Manager of Company Announcements
ASX Limited
Level 6
20 Bridge Street
SYDNEY NSW 2000

12 May 2009
BY E-LODGEMENT

Dear Sir / Madam

10Q for the 3 Months Ended 31 March 2009

Please see the attached Form 10-Q.

Yours faithfully

David McIntyre
Chief Financial Officer &
Company Secretary

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, 2009

☐ **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 or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Each Exchange on which Registered
Common Stock, $0.001 Par Value Per Share	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None
(Title of class)

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 ☑

As of April 30, 2009, the registrant had 8,868,102 ordinary shares outstanding.

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 Limited and HeartWare, Inc.
- "HeartWare International, Inc." and "Successor" refers to HeartWare International, Inc., a Delaware corporation incorporated on July 29, 2008.
- "HeartWare Limited" refers to HeartWare Limited, an Australian corporation.
- "HeartWare, Inc." and "Predecessor" refers to HeartWare, Inc., a Delaware corporation incorporated on April 3, 2003. HeartWare, Inc. was acquired by HeartWare Limited on January 24, 2005.

Dollars

Unless indicated otherwise in this Form 10-Q, all references to "$" or "dollars" refer to United States dollars, the lawful currency of the United States of America. References to "AU$" refer to Australian dollars, the lawful currency of the Commonwealth of Australia.

Trademarks

HeartWare, the HeartWare® Ventricular Assist System, and MVAD™ are the trademarks of HeartWare, Inc., 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.
(A Development Stage Company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)

	March 31, 2009	December 31, 2008
ASSETS		
Current assets:		
Cash and cash equivalents	$ 12,591,718	$ 20,803,656
Accounts receivable	1,179,179	244,198
Inventories, net	6,684,631	3,508,065
Prepaid expenses and other current assets	926,510	1,061,737
Total current assets	21,382,038	25,617,656
Property, plant and equipment, net	3,464,572	3,608,626
Other intangible assets, net	1,009,694	823,495
Restricted cash	288,429	288,429
Total Assets	$ 26,144,733	$ 30,338,206
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,674,071	$ 699,064
Accrued expenses and other current liabilities	4,219,664	2,883,587
Total current liabilities	5,893,735	3,582,651
Commitments and contingencies		
Shareholders' equity:		
Preferred stock — $.001 par value; 5,000,000 shares authorized; no shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	—	—
Common stock — $.001 par value; 25,000,000 shares authorized; 8,868,102 and 8,866,702 shares issued and outstanding at March 31, 2009 and December 31, 2008, respectively	8,868	8,867
Additional paid-in capital	112,715,327	112,400,642
Deficit accumulated during the development stage	(83,195,470)	(76,962,787)
Accumulated other comprehensive income (loss):		
Cumulative translation adjustments	(9,277,727)	(8,691,167)
Total Shareholders' Equity	20,250,998	26,755,555
Total Liabilities and Shareholders' Equity	$ 26,144,733	$ 30,338,206

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended March 31,		Cumulative Period from November 26, 2004 (Inception) Through March 31,
	2009	2008	2009
Revenues	$ 1,477,796	$ —	$ 1,809,595
Cost of revenues	718,308	—	795,940
Gross profit	759,488	—	1,013,655
Operating expenses:			
Selling, general and administrative expenses	4,199,663	2,187,625	32,819,952
Research and development expenses	3,489,780	4,252,715	59,152,121
Total operating expenses	7,689,443	6,440,340	91,972,073
Loss from operations	(6,929,955)	(6,440,340)	(90,958,418)
Foreign exchange gain (loss)	692,548	(723,302)	4,301,727
Interest income, net	6,756	325,771	3,764,214
Other, net	(2,032)	(2,240)	(302,993)
Loss before income taxes	(6,232,683)	(6,840,111)	(83,195,470)
Provision for income taxes	—	—	—
Net loss	$ (6,232,683)	$ (6,840,111)	$ (83,195,470)
Loss per common share — basic and diluted	$ (0.70)	$ (0.96)	
Weighted average shares outstanding — basic and diluted	8,866,889	7,088,579	

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	For the Three Months Ended March 31,		Cumulative Period from November 26, 2004 (Inception) Through March 31,
	2009	2008	2009
Net loss	$ (6,232,683)	$ (6,840,111)	$ (83,195,470)
Foreign currency translation	(586,560)	990,500	(9,277,727)
Comprehensive loss	$ (6,819,243)	$ (5,849,611)	$ (92,473,197)

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY
(unaudited)

	Common Shares		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Accumulated Other Comprehensive Income (Loss)	Total
	Shares Issued	Amount				
Balance December 31, 2008	8,866,702	$ 8,867	$112,400,642	$ (76,962,787)	$ (8,691,167)	$26,755,555
Issuance of common shares pursuant to stock option exercise	1,400	1	20,206	—	—	20,207
Share-based compensation	—	—	294,479	—	—	294,479
Net loss	—	—	—	(6,232,683)	—	(6,232,683)
Accumulated other comprehensive income (loss):						
Foreign currency translation adjustment	—	—	—	—	(586,560)	(586,560)
Balance March 31, 2009	8,868,102	$ 8,868	$112,715,327	$ (83,195,470)	$ (9,277,727)	$20,250,998

The accompanying notes are an integral part of these financial statements

HEARTWARE INTERNATIONAL, INC.
(A Development Stage Company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)

	Three Months Ended March 31,		Cumulative Period from November 26, 2004 (Inception) Through March 31,
	2009	2008	2009
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (6,232,683)	$ (6,840,111)	$ (83,195,470)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	206,263	138,772	2,007,173
Amortization	16,385	6,427	105,240
Share-based compensation expense	294,479	357,768	6,548,609
Loss on disposal of assets	2,032	2,240	305,380
Accrued interest on convertible note	—	6,901	(14,026)
Change in operating assets and liabilities:			
Accounts receivable	(934,981)	—	(1,179,179)
Inventories, net	(3,176,566)	—	(6,684,631)
Prepaid expenses and other current assets	3,271	69,302	(632,162)
Note receivable, current	—	—	794
Accounts payable	1,105,260	(12,594)	844,060
Accrued expenses and other current liabilities	1,336,586	289,177	4,251,072
Net cash used in operating activities	(7,379,954)	(5,982,118)	(77,643,140)
CASH FLOWS FROM INVESTING ACTIVITIES			
Additions to property, plant and equipment	(64,346)	(401,217)	(5,579,928)
Additions to patents	(202,583)	(46,666)	(1,114,934)
Cash paid for security deposits	—	—	(288,429)
Net cash provided by acquisition	—	—	126,380
Proceeds from dispositions of assets	—	—	32,136
Net cash used in investing activities	(266,929)	(447,883)	(6,824,775)
CASH FLOWS FROM FINANCING ACTIVITIES			
Repayment of convertible note	—	—	(1,360,929)
Proceeds from sale of common stock	20,207	—	113,302,657
Payment of offering costs	—	—	(5,903,581)
Net cash provided by financing activities	20,207	—	106,038,147
Effect of exchange rate changes on cash	(585,262)	1,033,116	(8,978,514)
INCREASE IN CASH AND CASH EQUIVALENTS	(8,211,938)	(5,396,885)	12,591,718
CASH AND CASH EQUIVALENTS — BEGINNING OF PERIOD	20,803,656	28,276,388	—
CASH AND CASH EQUIVALENTS — END OF PERIOD	$ 12,591,718	$ 22,879,503	$ 12,591,718

