
**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 March 31, 2010

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER: 001-34256

HEARTWARE INTERNATIONAL, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State of Incorporation)

26-3636023

(I.R.S. Employer Identification No.)

205 Newbury Street, Suite 101
Framingham, Massachusetts 01701
+1 508 739 0950

(Address of principal executive offices)
(Registrant's telephone number, including area code)

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

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

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

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

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

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

Class

Shares Outstanding as of April 23, 2010

Common Stock, \$0.001 Par Value Per Share

13,635,054

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References

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

- “HeartWare,” “the Company,” “HeartWare Group,” “we,” “us” and “our” refer to HeartWare International, Inc. and its consolidated subsidiaries, HeartWare Pty. Limited, HeartWare, Inc., HeartWare GmbH and HeartWare Limited.
- “HeartWare International, Inc.” refers to HeartWare International, Inc., a Delaware corporation incorporated on July 29, 2008.
- “HeartWare Pty. Limited” refers to HeartWare Pty. Limited (formerly known as HeartWare Limited), an Australian proprietary corporation originally incorporated on November 26, 2004.
- “HeartWare, Inc.” refers to HeartWare, Inc., a Delaware corporation incorporated on April 3, 2003. HeartWare, Inc. was acquired by HeartWare Pty. Limited on January 24, 2005.
- HeartWare GmbH refers to HeartWare GmbH, a German corporation established on February 19, 2010.
- HeartWare Limited refers to HeartWare Limited, a limited liability corporation established in the United Kingdom on February 19, 2010.

Currency

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

Trademarks

HEARTWARE, HVAD and MVAD, KRITON and various company logos are the trademarks of the Company, in the United States, Australia and other countries. All other trademarks and trade names mentioned in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

	March 31, 2010	December 31, 2009
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 87,282,917	\$ 50,834,714
Short-term investments, net	16,599,360	—
Accounts receivable	7,851,844	11,384,647
Inventories, net	11,991,051	8,870,903
Prepaid expenses and other current assets	2,909,853	1,663,157
Total current assets	126,635,025	72,753,421
Property, plant and equipment, net	4,313,077	3,719,415
Other intangible assets, net	1,305,913	1,191,917
Restricted cash	288,429	288,429
Total assets	<u>\$ 132,542,444</u>	<u>\$ 77,953,182</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,711,834	\$ 3,122,131
Accrued expenses and other current liabilities	3,783,639	3,848,086
Total current liabilities	5,495,473	6,970,217
Commitments and contingencies		
Stockholders' equity:		
Preferred stock — \$.001 par value; 5,000,000 shares authorized; no shares issued and outstanding at March 31, 2010 and December 31, 2009	—	—
Common stock — \$.001 par value; 25,000,000 shares authorized; 13,632,197 and 11,786,173 shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively	13,632	11,786
Additional paid-in capital	237,251,879	176,698,329
Accumulated deficit	(102,415,960)	(97,871,645)
Accumulated other comprehensive loss:		
Cumulative translation adjustments	(7,778,788)	(7,855,505)
Unrealized loss on short-term investments	(23,792)	—
Total stockholders' equity	<u>127,046,971</u>	<u>70,982,965</u>
Total liabilities and stockholders' equity	<u>\$ 132,542,444</u>	<u>\$ 77,953,182</u>

The accompanying notes are an integral part of these financial statements

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

	Three Months Ended March 31,	
	2010	2009
Revenues, net	\$ 10,703,120	\$ 1,477,796
Cost of revenues	<u>5,680,542</u>	<u>718,308</u>
Gross profit	5,022,578	759,488
Operating expenses:		
Selling, general and administrative	4,556,422	4,199,663
Research and development	<u>4,755,678</u>	<u>3,489,780</u>
Total operating expenses	9,312,100	7,689,443
Loss from operations	(4,289,522)	(6,929,955)
Other income (expense):		
Foreign exchange (loss) gain	(367,014)	692,548
Interest income, net	112,221	6,756
Other, net	<u>—</u>	<u>(2,032)</u>
Loss before income taxes	(4,544,315)	(6,232,683)
Provision for income taxes	<u>—</u>	<u>—</u>
Net loss	<u>\$ (4,544,315)</u>	<u>\$ (6,232,683)</u>
Net loss per common share — basic and diluted	<u>\$ (0.35)</u>	<u>\$ (0.70)</u>
Weighted average shares outstanding — basic and diluted	<u>12,958,326</u>	<u>8,866,889</u>

The accompanying notes are an integral part of these financial statements

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

	Three Months Ended March 31,	
	<u>2010</u>	<u>2009</u>
Net loss	\$ (4,544,315)	\$ (6,232,683)
Foreign currency translation adjustments	76,717	(586,560)
Unrealized loss on short-term investments	(23,792)	—
Comprehensive loss	<u>\$ (4,491,390)</u>	<u>\$ (6,819,243)</u>

The accompanying notes are an integral part of these financial statements

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

	<u>Common Shares</u>		<u>Additional</u>	<u>Accumulated</u>	<u>Accumulated</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>	<u>Paid-In</u>	<u>Deficit</u>	<u>Other</u>	
	<u>Issued</u>		<u>Capital</u>		<u>Comprehensive</u>	
					<u>Loss</u>	
Balance, December 31, 2009	11,786,173	\$ 11,786	\$176,698,329	\$ (97,871,645)	\$ (7,855,505)	\$ 70,982,965
Issuance of common stock pursuant to public offering, net of offering costs	1,767,900	1,768	58,487,069	—	—	58,488,837
Issuance of common stock pursuant to share-based awards	78,124	78	340,014	—	—	340,092
Share-based compensation expense	—	—	1,726,467	—	—	1,726,467
Net loss	—	—	—	(4,544,315)	—	(4,544,315)
Accumulated other comprehensive loss:						
Foreign currency translation adjustment	—	—	—	—	76,717	76,717
Unrealized loss on short-term investments	—	—	—	—	(23,792)	(23,792)
Balance, March 31, 2010	<u>13,632,197</u>	<u>\$ 13,632</u>	<u>\$237,251,879</u>	<u>\$(102,415,960)</u>	<u>\$ (7,802,580)</u>	<u>\$127,046,971</u>

