Canaccord Genuity*" beginning on page 53 of this proxy statement/prospectus.

Risks Relating to the Businesses of the Combined Company

Mitral and tricuspid valve repair and replacement represent a significant, unmet clinical need, which requires technological and market development that may (i) not be achieved at all or (ii) take longer to realize than expected.

Currently, mitral and tricuspid valve repair and replacement represent an underpenetrated market, which may be accessed through the introduction of new technologies, including transcatheter medical devices. Physician confidence in and market acceptance of new technologies is speculative and may not be realized, or take longer or cost more to realize than anticipated.

Uncertainties associated with the Transactions may cause a loss of employees and may otherwise materially adversely affect the future business and operations of the combined company.

The combined company's success after the Transactions will depend in part upon the ability of the combined company to retain executive officers and key employees of HeartWare and Valtech. In some of the fields in which HeartWare and Valtech operate, the competition for qualified personnel is particularly intense and there are only a limited number of people in the job market who possess the requisite skills and it may be difficult for the combined company to hire personnel over time. The combined company will operate in several geographic locations, including parts of Israel and Massachusetts, where the labor markets are particularly competitive. The combined company may experience difficulty in hiring and retaining sufficient numbers of qualified management, manufacturing, technical, application engineering, marketing, sales and support personnel for parts or all of its business.

Current and prospective employees of HeartWare and Valtech may experience uncertainty about their roles with the combined company following the Transactions. In addition, key employees may depart because of issues relating to the uncertainty and difficulty of integration or a desire not to remain with the combined company following the Transactions. The loss of services of any key personnel or the inability to hire new personnel with the requisite skills could restrict the ability of the combined company to develop new products or enhance existing products in a timely matter, to sell products to customers or to manage the business of the combined company effectively. Also, the business, financial condition and results of operations of the combined company could be materially adversely affected by the loss of any of its key employees, by the failure of any key employee to perform in his or her current position, or by the combined company's inability to attract and retain skilled employees, particularly engineers.

Third parties may claim that Holdco is infringing their intellectual property, and the combined company could suffer significant litigation or licensing expenses or be prevented from selling its products or services.

The medical device industry is characterized by uncertain and conflicting intellectual property claims and vigorous protection and pursuit of these rights. Each of HeartWare and Valtech may be involved in disputes regarding patent and other intellectual property rights. Each of HeartWare and Valtech may receive communications from third parties asserting that certain of its products, processes or technologies infringe upon third party patent rights, copyrights, trademark rights or other intellectual property rights. Third parties may claim that Holdco is infringing their intellectual property rights, and the combined company may be unaware of intellectual property rights of others that may cover some of its technology, products and services. Defending these claims may be costly and time consuming, and may divert the attention of management and key personnel from other business issues. The complexity of the technology involved and the uncertainty of intellectual property litigation increase these risks. Claims of intellectual property infringement also might require the combined company to enter into costly royalty or license agreements. Holdco may be unable to obtain royalty or license agreements on acceptable terms, or at all. Similarly, changing its products or processes to avoid infringing the rights of others may be costly or impractical and may be subject to regulatory approvals. The combined company may also be subject to significant damages or injunctions against development and sale of certain of its products and services. Resolution of whether any of the products or intellectual property of the combined company has infringed on valid rights held by others could have a material adverse effect on results of operations or financial condition and may require material changes in production processes and products.

The combined company will be subject to risks associated with doing business internationally.

The conduct of the combined business internationally is subject to certain risks inherent in international business, many of which are beyond the combined company's control. These risks include, among other things:

- adverse changes in tariff and trade protection measures;
- changes in foreign regulatory requirements;

- potentially negative consequences from changes in or interpretations of tax laws;
- differing labor regulations;
- differing product liability regimes;
- changing economic conditions in countries where the combined company's products are sold or manufactured or in other countries;
- differing local product preferences and product requirements, including regulatory requirements;
- exchange rate risks;
- restrictions on the repatriation of funds;
- political unrest and hostilities;
- differing degrees of protection for intellectual property; and
- difficulties in coordinating and managing foreign operations.