The accompanying notes are an integral part of these financial statements

1. Basis of Presentation

Development Stage

The Company is a development stage company with a limited operating history. To date, it has generated limited revenue from the Company's product sales, and it has incurred net losses in each year since the Company's inception. The Company also generates limited income from interest. The Company expects its losses to continue and to increase as the Company expands its clinical trial activities, seeks regulatory approvals and expands commercialization activities.

As such, the Company's financial statements have been prepared in accordance with the accounting and reporting principles prescribed by Statement of Financial Accounting Standards ("SFAS") No. 7, "Accounting and Reporting by Development Stage Enterprises," issued by the Financial Accounting Standards Board ("FASB").

Prior to marketing its products in the United States, the Company's products must undergo rigorous pre-clinical and clinical testing and an extensive regulatory approval process implemented by the FDA and other regulatory authorities. There can be no assurance that the Company will not encounter problems in clinical trials that will cause the Company, the FDA or other regulatory authorities to delay or suspend clinical trials. The Company's success will depend in part on its ability to successfully complete clinical trials, obtain and maintain necessary regulatory approvals, obtain patents and product license rights, maintain trade secrets and operate without infringing on the proprietary rights of others, both in the United States and other countries. There can be no assurance that patents issued to the Company will not be challenged, invalidated or circumvented, or that the rights granted there under will provide proprietary protection or competitive advantages to the Company. The Company will require further capital in order to meet its long-term objectives. The Company will need to seek substantial additional financing through public and/or private financing, and financing may not be available when the Company needs it or may not be available on acceptable terms.

Interim Financial Statements

The accompanying unaudited interim consolidated financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission 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 the financial statements and notes thereto for the year ended December 31, 2008 included in the Company's Annual Report on Form 10-K. The consolidated statement of operations for the three months ended March 31, 2009 is not necessarily indicative of the results to be expected for any future period or for the full year.

In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments (consisting of only normally recurring adjustments) necessary to present fairly the financial position and results of operations of the Company as of the dates and for the periods presented.

Proposed Acquisition by Thoratec Corporation

On February 12, 2009, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") and Loan Agreement with Thoratec Corporation ("Thoratec") pursuant to which the Company has agreed to merge with a wholly-owned subsidiary of Thoratec (the "Merger"). Also, in connection with the Merger Agreement, Apple Tree Partners I, L.P., a beneficial owner of approximately 30.2% of the Company's common stock, and all of the directors and certain executive officers of the Company, entered into support agreements with Thoratec (each, a "Support Agreement") pursuant to which such stockholders have agreed to vote the shares of the Company's common stock held by them to adopt the Merger Agreement and, subject to certain exceptions, not to dispose of their shares prior to the date of the Company's stockholder vote. The Support Agreements terminate upon termination of the Merger Agreement.

Concurrent with the Merger Agreement, Thoratec entered into a Loan Agreement with HeartWare pursuant to which Thoratec has agreed to loan HeartWare up to $28 million through one or more term loans subject to the terms and conditions set forth in the Loan Agreement. Thoratec has deposited $20 million into an escrow account in order to support the loan. Beginning on May 1, 2009, HeartWare may borrow up to $12.0 million and beginning on July 31, 2009 HeartWare may borrow up to an aggregate of $20.0 million. In the event that all of the conditions to closing the Merger other than the receipt of regulatory approvals have been satisfied and Thoratec exercises an option under the Merger Agreement to extend the outside date for the completion of the Merger until January 31, 2010, HeartWare may borrow up to an additional $8.0 million, which Thoratec must deposit into the escrow account at the time it exercises its extension option.

The terms of the Merger Agreement, Loan Agreement and Support Agreements are disclosed in the Company's Current Report on Form 8-K as filed with the SEC on February 13, 2009.

In connection with the Merger the Company entered into a retention bonus agreement with each of its President & Chief Executive Officer, its Chief Financial Officer & Chief Operating Officer, and its Chief Scientific Officer. The Company also determined to provide retention bonuses to a number of its senior management. The retention bonuses pertain solely to the Merger and are not valid in connection with, and have no application for, any other form of current or future corporate transaction, and all such agreements are contingent upon the closing of the Merger. The retention agreements and bonuses are disclosed in the Company's Current Report on Form 8-K as filed with the SEC on March 6, 2009.

Consummation of the Merger is subject to customary conditions, including adoption of the Merger Agreement by the Company's stockholders, the absence of legal impediments to consummation of the Merger and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Approval by Thoratec's shareholders is not required.

The financial statements as of March 31, 2009 do not reflect any adjustments related to these agreements but do however reflect all costs incurred by the Company in connection with the Merger through that date.

2. Liquidity

The accompanying 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. However, the Company has sustained substantial losses from operations since its inception, and such losses have continued through March 31, 2009. At March 31, 2009, the Company had a deficit accumulated during the development stage of approximately $83 million. On February 12, 2009, the Company entered into an Agreement and Plan of Merger with Thoratec and concurrently entered into a Loan Agreement to fund the Company's operations through consummation of the Merger. The loan amount is not to exceed $28.0 million (see Note 1 — Basis of Presentation for further information). In the remainder of 2009, cash on hand and the loan proceeds (the first $12.0 million of which became available to the Company on May 1, 2009) will primarily be applied for the purposes of meeting expected costs associated with establishing a European sales infrastructure, expanding the Company's human clinical trials, product development, regulatory and other compliance costs as well as for general working capital. The Company believes its cash on hand and cash available under the Loan Agreement are sufficient to support its planned operations throughout 2009 and into 2010.