The accompanying notes are an integral part of these financial statements

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

	Three Months Ended March 31,	
	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (4,544,315)	\$ (6,232,683)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	281,039	206,263
Amortization	23,226	16,385
Share-based compensation expense	1,726,467	294,479
Amortization of premium on short-term investments	21,448	—
Loss on disposal of assets	—	2,032
Change in operating assets and liabilities:		
Accounts receivable	3,553,778	(934,981)
Inventories, net	(3,120,148)	(3,176,566)
Prepaid expenses and other current assets	(1,244,721)	3,271
Accounts payable	(1,406,311)	1,105,260
Accrued expenses and other current liabilities	(83,833)	1,336,586
Net cash used in operating activities	(4,793,370)	(7,379,954)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of short-term investments	(16,644,600)	—
Additions to property, plant and equipment	(864,848)	(64,346)
Additions to patents	(137,222)	(202,583)
Net cash used in investing activities	(17,646,670)	(266,929)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock	62,760,450	—
Payment of offering costs	(4,259,079)	—
Proceeds from exercise of stock options	340,092	20,207
Net cash provided by financing activities	58,841,463	20,207
Effect of exchange rate changes on cash and cash equivalents	46,780	(585,262)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	36,448,203	(8,211,938)
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD	50,834,714	20,803,656
CASH AND CASH EQUIVALENTS — END OF PERIOD	\$ 87,282,917	\$ 12,591,718

The accompanying notes are an integral part of these financial statements

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

1. Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”) for reporting of interim financial information. Pursuant to such rules and regulations, certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States have been condensed or omitted. Accordingly, these statements do not include all the disclosures normally required by accounting principles generally accepted in the United States for annual financial statements and should be read in conjunction with Management’s Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited financial statements and notes thereto for the year ended December 31, 2009 included in our Annual Report on Form 10-K. The accompanying condensed consolidated balance sheet as of December 31, 2009 has been derived from our audited financial statements. The condensed consolidated statements of operations and cash flows for the three months ended March 31, 2010 are not necessarily indicative of the results to be expected for any future period or for the year ending December 31, 2010.

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.

2. Liquidity

The accompanying condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States, which contemplate continuation as a going concern. We have sustained substantial losses from operations since our inception, and such losses have continued through March 31, 2010. At March 31, 2010, we had an accumulated deficit of approximately \$102.4 million.

As discussed in Note 10, in February 2010, we completed a public offering of approximately 1.77 million shares of our common stock, including the underwriters’ exercise of their over-allotment option to purchase 230,595 shares, at an offering price of \$35.50 per share for aggregate gross proceeds of approximately \$62.8 million. After fees and related expenses, net proceeds from the offering were approximately \$58.5 million.

In 2010, our cash and cash equivalents will primarily be used to fund our ongoing operations including expanding our sales and marketing capabilities on a global basis, commencing and conducting a US destination therapy clinical study, continued product development, regulatory and other compliance functions as well as for general working capital. We believe our cash, cash equivalents and investment balances are sufficient to support our planned operations for at least the next twelve months.

3. Significant Accounting Policies

Principles of Consolidation

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

Accounting Estimates

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

Cash and Cash Equivalents

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

Investments

Our investments classified as available-for-sale are stated at fair value with unrealized gains and losses reported in accumulated other comprehensive loss within stockholders’ equity. We classify our available-for-sale investments as short-term if their remaining time to maturity is beyond three months and less than twenty-four months. Interest on investments classified as available-for-sale is included in interest income.

Receivables

Accounts receivable consists of amounts due from the sale of our HeartWare Left Ventricular Assist System (the “HeartWare System”) to our customers, which are primarily hospitals and health research institutions. As of March 31, 2010, one customer had an accounts receivable balance greater than 10% of total accounts receivable, representing approximately 12% of our total accounts receivable. As of December 31, 2009, one customer had an accounts receivable balance greater than 10% of total accounts receivable, representing approximately 16% of our total accounts receivable. As of March 31, 2010 and December 31, 2009, there was no allowance for doubtful accounts and no allowance for returns.

Inventories, net

Inventories are stated at the lower of cost or market. Cost is determined using a first-in, first-out, or FIFO, method. Work-in-process and finished goods includes direct and indirect labor and manufacturing overhead. Finished goods includes product which is ready-for-use and which is held by us or by our customers on a consignment basis. We review our inventory for excess or obsolete inventory and write-down obsolete or otherwise unmarketable inventory to its estimated net realizable value.

Product Warranty

Certain patient accessories sold with the HeartWare System are covered by a limited manufacturer’s warranty ranging from one to two years. Estimated contractual warranty obligations are recorded as an expense when the related revenue is recognized and is included in “Cost of revenues” on our condensed consolidated statements of operations. Factors that affect estimated warranty liability include the number of units sold, historical and anticipated rates of warranty claims and cost per claim. We periodically assess the adequacy of our recorded warranty liabilities and adjust the amounts as necessary. The amount of the reserve recorded is equal to the estimated costs to repair or otherwise satisfy claims made by customers. Accrued warranty expense is included as a component of accrued expenses and other current liabilities on the condensed consolidated balance sheet.

The costs to repair or replace products associated with product recalls and voluntary service campaigns, recorded when they are determined to be probable and reasonably estimable, are recorded as a cost of revenues and are not included in product warranty liability.

The following table summarizes the change in our warranty reserve for the three months ended March 31, 2010 and 2009:

	Three months ended March 31,	
	2010	2009
Beginning balance	\$ 99,169	\$ —
Accrual for warranties	40,962	—
Warranty costs incurred during the period	(21,075)	—
Ending balance	<u>\$ 119,056</u>	<u>\$ —</u>

Fair Value Measurements

The carrying amounts reported in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, accounts payable and accrued expenses and other current liabilities approximate their fair value based on the short-term maturity of these instruments. Short-term investments are considered available-for-sale as of March 31, 2010 and are carried at fair value. See Note 5 “Fair Value Measurements” for more information.

Vendor Concentration

For the three months ended March 31, 2010, we purchased approximately 53.4% of our inventory components and supplies from three vendors. In addition, one of the three vendors supplies consulting services and material used in research and development activities. As of March 31, 2010, the amounts due to these vendors totaled approximately \$633,000.

Concentration of Credit Risk

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

Concentration of credit risk with respect to our trade accounts receivable to our customers is primarily limited to hospitals and health research institutions. Credit is extended to our customers, based on an evaluation of a customer’s financial condition and collateral is not required. To date, we have not experienced any credit losses.