In addition, foreign sales subject the combined business to numerous stringent United States and foreign laws, including the Foreign Corrupt Practices Act ("FCPA"), and comparable foreign laws and regulations which prohibit improper payments or offers of payments to foreign governments and their officials and political parties by United States and other business entities for the purpose of obtaining or retaining business. As the combined company expands its international operations, there is some risk of unauthorized payments or offers of payments by one of the combined company's employees, consultants, sales agents or distributors, which could constitute a violation by the combined company of various laws including the FCPA, even though such parties are not always subject to the combined company's control. Safeguards that the combined company implements to discourage these practices may prove to be less than effective and violations of the FCPA and other laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against the combined company, including class action lawsuits and enforcement actions from the SEC, Department of Justice and overseas regulators, which could adversely affect the combined company's reputation, business, financial condition and results of operations.

Any of these factors, or any other international factors, could have a material adverse effect on the combined company, financial condition and results of operations. There can be no assurance that the combined company can successfully manage these risks or avoid their effects.

We may not realize all of the anticipated benefits of the Transactions or those benefits may take longer to realize than expected. We may also encounter significant unexpected difficulties in integrating the two businesses.

Our ability to realize the anticipated benefits of the Transactions will depend, to a large extent, on our ability to integrate the HeartWare and Valtech businesses. The combination of two independent businesses has the potential to be a complex, costly and time-consuming process. As a result, we will be required to devote significant management attention and resources to integrating the business practices and operations of HeartWare and Valtech. The integration process may disrupt the businesses and, if implemented ineffectively, would preclude realization of the full benefits expected of the Transactions. Our failure to meet the challenges involved in integrating the two businesses and to realize the anticipated benefits of the Transactions could cause an interruption of, or a loss of momentum in, the activities of HeartWare and Valtech and could adversely affect Holdco's operational results.

In addition, the overall integration of the businesses may result in material unanticipated problems, expenses, liabilities, competitive responses, loss of customer relationships, and diversion of management's attention. The difficulties of combining the operations of the companies include, among others:

- the diversion of management's attention to integration matters;
- difficulties in achieving anticipated synergies, business opportunities and growth prospects from combining the business of HeartWare with that of Valtech;

- difficulties in the integration of operations and systems;
- difficulties in the assimilation of employees;
- difficulties in managing the expanded operations of a larger and more complex company;
- challenges in keeping existing customers and obtaining new customers; and
- challenges in attracting and retaining key personnel.

Many of these factors will be outside of our control and any one of them could result in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy, which could materially impact the business, financial condition and results of operations of Holdco. In addition, the risks relating to the businesses of Valtech and the combined company are similar to the risks relating to HeartWare's business, including but not limited to, risks relating to intellectual property, competition, regulatory matters, future growth and the medical device industry. Even if the operations of the businesses of HeartWare and Valtech are integrated successfully, we may not realize the full benefits of the Transactions, including the synergies or sales or growth opportunities that we expect. These benefits may not be achieved within the anticipated time frame, or at all. Or, additional unanticipated costs may be incurred in the integration of the businesses of HeartWare and Valtech. All of these factors could cause dilution to the earnings per share of Holdco, decrease or delay the expected accretive effect of the Transactions, and negatively impact the price of Holdco's ordinary shares. As a result, we cannot assure you that the combination of the HeartWare and Valtech businesses will result in the realization of the full benefits anticipated from the Transactions.

Holdco will incur direct and indirect costs as a result of the Transactions.

Holdco will incur costs and expenses in connection with and as a result of the Transactions. These costs and expenses include costs related to expanded research and development expenditure, market development activities, creation of a field sales force, and greater scaling of manufacturing capacity, as well as any additional costs Holdco may incur going forward as a result of its new corporate structure. These costs may exceed the costs historically borne by HeartWare and Valtech.