3. Significant Accounting Policies

Principles of Consolidation

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

Accounting Estimates

The preparation of 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 period. 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. The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The Company maintains the majority of its cash and cash equivalents in Australia, denominated in both Australian and United States dollars. As of March 31, 2009 and December 31, 2008, the Company had approximately $11.9 million and $17.9 million, respectively, maintained in banks in Australia, as translated into US dollars at the spot rate at the end of the respective period.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost basis which approximates the FIFO method. Work-in-process and finished goods includes direct and indirect labor and manufacturing overhead. Provision is made to reduce excess and obsolete inventories to net realizable value.

Prior to September 1, 2008, the Company included all costs associated with manufacturing as part of R&D expense. Effective September 1, 2008, the Company began to capitalize in inventory the costs of manufacturing the HeartWare System. Until we sell the inventory for which costs were previously expensed, the carrying value of our inventories and our cost of sales does not include the cost of pre-launch inventory. The Company could be required to expense capitalized costs of the HeartWare System in the event of a denial or delay of approval by US regulatory bodies, a delay in commercialization, or other potential factors.

The Company includes all costs associated with manufacturing products other than the HeartWare System as part of R&D expense.

Property, Plant and Equipment

The Company records property, plant and equipment and leasehold improvements at historical cost. Expenditures for maintenance and repairs are charged to expense; additions and improvements are capitalized. The Company generally provides for depreciation using the straight-line method at rates that approximate the estimated useful lives of the assets. Leasehold improvements are amortized on a straight-line basis over the shorter of the useful life of the improvement or the remaining term of the lease.

Share-Based Payments

We elected to early adopt SFAS 123(R), *"Share-Based Payment"*, effective January 1, 2005. We use a Black-Scholes option pricing method. Under the fair value recognition provisions of SFAS 123(R), we recognize share-based compensation net of an estimated forfeiture rate and therefore only recognize compensation cost for those shares expected to vest over the service period of the award.

Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of expected life of the option, share price volatility and a forfeiture rate.

We estimate the volatility of our shares on the date of grant based on the historical volatility of our publicly-traded shares. When appropriate, we estimate the expected term calculation based upon the simplified method provided under SEC Staff Accounting Bulletin (SAB) No. 110. Under SAB No. 110, the expected term is developed 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 risk-free interest rate based on rates in effect for Australian Government bonds, with similar lives, at the time of grant. We estimate the forfeiture rate based on our historical experience of past forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, the share-based compensation expense could be significantly different from what we have recorded in the current period.

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 are required to use different assumptions, our share-based compensation expense could be materially different in the future.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable from future undiscounted cash flows. Impairment losses are recorded for the excess, if any, of the carrying value over the fair value of the long-lived assets. As of March 31, 2009, no indicators of impairment existed.

Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, "*Accounting for Income Taxes*" ("SFAS No. 109"), as clarified by FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes* ("FIN No. 48"). 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, the Company considers tax regulations of the jurisdictions in which it operates, estimates of future taxable income and available tax planning strategies. If tax regulations, operating results or the ability to implement tax-planning strategies varies, adjustments to the carrying value of the deferred tax assets and liabilities may be required. Valuation allowances are based on the "more likely than not" criteria of SFAS No. 109.

FIN No. 48 requires that the Company 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.

Translation of Foreign Currency

The Company translates all assets and liabilities of non-US entities at the year-end exchange rate and translates expenses at the average exchange rates in effect during the year. Equity transactions are translated at rates in effect at the times of the transactions. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of shareholders' equity, titled "Accumulated Other Comprehensive Income (Loss)." Items in Accumulated Other Comprehensive Income (Loss) are not tax affected as the Company has incurred a net loss in each period since inception.

In addition, the Australian subsidiary, HeartWare Limited, which operates in a functional currency of AU dollars, holds US dollar cash accounts. Exchange rate fluctuations affect the value of these accounts and may result in foreign currency gains and losses. Such gains and losses are included in the consolidated statements of operations. Any such gains and losses are initially recognized as they occur in AU$ and then converted to US$ at an average exchange rate.

The exchange rate between the US and Australian dollar has fluctuated substantially in the past. This fluctuation has resulted in significant changes in the cumulative translation adjustments and foreign exchange gains and losses during the three months ended March 31, 2009 and for the cumulative period from November 26, 2004 (Inception) through March 31, 2009.

Research and Development

Research and development costs, including new product development programs, regulatory compliance and clinical research, are expensed as incurred.

Vendor Concentration

For the three months ended March 31, 2009, we purchased approximately 58% 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, 2009, the amounts due to these vendors total approximately $300,000.

Marketing and Advertising Costs

Marketing, advertising and promotional costs are expensed when incurred.

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, with the number of shares outstanding for the 2008 period adjusted to reflect the reverse split consummated in November 2008. Diluted 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, plus the dilutive effect of common share equivalents, such as options. Due to the net loss for all periods presented, all common share equivalents were excluded because their inclusion would have been anti-dilutive.

New Accounting Standards

In December 2007, the FASB issued SFAS No. 141(R), Business Combinations and SFAS No. 160, Non-controlling Interests in Consolidated Financial Statements. SFAS No. 141(R) and SFAS No. 160 introduce significant changes in the accounting for and reporting of business acquisitions and non-controlling interests in a subsidiary. SFAS No. 141(R) continues the movement toward the greater use of fair values in financial reporting and increased transparency through expanded disclosures. SFAS No. 141(R) changes how business acquisitions are accounted for and will impact financial statements at the acquisition date and in subsequent periods. In addition, SFAS No. 141(R) will impact the annual goodwill impairment test associated with acquisitions that close both before and after its effective date. SFAS No. 141(R) and SFAS No. 160 apply prospectively to fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. An entity may not apply SFAS No. 141(R) or SFAS No. 160 before that date. The Company adopted these statements on January 1, 2009, which did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In April 2009, the FASB issued FSP-FAS No. 141(R)-1, *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies* ("FAS 141(R)-1"). This FSP amends and clarifies SFAS 141R and applies to assets acquired and liabilities assumed that arise from contingencies in a business combination. FAS 141(R)-1 must also be applied prospectively to business combinations consummated on or after the first annual reporting period beginning on or after December 15, 2008. Early application is not permitted.