New Accounting Standards

In October 2009, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2009-14, *Software (Topic 985): Certain Revenue Arrangements That Include Software Elements (a consensus of the FASB Emerging Issues Task Force)*. ASU No. 2009-14 amends ASC 985-605, *Software: Revenue Recognition*, such that tangible products, containing both software and non-software components that function together to deliver the tangible product’s essential functionality, are no longer within the scope of ASC 985-605. It also amends the determination of how arrangement consideration should be allocated to deliverables in a multiple-deliverable revenue arrangement. ASU No. 2009-14 will become effective for us for revenue arrangements entered into or materially modified after our fiscal year ending December 31, 2010. Earlier application is permitted with required transition disclosures based on the period of adoption. Adoption of the provisions of ASU No. 2009-14 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

In January 2010, the FASB issued ASU No. 2010-6, *Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements*. This update requires new disclosures for fair value measurements and provides clarification for existing disclosures requirements. The majority of the new disclosure requirements became effective for us on January 1, 2010. Certain of the disclosure requirements will be effective for us on January 1, 2011. As ASU No. 2010-6 only requires enhanced disclosures, the adoption of ASU No. 2010-6 did not have a material effect on our consolidated financial position, results of operations or cash flows and did not materially expand our financial statement footnote disclosures.

In April 2010, the FASB issued ASU No. 2010-13, *Compensation-Stock Compensation (Topic 718): Effect of Denominating the Exercise Price of a Share-Based Payment Award in the Currency of the Market in Which the Underlying Equity Security Trades*. ASU No. 2010-13 clarifies that an employee share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity securities trades should not be considered to contain a condition that is not a market, performance, or service condition. Therefore, an entity would not classify such an award as a liability if it otherwise qualifies as equity. The provisions of ASU No. 2010-13 will be effective for us on January 1, 2011. Early adoption is permitted. Adoption of the provisions of ASU No. 2010-13 is not expected to have a material effect on our consolidated financial position, results of operations or cash flows.

4. Investments

We have cash investment policies that limit investments to investment grade securities. At March 31, 2010, all of our investments were classified as available-for-sale and are carried at fair value. All of our investments had maturity dates of less than twenty-four months and were classified as short-term. Such investments consist of US corporate debt securities.

The amortized cost and fair value of our short-term investments, with gross unrealized gains and losses, at March 31, 2010 is as follows:

	<u>Amortized Cost Basis</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized Losses</u>	<u>Aggregate Fair Value</u>
US corporate bonds and notes	<u>\$ 16,623,152</u>	<u>\$ —</u>	<u>\$ (23,792)</u>	<u>\$ 16,599,360</u>
Total short-term investments	<u>\$ 16,623,152</u>	<u>\$ —</u>	<u>\$ (23,792)</u>	<u>\$ 16,599,360</u>

In the three month periods ended March 31, 2010 and 2009, we did not have any realized gains or losses on our investments.

5. Fair Value Measurements

FASB ASC 820 — *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. FASB ASC 820 requires disclosures about the fair value of all financial instruments, whether or not recognized, for financial statement purposes. Disclosures about the fair value of financial instruments are based on pertinent information available to us as of March 31, 2010 and December 31, 2009. Accordingly, the estimates presented in these condensed consolidated financial statements are not necessarily indicative of the amounts that could be realized on disposition of the financial instruments.

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

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

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

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

Level 3 — Instruments with primarily unobservable value drivers.

The fair values of our investments at March 31, 2010, based on the level of inputs are summarized below:

	Fair Value Measurements at the Reporting Date Using			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
US corporate bonds and notes	\$16,599,360	\$ —	\$16,599,360	\$ —
Total short-term investments	<u>\$16,599,360</u>	<u>\$ —</u>	<u>\$16,599,360</u>	<u>\$ —</u>

6. Inventories, Net

Components of Inventories, net are as follows:

	March 31, 2010	December 31, 2009
Raw material	\$ 4,316,776	\$ 2,984,486
Work-in-process	1,155,312	1,497,591
Finished goods	6,518,963	4,388,826
	<u>\$11,991,051</u>	<u>\$ 8,870,903</u>

Finished goods inventories includes inventory held on consignment at customer sites of \$3.3 million and \$3.8 million, at March 31, 2010 and December 31, 2009, respectively.

7. Property, Plant and Equipment, Net

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

	Estimated Useful Lives	March 31, 2010	December 31, 2009
Machinery and equipment	5 to 7 years	\$ 5,737,829	\$ 5,295,217
Leasehold improvements	3 to 7 years	227,631	210,570
Office equipment, furniture and fixtures	5 to 7 years	301,114	278,587
Purchased software	5 to 7 years	881,076	487,388
		<u>7,147,650</u>	<u>6,271,762</u>
Less: accumulated depreciation		(2,834,573)	(2,552,347)
		<u>\$ 4,313,077</u>	<u>\$ 3,719,415</u>

8. Other Intangible Assets, net

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

Amortizable Intangible Assets	Weighted Average Life (Years)	March 31, 2010		December 31, 2009	
		Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents	15	\$1,493,867	\$ (187,954)	\$1,356,645	\$ (164,728)

Amortization expense for the three months ended March 31, 2010 and 2009 was \$23,226 and \$16,385, respectively.

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

	March 31, 2010	December 31, 2009
Accrued payroll and other employee costs	\$ 1,543,476	\$ 2,487,066
Accrued material purchases and repair and replacement costs	1,124,653	370,226
Accrued research and development expenses	500,900	344,256
Accrued professional fees	312,842	347,063
Other accrued expenses	301,768	299,475
	<u>\$ 3,783,639</u>	<u>\$ 3,848,086</u>

Accrued payroll and other employee costs include estimated year-end employee bonuses of approximately \$513,000 at March 31, 2010 and \$1.7 million of actual costs at December 31, 2009, respectively.

10. Stockholders' Equity

In February 2010, we completed a public offering of approximately 1.77 million shares of our common stock, including the underwriter's exercise of their overallotment to purchase 230,595 shares, at an offering price of \$35.50 per share for aggregate gross proceeds of approximately \$62.8 million. The underwriters for the transaction received a fee of 6% of the gross proceeds. After fees and related expenses, net proceeds from the offering were approximately \$58.5 million.

The offering was completed pursuant to a prospectus supplement, dated January 27, 2010, to a shelf registration statement on Form S-3 that was previously filed with the SEC and which was declared effective on January 20, 2010. This shelf registration statement allows us to offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination of the securities described in the prospectus, up to an aggregate amount of \$100 million.