HeartWare's and Valtech's actual financial positions and results of operations may differ materially from the unaudited pro forma financial data included in this proxy statement/prospectus.

The pro forma financial information contained in this proxy statement/prospectus is presented for illustrative purposes only and may not be an indication of what Holdco's financial position or results of operations would have been had the Transactions been completed on the dates indicated. The pro forma financial information has been derived from the audited and unaudited historical financial statements of HeartWare and Valtech and certain adjustments and assumptions have been made regarding the combined company after giving effect to the Transactions. The assets and liabilities of Valtech have been measured at fair value based on various preliminary estimates using assumptions that HeartWare management believes are reasonable utilizing currently available information. The process for estimating the fair value of acquired assets and assumed liabilities requires the use of judgment in determining the appropriate assumptions and estimates. These estimates may be revised as additional information becomes available and as additional analyses are performed. Differences between preliminary estimates in the pro forma financial information and the final acquisition accounting will occur and could have a material impact on the pro forma financial information and the combined company's financial position and future results of operations.

In addition, the assumptions used in preparing the pro forma financial information may not prove to be accurate, and other factors may affect Holdco's financial condition or results of operations following Closing. Any potential decline in Holdco's financial condition or results of operations may cause significant variations in the share price of Holdco. Please see "*Unaudited Pro Forma Condensed Combined Financial Statements*" beginning on page 79.

The shares of Holdco common stock to be received by HeartWare stockholders and Valtech shareholders in connection with the Transactions will have different rights from the HeartWare common stock and the Valtech shares.

Upon completion of the Transactions, HeartWare stockholders and Valtech shareholders will become Holdco stockholders and their rights as stockholders will be governed by Holdco's Certificate of Incorporation and Bylaws and Delaware law. The rights associated with each of the HeartWare common stock and Valtech ordinary shares are different than the rights associated with shares of Holdco common stock. Material differences between the rights of stockholders of HeartWare and the rights of shareholders of Holdco include differences with respect to among other things, exclusive forum provisions, stockholder actions, stockholder proposals and nominations, and Australian exchange listing rules (which no longer applies). Material differences between the rights of Holdco shareholders following the Transactions and the rights of Valtech shareholders before the Transactions include, among other things, differences with respect to the board of directors and the special rights of preferred shareholders. See "*Comparison of the Rights of Holders of HeartWare Common Stock and Holdco Common Stock*" beginning on page 144 and "*Comparison of the Rights of Holders of Valtech Shares and Holdco Common Stock*" beginning on page 146.

Risks Relating to Valtech's Business

If Valtech fails to successfully introduce its products to the market, Valtech's growth prospects may suffer.

If Valtech is slow in bringing its products to market or otherwise fails to successfully develop, manufacture, design clinical trials for, obtain regulatory approvals of, introduce or commercialize its product pipeline on a timely basis, or if products are not well accepted by the market, Valtech's growth prospects may suffer.

Valtech has never generated any revenue from product sales and may never be profitable.

To date, Valtech has no commercial sales and has never generated any revenue from commercial product sales. Valtech's ability to generate revenue and achieve profitability depends on Valtech's ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize, one or more of its product candidates. Neither Valtech nor the combined company can predict when it will begin generating revenue from product sales, as this depends heavily on Valtech's success in many areas, including but not limited to:

- attracting, hiring and retaining qualified personnel;
- completing nonclinical and clinical development of Valtech's product candidates;
- developing and testing of Valtech's product designs;
- obtaining regulatory and marketing approvals for product candidates for which Valtech has completed clinical studies;
- developing a sustainable and scalable manufacturing process for any approved product candidates and establishing and maintaining supply and manufacturing relationships with third parties that can process and provide adequate (in amount and quality) products to support clinical development and the market demand for Valtech's product candidates, if approved;
- launching and commercializing product candidates for which Valtech obtains regulatory and marketing approval, either directly or with collaboration partners or distributors;
- obtaining adequate third-party coverage and reimbursements for Valtech's products;
- obtaining market acceptance of Valtech's product candidates as viable treatment options;
- addressing any competing technological and market developments;

- identifying, assessing and developing (or acquiring/in-licensing) new product candidates;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter; and
- maintaining, protecting and expanding Valtech's portfolio of intellectual property rights, including patents, trade secrets and know-how.