In February 2008, the FASB issued Staff Position ("FSP") FAS 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Lease Classification or Measurement under Statement 13*, which scopes out leasing transactions accounted for under SFAS No. 13, *Accounting for Leases*. In February 2008, FSP FAS 157-2, *Effective Date of FASB Statement No. 157*, was issued, which delays the effective date of SFAS No. 157 to fiscal years and interim periods within those fiscal years beginning after November 15, 2008 for non-financial assets and non-financial liabilities, except for items that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The implementation of SFAS No. 157 did not have a material impact on the Company's consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities*. SFAS No. 161 changes the disclosure requirements for derivative instruments and hedging activities. Entities are required to provide enhanced disclosures about (a) how and why an entity uses derivative instruments, (b) how derivative instruments and related hedged items are accounted for under FASB Statement 133 and its related interpretations, and (c) how derivative instruments and related hedged items affect an entity's financial position, financial performance and cash flows. SFAS No. 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged. The Company adopted SFAS No. 161 on January 1, 2009, which did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

In April 2008, the FASB issued FSP-FAS No. 142-3, *Determination of the Useful Life of Intangible Assets* ("FAS 142-3"). FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets* ("SFAS 142"). The objective of the Staff Position is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141 (Revised 2007): *Business Combinations* and other GAAP. FAS 142-3 is effective for fiscal years beginning after December 15, 2008. Early application is not permitted.

4. Inventories, Net

Components of Inventories, net are as follows:

	March 31, 2009	December 31, 2008
Raw material	$ 1,737,403	$ 813,276
Work-in-process	1,781,324	1,690,852
Finished goods	3,165,904	1,003,937
	$ 6,684,631	$ 3,508,065

5. Property, Plant and Equipment, Net

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

Property, Plant and Equipment	Useful Lives	March 31, 2009	December 31, 2008
Machinery and equipment	5 to 7 years	$ 4,438,402	$ 4,428,452
Leasehold improvements	3 to 7 years	219,301	212,891
Office equipment, furniture and fixtures	5 to 7 years	285,278	271,275
Software	5 to 7 years	438,336	406,983
		5,381,317	5,319,601
Less: accumulated depreciation		(1,916,745)	(1,710,975)
		$ 3,464,572	$ 3,608,626

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

Accrued expenses and other current liabilities	March 31, 2009	December 31, 2008
Accrued payroll and other employee costs	$ 854,395	$ 1,721,506
Accrued material purchases	106,214	417,344
Accrued research and development materials	501,263	494,997
Accrued milestone payment	750,000	—
Accrued professional fees	1,852,287	149,146
Other accrued expenses	155,505	100,594
	$ 4,219,664	$ 2,883,587

7. Other Intangible Assets

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

		March 31, 2009		December 31, 2008	
Amortizable Intangible Assets	Life (Years)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization
Patents	15	$ 1,114,935	$ (105,241)	$ 912,351	$ (88,856)

Estimated amortization expense for the succeeding five fiscal years based upon the Company's intangible asset portfolio at March 31, 2009 is as follows:

Remainder of 2009	$ 57,945
2010	74,329
2011	74,329
2012	74,329
2013	74,329
2014	74,329

8. Equity Incentive Plans

The Company has issued share-based payment awards to employees, non-executive directors and outside consultants through various approved plans and outside of any formal plan. The Company issues new shares upon exercise of stock awards.

On November 13, 2008, the Company completed an Australian court approved redomiciliation, whereby the ultimate parent company of the HeartWare Group became a US Company, HeartWare International, Inc. As part of redomiciliation all share-based plans of HeartWare Limited were cancelled and new plans were formed under HeartWare International, Inc. All awards outstanding at the time of the redomiciliation were cancelled and reissued by HeartWare International, Inc. The awards were issued on the same terms and conditions with the only exception being the number of shares and exercise prices were adjusted to reflect a reverse split in the ratio of 35 to 1 and any fractional shares were rounded down. The reverse split had no impact on the valuation of the grants and therefore did not result in any additional compensation. The exercise price of all grants to date is denominated in AU dollars; the amounts below have been translated to US dollars.

On February 24, 2009, the Company began trading on the NASDAQ stock market. No modifications have been made to our stock awards pursuant to this listing.

A detailed discussion of share-based payment awards granted and outstanding is below. For all periods presented the current and former plans have been combined. Original issuance dates have been retained but the number of shares issued and exercise prices have been adjusted to give retroactive effect to the redomiciliation and reverse split for all periods presented.

HeartWare International, Inc. Employee Share Option Plan ("ESOP") (formerly HeartWare Limited Employee Share Option Plan)

On August 5, 2008, the Company adopted the HeartWare International, Inc. Employee Share Option Plan. All plan issuances were made in accordance with previous grants under the HeartWare Limited Employee Share Option Plan with the exception of adjustments for the reverse split and rounding.

The ESOP allows the Company to grant options for common stock in the Company to employees and directors. The ESOP provides for the issuance of up to 11% of the then outstanding shares of common stock. At March 31, 2009, there were 347,697 shares reserved for future issuance under the ESOP.

Each option issued under the ESOP allows the holder to subscribe for and be issued one share of common stock of the Company. Options may generally 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 of grant of the option.

The options vest in accordance with the plan on an individual award basis. Though some options have had immediate vesting, the majority of options are granted with vesting on a pro-rata basis over periods ranging from two to four years. Prior to November 2007, all options were granted with time-based vesting.

In November 2007, the Company granted approximately 83,000 options, approximately 79,000 of which are still outstanding, with performance based vesting criteria. The performance based options will vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones related primarily to the development of the Company's products and the achievement of certain prescribed clinical and regulatory objectives. The Company currently estimates that the options will vest over a period of 16 to 54 months commencing on the grant date. Any options not vested after five years from the date of grant automatically expire.

At March 31, 2009, the Company has determined that vesting of only the first tranche of options (19,633) of the grants, issued with performance criteria, meet the definition of "probable" under SFAS No. 5, *Accounting for Contingencies*. As such, share-based compensation expense has only been recorded for the first tranche of options. At each period, we will review the likelihood that any of the remaining three tranches will vest, and if the vesting is deemed probable, we will 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.

Information in US$, as converted from AU$ at the then period-end spot rate, related to the ESOP, including all tranches of the performance options, at March 31 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	629,936	$ 18.62	6.39	$ —
Granted	—	—		
Exercised	—	—		
Forfeited	(2142)	13.71		
Expired	—	—		
Outstanding at March 31, 2009	627,794	$ 18.49	6.14	$ 3,043,830
Exercisable at March 31, 2009	310,308	$ 16.82	4.02	$ 2,020,138

The aggregate intrinsic value in the table above represents the quoted market value of the Company's Chess Depositary Interests ("CDI's"), as listed on the Australian Securities Exchange (multiplied by 35 to reflect that each CDI is equivalent to 1/35th of a share of common stock), less the weighted average exercise price at period end times the number of options outstanding. As the weighted average exercise price was above the quoted market price on December 31, 2008, there is no aggregate intrinsic value on that date.