11. Share-Based Compensation

We recognize share-based compensation expense for the portion of awards that are ultimately expected to vest using an accelerated accrual method over the vesting period. We estimate forfeitures at the time of grant. We have applied a forfeiture rate of approximately 12.5% to all unvested share-based awards as of March 31, 2010, which represents the portion that we expect will be forfeited over the vesting period. We reevaluate this analysis periodically and adjust the forfeiture rate as necessary. Vesting of share-based awards issued with performance-based vesting criteria must be “probable” before we begin recording share-based compensation expense. At each reporting period, we review the likelihood that these awards will vest and if the vesting is deemed probable, we begin to recognize compensation expense at that time. If ultimately performance goals are not met, for any awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed.

We allocate share-based compensation expense to cost of revenues, selling, general and administrative expense and research and development expense based on the award holders’ employment function. For the three months ended March 31, 2010 and 2009, we recorded share-based compensation expense as follows:

	Three Months Ended March 31,	
	2010	2009
Cost of revenues	\$ 268,650	\$ 15,887
Selling, general and administrative	902,058	140,217
Research and development	555,759	138,375
	<u>\$ 1,726,467</u>	<u>\$ 294,479</u>

No tax benefits were attributed to our share-based compensation expense 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.

HeartWare International, Inc. 2008 Stock Incentive Plan

On August 5, 2008, we adopted the HeartWare International, Inc. 2008 Stock Incentive Plan (“2008 SIP”). The 2008 SIP allows for the issuance of share-based awards to employees, directors and consultants. We have issued options and restricted stock units (“RSU’s”) to employees and directors under the 2008 SIP. The plan allows for the issuance of share-based awards representing up to 13% of the prior fiscal year’s weighted average shares outstanding, less share-based awards outstanding under our other equity plans. At March 31, 2010, there were approximately 398,000 shares available for future awards under the 2008 SIP. Future share-based awards will only be made from the 2008 SIP as awards granted under other plans reduce availability under the 2008 SIP.

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 fair market value 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.

In 2007 and 2008, we granted options with performance-based vesting criteria. These performance-based options vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones related primarily to the development of our products and the achievement of certain prescribed clinical and regulatory objectives. Any performance-based options that have not vested after five years from the date of grant automatically expire.

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model using the assumptions established at that time. The following table includes the assumptions used for options issued in the three months ended March 31, 2010. There were no options issued in the three months ended March 31, 2009.

	Three Months Ended March 31, 2010
Dividend yield	0%
Expected volatility	61.30%
Risk-free interest rate	2.90%
Estimated holding period (years)	6.25

Information related to options granted under all of our plans at March 31, 2010 and activity in the three months then ended is as follows (certain amounts in US\$ were converted from AU\$ at the then period-end spot rate):

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2009	520,835	\$ 27.96		
Granted	20,000	38.57		
Exercised	(10,992)	31.31		
Forfeited	(5,751)	26.17		
Expired	(6,707)	45.56		
Outstanding at March 31, 2010	<u>517,385</u>	\$ 28.72	7.11	\$ 8,149,120
Exercisable at March 31, 2010	<u>284,715</u>	\$ 29.79	6.29	\$ 4,180,714

The aggregate intrinsic values at March 31, 2010 noted in the table above represent the closing price of our common stock traded on NASDAQ, less the weighted average exercise price at period end multiplied by the number of options outstanding and exercisable.

At March 31, 2010, 36,076 of the 232,670 options outstanding that are not yet exercisable are subject to performance-based vesting criteria as described above.

The weighted average grant date fair value per share of options issued in the three months ended March 31, 2010 was \$22.99 per share. There were no options issued in the three months ended March 31, 2009.

The total intrinsic value of options exercised in the three months ended March 31, 2010 was approximately \$97,000. Cash received from options exercised in the three months ended March 31, 2010 was approximately \$340,000. The total intrinsic value of options exercised in the three months ended March 31, 2009 was approximately \$13,500. Cash received from options exercised in the three months ended March 31, 2009 was approximately \$20,000.

At March 31, 2010, there was approximately \$1.8 million of unrecognized compensation cost related to non-vested option awards, including performance-based options not yet deemed probable of vesting. The expense is expected to be recognized over a weighted average period of 1.4 years.

Restricted Stock Units

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

Information related to RSU's at March 31, 2010 and activity in the three months then ended is as follows (certain amounts in US\$ were converted from AU\$ at the then period-end spot rate):

	Number of Units	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2009	413,135		
Granted	15,500		
Vested/Exercised	(67,132)		
Forfeited	(4,357)		
Expired	—		
Outstanding at March 31, 2010	<u>357,146</u>	9.18	\$ 15,882,283
Exercisable at March 31, 2010	<u>—</u>	—	\$ —

The aggregate intrinsic value at March 31, 2010 noted in the table above represents the closing price of our common stock traded on NASDAQ, multiplied by the number of RSU's outstanding.

At March 31, 2010, 82,146 of the 357,146 RSU's outstanding that are not yet exercisable are subject to performance-based vesting criteria as described above.

The total intrinsic value of RSU's exercised in the three months ended March 31, 2010 was approximately \$2.6 million. There were no RSU's exercised in the three months ended March 31, 2009.

The fair value of each RSU award equals the quoted market value of our common stock on the date of grant. The weighted average grant date fair value per share of RSU's granted in the three months ended March 31, 2010 was \$38.57 per share. There were no RSU's issued in the three months ended March 31, 2009.

At March 31, 2010, there was approximately \$6.0 million of unrecognized compensation cost related to non-vested RSU awards, including awards not yet deemed probable of vesting. The expense is expected to be recognized over a weighted average period of 1.6 years.

12. Net Loss Per Common Share

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

	Three Months Ended March 31,	
	2010	2009
Common shares issuable upon:		
Exercise of share-based awards	874,531	837,678

13. Business Segment, Geographic Areas and Major Customers

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

Product sales by geographic location are as follows:

(in thousands)	Three Months Ended March 31,	
	2010	2009
Domestic	\$ 2,682	\$ 1,125
International	8,021	353
	<u>\$ 10,703</u>	<u>\$ 1,478</u>

For the three months ended March 31, 2010, two customers exceeded 10% of product sales individually and accounted for approximately 31% of product sales in the aggregate. For the three months ended March 31, 2009, four customers exceeded 10% of product sales individually and accounted for approximately 65% of product sales in the aggregate. The concentration of customers primarily results from a lower proportion of US-based revenue due to the completion of enrollment in our US bridge-to-transplant clinical trial in February 2010. As additional customers are acquired outside of the US and we begin enrolling patients in our anticipated US destination therapy clinical trial, the concentration of customers and relative sales volumes by geographic location will change.