Even if the product candidates that Valtech develops is approved for commercial sale, it anticipates incurring significant costs to commercialize Valtech's products. Valtech's expenses could increase beyond expectations if Valtech is required by the U.S. Food and Drug Administration, the European Medicines Agency, other regulatory agencies, domestic or foreign, or by any unfavorable outcomes in intellectual property litigation filed against Valtech, to change Valtech's manufacturing processes or to perform clinical, nonclinical or other types of studies in addition to those that Valtech currently anticipates. If the market for Valtech's product candidates (or Valtech's share of that market) is not as significant as expected, the indication approved by regulatory authorities is narrower than expected or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, Valtech may not generate significant revenue from sales of such products, even if approved. If Valtech is unable to successfully complete development and obtain regulatory approval for Valtech's product candidates, particularly Cardioband and Cardiovalve, Valtech's future business and the business of the combined company may suffer. Additionally, if Valtech is not able to generate revenue from the sale of any approved products, Valtech and the combined company may never become profitable.

Claims that Valtech's current or future products infringe or misappropriate the proprietary rights of others could adversely affect Valtech or the combined company's ability to sell those products and cause Valtech or the combined company to incur additional costs.

Substantial litigation over intellectual property rights exists in the medical device industry. HeartWare and Valtech expect that Valtech could be increasingly subject to third-party infringement claims as its revenue increases, the number of technology holders grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which Valtech's current or future products or technologies may allegedly infringe.

There can be no certainty that litigation will not arise in relation to third party intellectual property or, if it does arise, whether or not it will be determined in a manner which is favorable to Valtech. Any litigation, regardless of its outcome, would likely result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, litigation in which Valtech is accused of infringement may cause negative publicity, adversely impact prospective customers, cause product shipment delays, prohibit Valtech and the combined company from manufacturing, marketing or selling Valtech's current or future products, require Valtech to develop non-infringing technology, make substantial payments to third parties or enter into royalty or license agreements, which may not be available on acceptable terms or at all. If a successful claim of infringement were made against Valtech and Valtech could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, the expected future revenue of Valtech or the combined company may decrease substantially and Valtech or the combined company could be exposed to significant liability. A court could enter orders that temporarily, preliminarily or permanently enjoin Valtech or Valtech's customers from making, using, selling, offering to sell or importing Valtech's current or future products, or could enter an order mandating that we undertake certain remedial activities. Claims that Valtech has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on Valtech's reputation, business, financial condition or results of operations.

If Valtech is unable to commence or complete successfully its clinical trials, or if it experiences significant delays in the successful commencement or completion of its clinical trials, Valtech's ability to obtain regulatory approval to commercialize its products, and its ability to generate revenue, will be materially adversely affected.

Regulatory approvals to sell Valtech's existing and future products typically require clinical trials, which can be time consuming, unpredictable and expensive. Significant technical, bench and preclinical testing may be required prior to submitting for regulatory authorization to commence a clinical trial. The cost, timing and outcome of any of these trials or testing may be unfavorable or may be insufficient to obtain the required approvals.

Completion of any of Valtech's clinical trials could be delayed or adverse events during a trial could cause Valtech to amend, repeat or terminate the trial. If this were to happen, Valtech's costs associated with the trial will increase, and it will take Valtech longer to obtain regulatory approvals and to commercialize the product, or Valtech may never obtain regulatory approvals. Valtech's clinical trials may also be suspended or terminated at any time by regulatory authorities, the data safety and monitoring board, site investigational review boards, or by Valtech including during the closing stages of enrollment of the trial and the subsequent patient data follow-up period in the event that, for example, there should be an unacceptable level of adverse clinical events. Any failure or significant delay in completing clinical trials for Valtech's products may materially harm Valtech's or the combined company's financial results and the commercial prospects for Valtech's products.