The fair value of each option award is estimated on the date of grant using the Black-Scholes option pricing valuation model using the assumptions established by the Company at that time. Compensation is recognized on an accelerated accrual method over the estimated vest period.

At March 31, 2009, the Company had approximately $1.5 million of unrecognized compensation cost related to non-vested share option awards, including performance based awards not yet deemed probable of vesting. The expense is expected to be recognized over a weighted average period of 1.33 years.

HeartWare International, Inc. Restricted Stock Unit Plan (formerly HeartWare Limited Performance Rights Plan)

On August 5, 2008, the Company adopted the HeartWare International, Inc. Restricted Stock Unit Plan ("RSUP"). The plan replaces the HeartWare Limited Performance Rights Plan. All plan issuances were made in accordance with previous grants under the HeartWare Limited Performance Rights Plan, with the exception of adjustments for the reverse split and rounding). The RSUP permits the Company to grant restricted stock units ("RSU's") to employees to acquire common shares of the Company at an exercise price of $0.00. The RSUP allows for the issuance of RSU's to acquire up to approximately 149,000 shares of the Company's common stock. Each RSU issued under the RSUP allows the holder to subscribe for and be issued one share of common stock of the Company. The RSU's that ultimately vest expire 10 years from the date of grant. At March 31, 2009, there were 6,154 shares reserved for future issuance under the RSUP.

The RSU's granted with original Performance Rights Plan issuance dates from November 2007 and May 2008 vest in four equal tranches contingent upon the achievement of pre-determined corporate milestones. The RSU's granted in November 2007 have performance conditions consistent with the performance ESOP shares mentioned above. The Company currently estimates that the RSU's will vest over a period of 16 to 54 months commencing on the grant date. Any RSU's not vested after five years from the date of grant automatically expire.

On August 13, 2008, the Company also approved the issuance of approximately 96,000 RSU's under its annual equity award grant. These RSU's vest in three tranches, the first being 50% and the remaining two tranches being equal, and all are contingent upon the achievement of pre-determined corporate milestones. The Company currently estimates that the performance rights will vest over a period of 22 to 43 months commencing on the grant date. Any performance rights not vested after five years from the date of grant automatically expire.

At March 31, 2009, the Company has determined that only the first tranche of awards issued under the RSUP (19,639) related to the original issuances from November 2007 and May 2008, issued with performance criteria, meet the definition of "probable" under SFAS No. 5. As such, share-based compensation expense has only been recorded for the first tranche of awards. At the end of each reporting period, the Company will review the likelihood that the tranches will vest and if the vesting is deemed probable, the Company will 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.

Information in US$, as converted from AU$ at the then period-end spot rate, related to the RSU at March 31 is as follows:

	Shares	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	142,846	9.32	$ 2,078,238
Granted	—		
Exercised	—		
Forfeited	—		
Expired	—		
Outstanding at March 31, 2009	142,846	9.07	$ 3,333,145
Exercisable at March 31, 2009	—	—	$ —

The aggregate intrinsic value in the table above represents the quoted market value of the Company's Chess Depositary Interests ("CDI's"), as listed on the Australian Securities Exchange (multiplied by 35 to reflect that each CDI is equivalent to 1/35th of a share of common stock) times the number of RSU awards outstanding.

The fair value of each RSU award equals the quoted market value of the Company's common stock on the date of grant. Compensation is recognized on an accelerated accrual method over the estimated vest period.

At March 31, 2009, the Company had approximately $1.7 million of unrecognized compensation cost related to non-vested RSU awards, including awards not yet deemed probable of vesting that is expected to be recognized over a weighted average period of 1.87 years.

Non-Plan Options

The Company also has an aggregate of 67,038 options outstanding that were granted outside of any formal plan. Of these options, 28,569 were granted to 3 non-executive directors and 38,469 were granted to third parties for services rendered to the Company.

The options granted to the non-executive directors had three-year vest plans and were fully vested as of January 31, 2008. The options granted to third parties prior to 2007 had immediate vesting. The third party options granted in 2007 vest in three tranches; 40% on the first anniversary, 40% on the second anniversary and 20% on the third anniversary of the date of grant.

Information, in US$ as converted from AU$ at the then period-end spot rate for non-plan options is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	68,438	$ 18.03	2.17	$ —
Granted	—			
Exercised	(1,400)	14.43		
Forfeited	—			
Expired	—			
Outstanding at March 31, 2009	67,038	$ 17.96	1.95	$ 360,170
Exercisable at March 31, 2009	61,038	$ 17.95	1.29	$ 328,396

The aggregate intrinsic value in the table above represents the quoted market value less the weighted average exercise price at period end times the number of options outstanding. As the weighted average exercise price was above the quoted market price of the Company's CDI's on December 31, 2008, there was no aggregate intrinsic value on that date.

The fair value of each non-plan option award was estimated on the date of grant using the Black-Scholes option pricing valuation model using the assumptions established by the Company at that time. Compensation is recognized on an accelerated accrual method over the vest period.

The intrinsic value for options exercised during the three months ended March 31, 2009 was approximately $13,500. Cash received from share option exercises for the three months ended March 31, 2009 was approximately $20,000.

At March 31, 2009, the Company had approximately $26,000 of unrecognized compensation cost related to non-vested share non-plan option awards that is expected to be recognized over a weighted average period of 0.96 years.

HeartWare International, Inc. 2008 Stock Incentive Plan

On August 5, 2008, the Company adopted the HeartWare International, Inc. 2008 Stock Incentive Plan. The 2008 Stock Incentive Plan allows for the issuance of awards representing up to 469,140 shares of the Company's common stock. Through March 31, 2009, there have been no awards granted under this plan.

Summary

The following table summarizes information about all outstanding awards, including the ESOP, RSU and non-plan options, as of March 31, 2009:

	Awards Outstanding			Awards Exercisable		
Range of Exercise Prices	Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Shares Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)
$0.00 – $0.00	142,846	$ —	9.07	—	$ —	—
$0.24 – $17.80	275,982	9.69	4.46	168,967	7.19	1.47
$18.19 – $33.68	399,365	23.61	6.86	188,352	24.40	5.66
$33.92 – $36.08	19,485	36.08	0.87	14,027	36.08	0.79
	837,678	$ 15.29	6.30	371,346	$ 17.01	3.57

We generally recognize compensation expense for our share awards deemed probable of vesting using an accelerated accrual method over the substantive vesting period. The Company allocates expense to general and administrative expense, the cost of manufacturing and research and development expense based on the award holders' employment function.