14. Commitments and Contingencies

The following contingent liabilities and commitments resulting from the 2003 acquisition by HeartWare, Inc. of a business that previously held our technology exist as of March 31, 2010:

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

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

We will record the effect of these payment obligations when and if these events occur or are deemed probable of occurring.

At March 31, 2010, we had purchase order commitments of approximately \$14.0 million related to product costs and property, plant and equipment purchases. Many of our materials and supplies require long lead times and as such purchase order commitments reflect materials that may be received up to one year from the date of order.

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

From time to time we may be involved in litigation arising out of claims in the normal course of business. Except as set forth below, and based on the information presently available, management believes that there are no claims or actions pending or threatened against us, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or results of operations, although the results of litigation are inherently uncertain and adverse outcomes are possible.

We received a letter from Abiomed, Inc. in September 2009 in which Abiomed suggested that we “may be interested in licensing Abiomed’s technology” as it relates to an Abiomed patent concerning bearingless blood pumps. Further, in a subsequent letter received in February 2010, it was stated that Abiomed was “concerned that HeartWare’s left ventricular assist rotary blood pump infringes one or more claims” of an Abiomed patent. The patent referenced by these letters relates to technology that is potentially material to our business and any litigation in this regard, irrespective of the outcome, may have a material adverse effect on our financial position, liquidity or results of operations. We have ongoing communications with Abiomed regarding this patent and we believe that the HeartWare System does not infringe this patent.

On February 24, 2010, we received a letter from two holders of Series A Preferred Stock in HeartWare, Inc., an indirect subsidiary of HeartWare International, Inc., requesting various financial and other information regarding HeartWare, Inc. for the purposes of determining the Company’s compliance with their rights as Series A Preferred stockholders, including whether a liquidation event has occurred since inception in 2003. HeartWare, Inc. issued Series A-1 and Series A-2 Preferred Stock to certain creditors of Kriton Medical, Inc. when HeartWare, Inc. purchased substantially all of the assets of Kriton in July 2003. The Series A-1 and Series A-2 Preferred Stock do not have voting or dividend rights but entitle the holders thereof to receive, upon certain liquidation events of HeartWare, Inc. (but not the liquidation of or change of control of HeartWare International, Inc.), an amount equal to \$10 per share of Series A-1 and an amount equal to \$21 per share of Series A-2, which currently represent an aggregate liquidation preference of approximately \$15 million. We do not believe we have abrogated the rights, or in any way failed to satisfy obligations owed to any of our stockholders, including holders of Series A Preferred Stock in HeartWare, Inc.

There can be no certainty that litigation will not arise in relation to the above matters or, if it does arise, whether or not it will be determined in a manner which is favorable to us. As at the date of this report, we are not able to determine the amount, if any, of any costs or damages that could be associated with either of the above matters.

15. Subsequent Events

We have evaluated events and transactions that occurred subsequent to March 31, 2010 through the date the financial statements were issued, for potential recognition or disclosure in the accompanying condensed consolidated financial statements.

On April 23, 2010, as disclosed on a current report on Form 8-K dated April 26, 2010, and as discussed in Management's Discussion in Analysis — Cost of Revenues, we initiated a voluntary field corrective action resulting in replacements or in-field repairs of certain HeartWare controllers due to a small number of reported issues related to the reduced speaker volume in the controllers. The action taken will result in the repair or replacement of controllers in inventory, including held on consignment at customer sites, and units previously distributed through clinical trials or sold to customers. The total cost of the repairs and replacements is estimated at approximately \$400,000 and has been accrued for as of March 31, 2010 as part of cost of revenues.

Other than the disclosures above, 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

Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on our management's beliefs, assumptions and expectations and on information currently available to our management. Generally, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements, which generally are not historical in nature. All statements that address operating or financial performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to regulatory submissions and approvals, the progress of clinical trials, or the commercial success of our products. We may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements. Our management believes that these forward-looking statements are reasonable as and when made. However, you should not place undue reliance on forward-looking statements because they speak only as of the date when made. We do not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by federal securities laws and the rules 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 filed with the SEC on February 23, 2010, and those described from time to time in our future reports filed with the SEC.

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

Overview

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

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

In January 2009, the HeartWare System received Conformite Europeenne ("CE") Marking approval, which allows us to market and sell the device in Europe. Our first commercial sale in Europe occurred in March 2009.

In April 2008, we received conditional Investigational Device Exemption ("IDE") approval from the United States Food and Drug Administration ("FDA") to enroll 150 patients in a bridge-to-transplant clinical study in the United States (called "ADVANCE"). Full IDE approval for the HeartWare System was received from the FDA in September 2008 and, in October 2009 we received FDA approval to expand the number of participating sites from 28 to 40 centers.

In August 2008, our first US patient received the HeartWare System at the Washington Hospital Center in Washington, DC, marking the commencement of our ADVANCE trial. In February 2010, we completed enrollment in this trial with 140 patients receiving the HeartWare System. The remaining 10 patients were enrolled but did not receive an implant of the HeartWare System because they failed to meet the trial's inclusion and exclusion criteria after being enrolled.

On April 7, 2010, the FDA approved an IDE Supplement that allows us to enroll up to an additional 54 patients in our "ADVANCE" bridge-to-transplant clinical trial under a Continued Access Protocol ("CAP"). The CAP makes the HeartWare System available to patients and clinicians while also providing additional data for the FDA to evaluate prior to determining whether or not to approve the HeartWare System. Patient enrollment under the CAP can now commence at the 30 centers participating in the ADVANCE trial, subject to Institutional Review Board approvals at the centers. The CAP patients will be enrolled and followed under a modified protocol of the ADVANCE trial. We anticipate submission to the FDA of the PMA seeking approval of the HeartWare System for the bridge-to-transplant indication in December 2010.

On November 23, 2009, we filed a submission for an IDE study with the FDA relating to the proposed use of the HeartWare System in a destination therapy clinical study in the United States. We are actively engaged in discussions with the FDA to finalize the protocol for the destination therapy trial and hope to receive approval to commence enrollment in the second quarter of 2010.