The completion of any of Valtech's clinical trials could be substantially delayed or prevented by several factors, including: slower than expected rates of patient recruitment and enrollment, including as a result of study inclusion and exclusion criteria; Valtech's competitors undertaking similar clinical trials at the same time as Valtech, or having functionally comparable products that have received approval for sale; physicians or patients preferring to use approved devices or other experimental treatments or devices rather than Valtech's devices; prevalence and severity of adverse events, such as thrombus or stroke rates, and other unforeseen safety issues; and governmental and regulatory delays or changes in regulatory requirements, policies or guidelines.

If Valtech fails to protect its intellectual property rights, its competitors may take advantage of its ideas and compete directly against Valtech or the combined company.

Valtech's success will depend to a significant degree on Valtech's ability to secure and protect intellectual property rights and to enforce patent and trademark protections relating to Valtech's technology. From time to time, litigation may be advisable to protect Valtech's intellectual property position. However, these legal means afford only limited protection and may not adequately protect Valtech's rights or permit it to gain or keep any competitive advantage. Any litigation in this regard could be costly, and it is possible that Valtech will not have sufficient resources to fully pursue litigation or to protect Valtech's other intellectual property rights. Litigation could result in the rejection or invalidation of Valtech's existing and future patents. Any adverse outcome in litigation relating to the validity of Valtech's patents, or any failure to pursue litigation or otherwise to protect Valtech's patent position, could have a material adverse effect on the future business, financial condition, results of operations and cash flows of Valtech or the combined company. Also, even if Valtech prevails in litigation, the litigation would be costly in terms of management distraction as well as in terms of cash resources.

Consolidation in the health care industry could have an adverse effect on Valtech's expected revenues and results of operations.

Many health care industry companies, including health care systems, are consolidating to create new companies with greater market power. As the health care industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for medical devices that Valtech plans to produce and sell.

The continuing development of many of Valtech's products depends upon Valtech maintaining strong relationships with health care professionals. Notably, consolidation has occurred recently in the structural heart space as strategic players have acquired new technologies. Most of these players have greater financial resources and larger employee pools than Holdco and Valtech.

The research, development, marketing and sales of many of Valtech's proposed products is dependent upon Valtech maintaining working relationships with health care professionals. Valtech relies on these professionals to provide Valtech with knowledge and experience regarding the development, marketing and planned sale of Valtech's products. Health care professionals assist Valtech as researchers, marketing and product consultants, inventors and public speakers. If Valtech is unable to maintain Valtech's strong relationships with these professionals and continue to receive their advice and input, the development and marketing of Valtech's planned products could suffer, which could have a material adverse effect on Valtech's future earnings and financial condition.

Valtech's products are the subject of clinical trials, the results of which may be unfavorable, or perceived as unfavorable, and could have a material adverse effect on Valtech's future business, financial condition, and results of operations.

As a part of the regulatory process of obtaining marketing clearance or approval for new products and modifications to or new indications for existing products, Valtech conducts and participates in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials, or the market's or a regulatory body's perception of this clinical data, may adversely impact Valtech's ability to obtain product clearances or approvals in some or all geographies. Success in pre-clinical testing and early clinical trials does not always ensure that later clinical trials will be successful, and Valtech cannot be sure that later trials will replicate the results of prior trials and studies. Any delay or termination of Valtech's clinical trials will delay the filing of product submissions and, ultimately, Valtech's ability to commercialize new products or product modifications. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product's profile, which could inhibit further marketing and development of such products.

Valtech's success is related to management's performance.