We recognize share-based compensation for the value of the portion of awards that are ultimately expected to vest. Statement No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered award. We have applied an annual forfeiture rate of approximately 12.5% to all unvested share awards as of March 31, 2009, which represents the portion that we expect will be forfeited each year over the vesting period. We will re-evaluate this analysis periodically and adjust the forfeiture rate as necessary. Ultimately, we will only recognize expense for those shares that vest.

If the proposed acquisition by Thoratec is consummated, all of the Company's outstanding unvested options as of the consummation date will vest in full in accordance with the terms of the Merger Agreement.

For the three months ended March 31, 2009 and 2008, the Company recorded share-based payment expenses as follows:

(in thousands)	2009	2008
General and administrative	$ 140	$ 273
Cost of goods sold	16	—
Research and development	138	85
	$ 294	$ 358

9. Net Loss Per Share

Basic earnings (loss) per share is computed by dividing net income (loss) applicable to common shares by the weighted-average number of common shares outstanding during the period. The number of common shares outstanding during the three months ended March 31, 2008 has been adjusted to reflect the reverse split consummated in November 2008. Diluted earnings (loss) per share adjusts basic earnings (loss) per share for the dilutive effects of convertible securities, options and other potentially dilutive instruments, only in the periods in which such effect is dilutive. The following securities have been excluded from the calculation of diluted loss per share, as their effect would be anti-dilutive.

	Three Months Ended March 31,	
	2009	2008
Common shares issuable upon:		
Exercise of share-based payment awards	837,678	727,899
Conversion of convertible note	—	43,220

10. Commitments and Contingencies

The Company has the following contingent liabilities and commitments resulting from the acquisition by HeartWare, Inc. of a business that previously held the Company's technology:

• 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 the Company has at least $25,000,000 in cash on hand and, if the Company does not have $25,000,000 at that time, then the payment is deferred until such time that the Company has $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.

At March 31, 2009, we had purchase order commitments of approximately $2.3 million related to product costs and property, plant and equipment purchases.

In addition to the above, the Company has entered into employment agreements with all of its 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 in control of the Company, as defined in such agreements.

11. Business Segment, Geographic Areas and Major Customers

The Company, which designs, manufactures and markets medical devices for the treatment of advanced heart failure, operates as one business segment for financial reporting purposes. Products are sold in the US through a 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)	2009	2008
Domestic	$ 1,125	$ —
International	353	—
	$ 1,478	$ —

Four customers individually exceeded 10% of product sales and approximately 65% of product sales in the aggregate for the three months ended March 31, 2009. The concentration of customers is a result of the early stage of our US clinical trial and International commercial launches. Our US clinical trial has a phased site and patient enrollment. Also, a limited number of customers represent International product sales as the Company received CE Marking in late January 2009. As additional customers are acquired outside of the US and additional sites are enrolled in the US clinical trial, the concentration of customers is likely to be diluted.

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

Overview

HeartWare is a medical device company focused on developing the world's smallest implantable pumps for the treatment of advanced heart failure.

The HeartWare Ventricular Assist System (the "HeartWare System"), which includes a left ventricular assist device ("LVAD"), 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.

The HeartWare System received CE Marking, which allows us to sell the device in Europe, in January 2009 and is the subject of clinical trials under a Food & Drug Administration ("FDA") Investigational Device Exemption ("IDE") clinical trial in the United States for a bridge-to-transplant indication.

In 2008, we successfully completed enrollment of a combined European and Australian human clinical trial for the HeartWare System. This international trial began in March 2006 and called for the implantation of 20 patients. The trial had been expanded to permit enrollment of 50 patients so as to provide increased depth of clinical data. Enrollment in this trial was the basis for application for and subsequent receipt of CE Marking for the HeartWare System.

In April 2008, we received conditional IDE approval from the FDA and began enrolling centers for a US bridge-to-transplant clinical study. In August 2008, our first patient in the United States received the HeartWare System at Washington Hospital Center in Washington, DC. This marked the start of our US bridge-to-transplant clinical trial, under which 150 patients awaiting heart transplantation will be enrolled at up to 28 participating centers. Full IDE approval was received in September 2008.

Beyond the HeartWare System, we are also evaluating our next generation device, the Miniaturized Ventricular Assist Device, or 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. The MVAD, which is currently at the prototype stage and undergoing animal studies focused on minimally invasive implantation techniques, is approximately one-third the size of the HVAD Pump. We believe that the MVAD will be implantable by surgical techniques that are even less invasive than those required to implant the HVAD Pump.

We are a development stage company with a limited operating history. To date, we have generated limited revenue from our product sales and we have incurred net losses in each year since our inception. We also have generated limited income from interest. We expect our losses to continue and to increase as we expand our clinical trial activities, seek regulatory approvals and initiate commercialization activities.

We have financed our operations primarily through the issuance of common shares. In January 2005, we issued shares through an initial public offering in Australia and a concurrent US private placement of shares which raised aggregate net proceeds of approximately $23.4 million. We also issued shares through private placements to both US and Australian investors, in May 2006, July 2007 and July 2008, which raised net proceeds of approximately $23.4 million, $30.9 million and $29.4 million, respectively.

As described under the heading of "Proposed Acquisition by Thoratec" of Note 1 of Notes to the Condensed Financial Statements, on February 12, 2009, we entered into the Merger Agreement, pursuant to which Merger Subsidiary will merge with and into HeartWare, with HeartWare continuing as the surviving corporation (the "Merger") and, if the stock value of the consideration is at least 41% of the aggregate merger consideration at closing, immediately following the Merger, HeartWare, as the surviving corporation in the Merger, will merge with and into Merger Subsidiary Two, with Merger Subsidiary Two continuing as the surviving corporation and a wholly owned subsidiary of Thoratec.

We are headquartered in Framingham, Massachusetts. We have an administrative office in Sydney, Australia and an operations and manufacturing facility in Miami Lakes, Florida.

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 the 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. 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, translation of foreign currency, accounting for research and development costs, accounting for share-based payments 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 for product sales in accordance with SEC Staff Accounting Bulletin No. 104 ("SAB 104"), *Revenue Recognition*. We ship product on a consignment basis to our customers. Revenue from product sales is only recognized when substantially all the risks and rewards of ownership have transferred to our customers (which generally occurs on the date the product is implanted), the selling price is fixed and collection is reasonably assured. Revenue recognized to date is from sales of devices in connection with our US clinical trial and commercial sales in Europe and under special access in Australia.