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

We began generating revenue from sales of our product in August 2008 and have incurred net losses in each year since our inception. We expect our losses to continue as we advance and expand our clinical trial activities in the US, continue to develop commercial markets outside of the United States and expand our research and development into next generation products including the MVAD.

We have financed our operations primarily through the issuance of shares of our common stock. Most recently, in February 2010, we completed a public offering of approximately 1.77 million shares of our common stock, including the underwriter's exercise of their over-allotment option to purchase 230,595 shares, at an offering price of \$35.50 per share for aggregate gross proceeds of approximately \$62.8 million. After fees and related expenses, net proceeds from the offering were approximately \$58.5 million.

We are headquartered in Framingham, Massachusetts. We have an operations and manufacturing facility in Miami Lakes, Florida and a small development and operations facility in Sydney, Australia.

Critical Accounting Policies and Estimates

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

Revenue Recognition

We recognize revenue from product sales in accordance with FASB ASC 605 — *Revenue Recognition*. Pursuant to agreements or orders from customers, we ship product to our customers. Revenue from product sales is only recognized when substantially all the risks and rewards of ownership have transferred to our customers, the selling price is fixed and collection is reasonably assured. A majority of product sales are made on a consignment basis and as such, pursuant to the terms of the consignment arrangements, revenue is generally recognized on the date the consigned product is implanted or otherwise consumed. Revenue from product sales not sold on a consignment basis is generally recognized upon customer receipt and acceptance of the product. Revenue recognized to date is from sales of our devices in connection with our US clinical trial and commercial sales in Europe and under special access in Australia.

Inventories

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

Inventories are stated at the lower of cost or market. Cost is determined on a first-in, first out (FIFO) method. We utilize a standard costing system, which requires significant management judgment and estimates in determining and applying standard labor and overhead rates. Labor and overhead rates are estimated based on our best estimate of annual production volumes and labor rates and hours per manufacturing process. These estimates are based on historical experience and budgeted expenses and production volume. Estimates are set at the beginning of the year and updated periodically. While we believe our standard costs are reliable, actual production costs and volume changes may impact inventory, costs of sales and the absorption of production overhead expenses.

We review our inventory for excess or obsolete inventory and write down obsolete or otherwise unmarketable inventory to its estimated net realizable value.

We include in inventory materials and finished goods that can be held for sale or used in non-revenue clinical trials. Products consumed in non-revenue clinical trials are expensed as part of research and development costs when consumed.

Share-Based Compensation

We recognize share-based compensation expense in connection with our share-based awards, net of an estimated forfeiture rate and therefore only recognize compensation cost for those awards expected to vest over the service period of the award. We value Restricted Stock Units (“RSU’s”) at their intrinsic value on the date of grant. We use a Black-Scholes option pricing model to estimate the fair value of our stock options. Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of expected life of the award, stock price volatility, forfeiture rates and risk-free interest rates. The assumptions used in calculating the fair value of share-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our share-based compensation expense could be materially different in the future.

When appropriate, we estimate the expected life of an option by averaging the contractual term of the stock option grants (up to 10 years) with the associated vesting term (typically 4 years). We estimate the volatility of our shares on the date of grant considering several factors, including the historical volatility of our publicly-traded shares. We estimate the forfeiture rate based on our historical experience of forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, share-based compensation expense could be significantly different from what we have recorded in the current period. We estimate the risk-free interest rate based on rates in effect for United States government bonds with similar lives, at the time of grant.

We have issued share-based awards with performance-based vesting criteria. Achievement of the milestones must be “probable” before we begin recording share-based compensation expense. At each reporting period, we review the likelihood that these awards will vest and if the vesting is deemed probable, we begin to recognize compensation expense at that time. In the period that achievement of the performance based criteria is deemed probable, US GAAP requires the immediate recognition of all previously unrecognized compensation since the original grant date. As a result, compensation expense recorded in the period that achievement is deemed probable could include a substantial amount of previously unrecorded compensation expense related to the prior periods. If ultimately performance goals are not met, for any awards where vesting was previously deemed probable, previously recognized compensation cost will be reversed. At March 31, 2010, we had approximately 95,000 options and RSU’s outstanding for which achievement of the performance-based vesting criteria has not yet been deemed probable. The aggregate amount of unrecognized compensation expense related to these options and RSU’s was approximately \$1.6 million.

Income Taxes

We account for income taxes in accordance with the liability method presented by FASB ASC 740 — *Income Taxes*. Under this method, deferred income taxes are determined based on the estimated future tax effects of differences between the financial statement and tax basis of assets and liabilities given the provisions of enacted tax laws. Deferred income tax provisions and benefits are based on changes to the assets or liabilities from year to year. In providing for deferred taxes, we consider tax regulations of the jurisdictions in which we operate, estimates of future taxable income, and available tax planning strategies. If tax regulations, operating results or the ability to implement tax-planning strategies vary, adjustments to the carrying value of deferred tax assets and liabilities may be required. Valuation allowances are recorded related to deferred tax assets based on the “more likely than not” criteria of FASB ASC 740. Through March 31, 2010, we have historically concluded that a full valuation allowance is required to offset our net deferred tax assets.

FASB ASC 740 requires that we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the “more-likely-than-not” threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50 percent likelihood of being realized upon ultimate settlement with the relevant tax authority.

Results of Operations

Three months ended March 31, 2010 and 2009

Revenues, net

For the three months ended March 31, 2010 and 2009, we generated net revenue of approximately \$10.7 million and \$1.5 million, respectively, from product sales in connection with our US clinical trial and commercial sales outside of the US. For the three months ended March 31, 2010, approximately 75% of our product sales were derived from commercial sales outside of the US. The increase is due to the continued commercial rollout in Europe including an increase in patients per site and the addition of new sites.

Due to completion of enrollment in our US bridge-to-transplant clinical trial in February 2010, US-based revenues ceased temporarily. Revenues from US sales are expected to re-commence in the second quarter of 2010 with the FDA approval of a CAP to continue to enroll in the ADVANCE trial. For the three months ended March 31, 2009, revenue consisted of a limited number of unit sales as we were in the early stages of enrollment in our US bridge-to-transplant clinical trial and we had just begun generating commercial revenue in Europe upon receipt of CE Marking approval for our HeartWare System in January 2009.

Cost of Revenues

Cost of revenues totaled approximately \$5.7 million and \$718,000 in the three months ended March 31, 2010 and 2009, respectively.