To a large extent, Valtech's success is predicated on the ability of its management team to effectively manage Valtech and the individual businesses that it operates. The loss of the services of a senior manager or other key employee without an adequate replacement or the inability to attract and retain new and qualified resources could have a negative impact on Valtech's business outlook, activities and operating and financial results.

Valtech's business is dependent on its relationship with suppliers.

Valtech currently manufactures its products at its own facilities or through subcontractors located in various countries, purchasing the components and materials used to manufacture these products from various suppliers. However, specific components and raw materials are purchased from primary or main suppliers (or in some cases, a single supplier) for reasons related to quality assurance, cost-effectiveness and availability. While Valtech works closely with its suppliers to expand capacity and ensure supply continuity, it cannot guarantee that its efforts will always be successful. Moreover, due to the strict standards and regulations governing the manufacture and marketing of its products, Valtech may not be able to quickly locate new supply sources in response to a supply reduction or interruption, with negative effects on its ability to manufacture its products effectively and in a timely fashion.

Natural disasters, war, acts of terrorism and other events could adversely affect Valtech's future revenues and operating income.

Natural disasters (including pandemics), war, terrorism, labor disruptions and international conflicts, and actions taken by governmental entities or by Valtech's potential customers or suppliers in response to such events, could cause significant economic disruption and political and social instability in the areas in which Valtech operates.

Valtech needs to attract and retain key employees to be competitive.

Valtech's ability to compete effectively depends upon its ability to attract and retain executives and other key employees, including people in technical, marketing, sales and research positions. Competition for experienced employees, particularly for persons with specialized skills, can be intense. Valtech's ability to recruit such talent will depend on a number of factors, including compensation and benefits, work location and work environment. If Valtech cannot effectively recruit and retain qualified executives and employees, its business could be adversely affected.

Valtech is incorporated under the laws of, and its principal offices are located in, the State of Israel and therefore its business operations may be harmed by adverse political, economic and military conditions affecting Israel.

Valtech is incorporated under the laws of, and its principal executive offices and research and development facilities are located in, the State of Israel. In addition, some of its subcontractors and suppliers are located in Israel. Accordingly, political, economic and military conditions in Israel may directly affect its business.

In addition, a change in the security and political situation in Israel could have a material adverse effect on Valtech's business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. In recent years, these have included hostilities between Israel and Hezbollah in Lebanon, and Israel and Hamas in the Gaza Strip, both of which resulted in rockets being fired into Israel causing casualties and disruption of economic activities. In addition, Israel faces internal uprisings resulting in organized and individual violent behavior and external threats. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could affect adversely Valtech's operations. Ongoing and increased hostilities, the interruption or curtailment of trade between Israel and its trading partners or other Israeli political or economic factors could harm Valtech's operations and product development and cause its sales to decrease.

Civil unrest in various countries in the Middle East and North Africa are affecting the political stability of those countries. Such instability may lead to deterioration in the political and trade relationships that exist between the State of Israel and these countries. Furthermore, several countries, principally in the Middle East, restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies whether as a result of hostilities in the region or otherwise. In addition, any hostilities involving Israel could have a material adverse effect on Valtech's facilities. Similarly, Israeli corporations are limited in conducting business with entities from some countries in the region. These restrictive laws and policies may seriously limit Valtech's ability, and that of the combined company, to sell its products in these countries.

Valtech's property insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. However, the Israeli government is currently committed to covering the actual value of physical damages (but not business interruption costs) that are caused by terrorist attacks or acts of war, Valtech cannot assure you that this government coverage will be maintained, or if maintained, will be sufficient to compensate Valtech fully for damages incurred. Any losses or damages incurred by Valtech could have a material adverse effect on its business. Any armed conflicts or political instability in the region would likely negatively affect business conditions generally and could harm Valtech's results of operations.