Inventory Capitalization

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 product line and subsequently began selling our product through our US clinical trial, and subsequently outside of the United States upon receipt of CE Marking. Therefore, effective September 1, 2008, we adopted a policy for capitalizing inventory and recognizing cost of sales.

Prior to September 1, 2008, all costs associated with manufacturing the HeartWare System and related surgical and peripheral products were expensed as R&D costs. Until we sell the inventory for which costs were previously expensed, the carrying value of our inventories and our cost of sales does not include the cost of pre-launch inventory. As such, as we sell that portion of our existing inventory there will be a period of time where we will recognize manufacturing revenue with little or no corresponding cost. Therefore we anticipate our gross margin on sales of our product will fluctuate and will not be comparable from quarter to quarter.

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost basis which approximates the FIFO method. 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 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.

Research and Development

Research and development costs, including new product development programs, regulatory compliance and clinical research, are expensed as incurred.

Share-Based Payments

We elected to early adopt SFAS 123(R), *"Share-Based Payment"*, effective January 1, 2005. We use a Black-Scholes option pricing method. Under the fair value recognition provisions of SFAS 123(R), we recognize share-based compensation net of an estimated forfeiture rate and therefore only recognize compensation cost for those shares expected to vest over the service period of the award.

Calculating share-based compensation expense requires the input of highly subjective judgment and assumptions, including estimates of expected life of the option, share price volatility and a forfeiture rate.

We estimate the volatility of our shares on the date of grant based on the historical volatility of our publicly-traded shares. We estimate the forfeiture rate based on our historical experience of past forfeitures and our employee retention rate. If our actual forfeiture rate is materially different from our estimate, the 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 at the time of grant for Australian government bonds with similar lives. When appropriate, we estimate the expected term calculation based upon the simplified method provided under SEC Staff Accounting Bulletin (SAB) No. 110. Under SAB No. 110, the expected term is developed by averaging the contractual term of the stock option grants (up to 10 years) with the associated vesting term (typically 4 years).

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.

Income Taxes

We account for income taxes in accordance with Statement of Financial Accounting Standard No. 109, or SFAS 109, *Accounting for Income Taxes*, as clarified by FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* ("FIN No. 48"). 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 SFAS No. 109.

FIN No. 48 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.

Translation of Foreign Currency

The Company translates all assets and liabilities of non-US entities at the period-end exchange rate and translates expenses at the average exchange rates in effect during the year. Equity transactions are translated at the spot rates on the dates of the original transactions. The net effect of these translation adjustments is shown in the accompanying consolidated financial statements as a component of shareholders' equity, titled "Accumulated Other Comprehensive Income (Loss)." Items in Accumulated Other Comprehensive Income (Loss) are not tax affected as the Company has incurred a net loss in each period since inception.

The exchange rates between the US and Australian dollars have fluctuated significantly since inception and the exchange rate was 0.6873 AU dollars for each US dollar at March 31, 2009, resulting in a significant change in the cumulative translation adjustment for the period then ended.

In addition, HeartWare Limited, which operates in a functional currency of AU dollars, holds US dollar cash accounts. Exchange rate fluctuations affect the value of these accounts and may result in foreign currency gains and losses. Such gains and losses are included in the consolidated statements of operations. Any such gains and losses are initially recognized in AU$ and then converted to US$ at an average exchange rate.

If the exchange rate declines, the value in Australian dollars of our US dollar denominated cash holdings held by our Australian subsidiary increases, resulting in foreign exchange translation gains in that period. During 2008, we saw a significant decline in the exchange rate between AU and US dollars. Foreign exchange gains and losses will continue to fluctuate as the exchange rate varies.

Three months ended March 31, 2009 and 2008

Revenue

We are a development stage company and have generated revenue of approximately $1.5 million in the three months ended March 31, 2009 from product sales through our US clinical trial as well as commercial sales in Europe and Australia. We completed enrollment of our combined European and Australian clinical trial for the HeartWare System in December 2008 and received CE Marking approval in January 2009. We had no revenue from product sales prior to August 2008. We expect to continue to generate revenue from our US clinical trial and commercial revenue from product sales outside of the United States. However, even if we receive the necessary regulatory approvals in the United States, future product sales are dependent on many factors, including market acceptance among physicians, patients, health care payers or the medical community as well as our capacity to supply customers by manufacturing sufficient quantities of our products.

Cost of Goods Sold

Cost of goods sold totaled $0.7 million during the three months ended March 31, 2009. There was no cost of goods sold recognized during the same period in the prior year. We began capitalizing inventory on September 1, 2008. Prior to that time, product costs were expensed as R&D costs (see Critical Accounting Policies and Estimates — Inventory Capitalization). However, at September 1, 2008 we had product on hand that was previously expensed as R&D costs but is being utilized in the production and sale of finished goods. Therefore, cost of goods sold does not include the cost of pre-launch inventory. In addition, as we have limited manufacturing experience and our processes are in their infancy and we use a standard costing method for determining costs of inventory our actual results may differ from standards which could result in inconsistent gross margins from quarter to quarter.

Selling, General and Administrative

Selling, general and administrative expenses include office expenses associated with general corporate administration. 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.

Selling, general and administrative expenses were approximately $4.2 million, or 55%, of operating expenses for the three months ended March 31, 2009, as compared to $2.2 million, or 34% of operating expenses for the same period in the prior year. The increase was primarily a result of approximately $1.7 million of direct expenses related to the Thoratec transaction. In addition, increased headcount resulted in higher salaries and wages and related employee costs for the three months ended March 31, 2009 as compared to the same period in the prior year.

Research and Development

Research and development expenses are the direct and indirect costs associated with developing our products prior to commercialization. These expenses consist primarily of salaries and wages and related employee costs, external research and development costs, materials and expenses associated with clinical trials associated with our US clinical trial. Additional costs include travel, facilities and overhead allocations.

Even as we attain commercialization of the HeartWare System product line outside of the US, we expect that research and development expenses will continue to represent a significant portion of our operating expenses for the foreseeable future related to new and existing product development. In addition, we expect increased clinical costs that will be expensed to research and development relating to the HeartWare System for US clinical trials.

Research and development expenses were $3.5 million, or 45%, of operating expenses for the three months ended March 31, 2009, as compared to $4.3 million, or 66% of operating expenses for the same period in the prior year. The decrease of approximately $0.7 million was primarily related to manufacturing activities capitalized as inventory related to the manufacturing of the HeartWare system for sale for the three months ended March 31, 2009 as opposed to being expensed as research and development expenses for the same period in the prior year. Research and development activities, including those related to the MVAD, continue to be expensed as incurred.