Gross profit and gross margin percentage are as follows:

	Three Months Ended March 31,	
	2010	2009
Gross profit (in thousands)	\$ 5,023	\$ 759
Gross margin %	47%	51%

As discussed in Note 15- Subsequent Events, to the accompanying condensed consolidated financial statements, on April 23, 2010, we initiated a voluntary field corrective action resulting in replacements and in-field repairs of certain HeartWare controllers as a result of a limited number of reported issues related to the volume of alarm notifications. The action taken will result in the repair or replacement of controllers in inventory, including controllers held on consignment at customer sites, and units previously distributed through clinical trials or sold to customers. The total cost of the repairs and replacements is estimated at approximately \$400,000 and has been accrued for as of March 31, 2010 as part of cost of revenues. The decrease in gross margin from 51% for the three months ended March 31, 2009 to 47% for the three months ended March 31, 2010 is a result of the expenses accrued for this field action, and because the March 31, 2009 gross margin benefits from the existence of pre-launch inventory (i.e. inventory that had previously been expensed in earlier reporting periods).

In addition, we do not possess long-term manufacturing experience and use a standard costing method for determining costs of inventory based on limited historical data, therefore, our actual results may differ from standards. As a result, gross margins have been and may continue to be inconsistent from quarter to quarter.

Selling, General and Administrative

Selling, general and administrative expenses include 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, depreciation of fixed assets, travel, external consultants and contractors, legal and accounting fees and general infrastructure costs and include all operating costs not associated with or otherwise classified as research and development costs or cost of revenues.

In the three months ended March 31, 2010, selling, general and administrative expenses were approximately \$4.6 million, or 49%, of operating expenses, as compared to \$4.2 million, or 55% of operating expenses in the same period in the prior year.

(in thousands)	Three Months Ended March 31,		
	2010	2009	Change
Total selling, general and administrative expenses	\$ 4,556	\$ 4,200	8.5%

The increase in selling, general and administrative expenses was primarily a result of an increase in salaries and related employee costs aggregating approximately \$1.4 million, primarily due to increased headcount, which included share-based compensation of approximately \$762,000. We also experienced increases in travel and marketing expenses of approximately \$423,000 along with increased consulting and professional services fees of approximately \$205,000. However, increases in these areas were significantly offset by a reduction in legal fees of approximately \$1.8 million, primarily related to the terminated merger with Thoratec Corporation.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products prior to commercialization 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 and clinical and regulatory staff external research and development costs, materials and expenses associated with clinical trials. Additional costs include travel, facilities and overhead allocations.

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

In the three months ended March 31, 2010, research and development expenses were \$4.8 million, or 51%, of operating expenses as compared to \$3.5 million, or 45% of operating expenses, in the same period in the prior year.

(in thousands)	Three Months Ended March 31,		
	2010	2009	Change
Total research and development expenses	\$ 4,756	\$ 3,490	36.3%

The increase was primarily a result of an increase in salaries and related employee costs aggregating approximately \$906,000, primarily due to increased headcount, which included share-based compensation of approximately \$417,000. We also experienced increased expenses related to existing and next generation research projects and on-going clinical trials and regulatory activities aggregating approximately \$296,000.

Foreign Exchange

Foreign exchange losses totaled approximately \$367,000 in the three months ended March 31, 2010, as compared to a gain of approximately \$693,000 for the same period in the prior year. In the three months ended March 31, 2010, we experienced losses upon the collection of certain accounts receivable that were denominated in foreign currencies, primarily the Euro.

In the three months ended March 31, 2009, we experienced a net gain upon the remeasurement of our cash holdings denominated in US dollars held by our Australian subsidiary as a result of movements in the exchange rate between the Australian dollar and the US dollar. During that period, we maintained the majority of our cash and cash equivalents in Australia, denominated in both Australian and US dollars. However, throughout the remainder of 2009 and at March 31, 2010, the majority of our cash and cash equivalents were in US dollars on deposit with banks located in the United States.

Interest Income, net

Interest income is primarily derived from short-term investments and cash and short-term deposit accounts held in the US. The amortization of premium on our short-term investments is also included in interest income, net. Interest income, net was approximately \$112,000 and \$7,000 in the three months ended March 31, 2010 and 2009, respectively. The increase in interest income was primarily due to higher average daily cash balances during the 2010 period resulting from the capital raises completed in the second half of 2009 and February 2010. However, we experienced lower interest rates in 2010 compared to 2009.

Other, net

Other, net consists of losses on the disposal of fixed assets. For the three months ended March 31, 2009, we incurred a loss on the disposal of fixed assets of approximately \$2,000.

Income Taxes

We are subject to taxation in the United States jurisdictions outside of the United States. These jurisdictions have different marginal tax rates. We have incurred 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 as such a 100% valuation allowance has been recorded against our net deferred tax assets.

As of March 31, 2010, we did not have revenues or profit which would be sufficient to allow any portion of our deferred tax assets to be recorded. We intend to closely consider whether to record a deferred tax asset as we further expand the commercialization of our products.

Liquidity and Capital Resources

As of March 31, 2010, we had approximately \$103.9 million in cash, cash equivalents and investments, compared to \$50.8 million at December 31, 2009. The increase is primarily a result of the cash proceeds from our public offering of common stock, which closed in February 2010.

Cash used in operating activities for the three months ended March 31, 2010 was approximately \$4.8 million as compared to approximately \$7.4 million for the same period in the prior year. For the three months ended March 31, 2010, this amount included a net loss of approximately \$4.5 million and non-cash adjustments to net loss of approximately \$2.1 million, which primarily consisted of approximately \$1.7 million of share-based compensation and \$304,000 of depreciation and amortization. Included in cash used in operating activities in the three months ended March 31, 2010 is approximately \$3.1 million for the purchase and manufacture of inventories, \$1.2 million for prepayment of expenses and \$1.4 million for the reduction of accounts payable. These cash expenditures were partially offset by approximately \$3.6 million in accounts receivable collections. We expect increases in accounts receivable and inventory purchases to be a significant use of cash for the remainder of 2010 as we continue to enroll patients in clinical trials in the US and increase our international commercial sales.

In the three months ended March 31, 2009, cash used in operating activities included a net loss of \$6.2 million and non-cash adjustments to net income of approximately \$519,000, which primarily consisted of approximately \$223,000 of depreciation and amortization and \$294,000 of share-based compensation. Included in cash used in operating activities in the three months ended March 31, 2009 is approximately \$3.2 million for the purchase and manufacture of inventories.