In the past, Valtech received Israeli government grants for certain of its research and development activities. The terms of those grants may require Valtech to satisfy specified conditions in order to manufacture products and transfer technologies outside of Israel. Valtech may be required to pay penalties in addition to repayment of the grants.

Valtech's research and development efforts were financed in part, through grants that Valtech received from the OCS. Notwithstanding the full repayment of these OCS grants, Valtech nevertheless must continue to comply with the requirements of the Israeli Law for the Encouragement of Industrial Research and Development, 1984, and related regulations. When a company develops know-how, technology or products using OCS grants, the transfer of such know-how, and the transfer of manufacturing or manufacturing rights of such products, technologies or know-how outside of Israel is restricted without the prior approval of the OCS. Therefore, if aspects of Valtech's technologies are deemed to have been developed with OCS funding, the discretionary approval of an OCS committee would be required for any transfer to third parties outside of Israel of know-how or manufacturing rights related to those aspects of such technologies. Furthermore, the OCS may impose certain conditions on any arrangement under which it permits Valtech to transfer technology or development out of Israel. Valtech may not receive those approvals or Valtech may find these conditions unfavorable.

Valtech is subject to risks arising from currency exchange rates, which could increase its costs and may have a negative effect on its results of operations.

Inflation in Israel or Europe or a weakening of the U.S. dollar against other currencies may have the effect of increasing the U.S. dollar cost of Valtech's operations in that jurisdiction, which may have a material adverse impact on its results of operations. If the U.S. dollar declines in value in relation to one or more currencies, it may become more expensive to fund Valtech's operations in the jurisdictions that use those other currencies.

In the future, Valtech expects that a substantial portion of its revenues will be generated in U.S. Dollars and Euros. Valtech's financial records are maintained in New Israel Shekels ("NIS"), which is the functional currency of Valtech. As a result, Valtech's financial results might be affected by fluctuations in the exchange rates of currencies in the countries in which Valtech's products may be sold.

Currency exchange controls may restrict Valtech's ability to utilize our cash flows.

Valtech intends to receive proceeds from sales of any prospective product Valtech may develop and also to pay its operational costs and expenses in U.S. Dollars, Euros and other foreign currencies. However, Valtech may be subject to existing or future rules and regulations on currency conversion. In 1998, the Israeli currency control regulations were liberalized significantly, and there are currently no currency controls in place. Legislation remains in effect, however, pursuant to which such currency controls could be imposed in Israel by administrative action at any time. Valtech cannot assure you that such controls will not be reinstated, and if reinstated, would not have an adverse effect on Valtech's operations.

It may be difficult to enforce a U.S. judgment against Valtech, Valtech executive officers and directors and some of the experts named in this proxy statement/prospectus, or assert U.S. securities law claims in Israel.

It may be difficult to effect service of process on some or all of Valtech's executive officers, directors and the experts named in this proxy statement/prospectus. Furthermore, much of Valtech's assets and some of the assets of Valtech's executive officers and directors and some of the experts named in this proxy statement/prospectus are located outside the United States. Therefore, a judgment obtained against Valtech or any of Valtech's executive officers or directors in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States and may not be enforced by an Israeli court. It also may be difficult to assert U.S. securities law claims in original actions instituted in Israel.

Israeli courts may refuse to hear a claim based on an alleged violation of U.S. securities laws reasoning that Israel is not the most appropriate forum in which to bring such a claim. Even if an Israeli court agrees to hear such a claim, it may determine that Israeli, and not U.S., law is applicable to the claim. Under Israeli law, if U.S. law is found to be applicable to such a claim, the content of applicable U.S. law must be proved as a fact by expert witness, which can be a time-consuming and costly process, and certain matters of procedure would be governed by Israeli law. There is little binding case law in Israel addressing these matters.

Furthermore, Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against Valtech.

It is recommended that each stockholder or shareholder consult his or her own tax advisor as to the tax consequences of holding shares in, and receiving dividends from, Holdco. Holdco does not presently anticipate distributing dividends.