Other Income

Other income consists primarily of interest income and foreign exchange income or loss.

Interest income is primarily derived from cash and short-term deposits accounts, denominated in both Australian and United States dollars, held in Australia. Interest income was approximately $7,000 in the three months ended March 31, 2009 as compared to $0.3 million for the same period in the prior year. The decrease was primarily due to lower average cash balances and lower interest rates in 2009.

Foreign exchange gain was approximately $0.7 million in the three months ended March 31, 2009, as compared to a loss of approximately $0.7 million for the same period in the prior year. The difference was due to fluctuations in the value of our US dollar-based cash holdings held by our Australian subsidiary as a result of movements in the exchange rate between the Australian dollar and the US dollar.

Income Taxes

We are subject to taxation in the United States and Australia. We have incurred losses since inception in both jurisdictions. Changes in 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, 2009, 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, 2009, our cash and cash equivalents were $12.6 million as compared to $20.8 million at December 31, 2008. The decrease is primarily a result of cash used in operating activities.

Cash used in operating activities for the three months ended March 31, 2009 was approximately $7.4 million as compared to $6.0 million for the same period in the prior year. For the three months ended March 31, 2009, this amount included a net loss of $6.2 million and non-cash adjustments to net income of approximately $0.5 million which primarily consisted of approximately $0.2 million of depreciation and amortization and $0.3 million of share-based compensation. Included in cash used in operating activities in 2009 is approximately $3.2 million for the purchase of inventories. As noted above, we began capitalizing inventory in September 2008. We expect inventory purchases to significantly increase throughout 2009 in support of our US clinical trial and commercial sales in Europe.

For the three months ended March 31, 2008, cash used in operating activities included a net loss of $6.8 million and non-cash adjustments to net income of approximately $0.5 million which primarily consisted of approximately $0.1 million of depreciation and amortization and $0.4 million of share-based compensation.

Investing activities used cash of approximately $0.3 million and $0.4 million for the three months ended March 31, 2009 and 2008, respectively. These amounts were primarily to acquire property, plant and equipment and capitalized patent costs.

Cash provided by financing activities for the three months ended March 31, 2009 was approximately $20,000 as a result of an option exercise during the period. There were no financing cash activities during the three months ended March 31, 2008.

We will require additional funds to support our long-term operations, expand our sales and marketing infrastructure to support commercial distribution of our products and continue research and development. 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.

On February 12, 2009, concurrent with the execution and delivery of the Merger Agreement, we entered into a Loan Agreement in order to fund our ongoing operations until the closing of the Merger. Thoratec has deposited $20.0 million into an escrow account pursuant to the Loan Agreement. Beginning on May 1, 2009, HeartWare may borrow up to an aggregate of $12.0 million and beginning on July 31, 2009, HeartWare may borrow up to an aggregate of $20.0 million. In the event that all of the conditions to closing the Merger other than the receipt of regulatory approvals have been satisfied and Thoratec exercises an option under the Merger Agreement to extend the outside date for the completion of the Merger until January 31, 2010, HeartWare may borrow up to an additional $8.0 million, which Thoratec must deposit into the escrow account at the time it exercises its extension option. The maximum aggregate amount that HeartWare may borrow under the Loan Agreement will not exceed $28.0 million.

The loans to HeartWare under the Loan Agreement accrue interest at the rate of 10% per annum and are due and payable, together with accrued and unpaid interest, on the earlier of (i) November 1, 2011, (ii) the Termination date and (iii) the date on which all of the loans accelerate and become due and payable in full in accordance with the Loan Agreement. The loans may accelerate upon a change in control of the borrower or events of default.

Consummation of the Merger is subject to customary conditions, including adoption of the Merger Agreement by HeartWare's stockholders, the absence of legal impediments to consummation of the Merger and the expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976. Approval by Thoratec's shareholders is not required.

Thoratec and HeartWare may terminate the Merger Agreement under certain circumstances specified in the Merger Agreement. Upon the termination of the Merger Agreement in specified circumstances, HeartWare may be required to pay Thoratec a termination fee equal to $11.3 million, and in other specified circumstances, HeartWare may be obligated to pay Thoratec a termination fee equal to $5.0 million.

We believe that cash and cash equivalents on hand, expected cash flows from operations and the access to capital pursuant to the above described loan agreement will be sufficient to fund our operations for at least the next twelve months.

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 that is invested in highly liquid money market funds. 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. 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.

Foreign Currency Rate Fluctuations

We conduct business in foreign countries. For US reporting purposes, the Company translates all assets and liabilities of its non-US entities at the period-end exchange rate and translates 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 consolidated financial statements as a component of shareholders' equity.

Our Australian subsidiary holds US and Australian dollar denominated cash accounts. Fluctuations in the exchange rate of the US dollar against the AU dollar can result in foreign currency exchange gains and losses that impact our financial results and our overall cash position. These foreign currency transaction gains and losses are included in other, net in the consolidated statements of operations. The gains and losses are recorded in AU dollars, the functional currency of the Australian entity, and translated to US dollars, at an average exchange rate, for US reporting purposes. Continued fluctuation of the exchange rate could result in financial results that are not comparable from quarter to quarter.

We do not presently utilize foreign currency forward contracts and instead hold cash reserves in the currency in which those reserves are anticipated to be expended.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer, we conducted an evaluation of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) under the Securities Exchange Act of 1934. Based on such evaluation, the chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective as of March 31, 2009.

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, 2009 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.

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

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

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 8, 2009

/s/ Douglas Godshall
Douglas Godshall
Chief Executive Officer

Date: May 8, 2009

/s/ David McIntyre
David McIntyre
Chief Financial Officer and Chief Operating Officer

EXHIBIT INDEX

31.1	Certification of Chief Executive Officer pursuant to Rule 13A-14(a) or Rule 15d-14(a) of the Securities Exchange Act
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Exhibit 31.1

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)) 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 8, 2009

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIALOFFICER 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)) 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 8, 2009

/s/ David McIntyre
David McIntyre
Chief Financial Officer
(Principal Financial Officer)

Exhibit 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

In connection with the Quarterly Report on Form 10-Q of HeartWare International, Inc. (the "Company") for the quarterly period ended March 31, 2009 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 8, 2009

/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, 2009 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 8, 2009

/s/ David McIntyre
David McIntyre
Chief Financial Officer
(Principal Financial Officer)