In the three months ended March 31, 2010 we utilized approximately \$16.6 million for the purchase of investments. These investments consist of investment grade US corporate debt. Other investing activities in the three months ended March 31, 2010 and 2009 used cash of approximately \$1.0 million and \$267,000, respectively. These amounts were expended to acquire property, plant and equipment and for capitalized patent costs.

Cash provided by financing activities in the three months ended March 31, 2010 was approximately \$58.8 million. In February 2010, we completed a public offering of approximately 1.77 million shares of our common stock, including the underwriter's exercise of their over-allotment option to purchase 230,595 shares, at an offering price of \$35.50 per share for aggregate gross proceeds of approximately \$62.8 million. After fees and expenses, net proceeds from the offering were approximately \$58.5 million. The offering was completed pursuant to a prospectus supplement, dated January 27, 2010, to a shelf registration statement previously filed with the SEC and which was declared effective on January 20, 2010. This shelf registration statement allows us to offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, any combination of the securities described in the prospectus, up to an aggregate amount of \$100 million.

For the remainder of 2010, cash and cash equivalents are expected to primarily be used to fund our ongoing operations, including expanding our sales and marketing capabilities on a global basis, continuing implants under a Continued Access Program, commencing a US destination therapy clinical study, continued product development, regulatory and other compliance functions as well as for general working capital. We believe our cash, cash equivalents and investments as of March 31, 2010 are sufficient to support our planned operations for at least the next twelve months.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

The primary objective of our investment activities is to preserve our capital to fund operations. We also seek to maximize income from our investments without assuming significant risk. Our investment portfolio is made up of marketable investments in money market funds and debt instruments of high quality corporate issuers. All investments are carried at fair value and are treated as available-for-sale. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. If interest rates rise, the market value of our investments may decline, which could result in a loss if we were forced to sell an investment before its scheduled maturity. We do not presently use derivative financial instruments in our investment portfolio.

Foreign Currency Rate Fluctuations

We conduct business in foreign countries. We generate a substantial proportion of our revenue and collect receivables in foreign currencies. Fluctuations in the exchange rate of the US dollar against the Euro and the Australian dollar can result in foreign currency exchange gains and losses that may significantly impact our financial results and our overall cash position. We do not currently utilize foreign currency contracts to mitigate the gains and losses generated by the remeasurement of non-functional currency assets and liabilities but do hold cash reserves in currencies in which those reserves are anticipated to be expended.

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, carried out an evaluation required by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) of the Exchange Act, as of March 31, 2010. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2010, 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 has been no change in our internal control over financial reporting during the three months ended March 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1A. RISK FACTORS

In addition to the information set forth in this report you should carefully consider the risk factors discussed in Item 1A — Risk Factors in our Annual Report on Form 10-K.

The following risk factor reflects a material change to the Risk Factors set forth in our 2009 Annual Report on Form 10-K.

Recently adopted healthcare reform legislation may impact our profitability.

On March 23, 2010, the Patient Protection and Affordable Care Act (“PPACA”) was signed into law by President Obama. On March 30, 2010, a companion bill, the Health Care and Education Reconciliation Act of 2010 (the “Reconciliation Act”) was also signed into law by President Obama. Among other things, the PPACA and the Reconciliation Act (collectively, the “Acts”), when taken together, impose a 2.3% excise tax on the sale of certain medical devices that will take effect in 2013. In addition, it is possible that standard setters or regulators may address certain unique aspects of the accounting for the Acts in the future. In light of the inherent uncertainty of how these Acts and other companion legislation, if any, will be implemented and applied, we are unable to fully predict the actual impact on our financial statements.

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

On February 2, 2010, we completed an underwritten public offering of 1,767,900 shares of our common stock (including 230,595 shares issued as a result of the full exercise of an overallotment option by the underwriter) at a price to the public of \$35.50 per share, or an aggregate offering price of \$62.8 million. The offer and sales of the shares in the offering were registered under the Securities Act of 1933 pursuant to a shelf registration statement on Form S-3 (File No. 333-164004), which became effective upon on January 20, 2010 and which registered up to \$100 million of our common stock. The offering did not terminate before all of the securities offered were sold. J.P. Morgan acted as sole book-running manager of the offering.

We raised approximately \$58.5 million in the offering, after deducting underwriting discounts and commissions of \$3.8 million and other estimated offering costs of \$470,000. No payments were made by us to our directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates. We have used to date approximately \$6.2 million of the net proceeds of the offering, including approximately \$2.4 million for the purchase of inventories, approximately \$3.4 million for general working capital and approximately \$334,000 for purchases of property, plant and equipment. Approximately \$16.6 million of the cash proceeds were used to purchase short-term investments, which we expect to liquidate from time to time as necessary or desirable.

ITEM 6. EXHIBITS

- | | |
|------|---|
| 31.1 | Certification of Chief Executive Officer pursuant to Rule 13A-14(a) or Rule 15d-14(a) of the Securities Exchange Act |
| 31.2 | Certification of Chief Financial Officer pursuant to Rule 13A-14(a) or Rule 15d-14(a) of the Securities Exchange Act |
| 32.1 | Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| 32.2 | Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |

Signatures

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

HEARTWARE INTERNATIONAL, INC.

Date: May 4, 2010

/s/ Douglas Godshall

Douglas Godshall

Chief Executive Officer

Date: May 4, 2010

/s/ David McIntyre

David McIntyre

Chief Financial Officer and Chief Operating Officer

EXHIBIT INDEX

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

I, Douglas Godshall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HeartWare International, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2010

/s/ Douglas Godshall

Douglas Godshall
Chief Executive Officer
(Principal Executive Officer)

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

I, David McIntyre, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of HeartWare International, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2010

/s/ David McIntyre

David McIntyre
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Quarterly Report on Form 10-Q of HeartWare International, Inc. (the “Company”) for the quarterly period ended March 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned Chief Executive Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 4, 2010

/s/ Douglas Godshall

Douglas Godshall
Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Quarterly Report on Form 10-Q of HeartWare International, Inc. (the “Company”) for the quarterly period ended March 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), the undersigned Chief Financial Officer of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that based on his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 4, 2010

/s/ David McIntyre

David McIntyre
Chief Financial Officer
(Principal Financial Officer)