

THORATEC CORP  
Form 10-Q  
November 12, 2004

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**U.S. SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark one)

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

**For the quarterly period ended October 2, 2004**

**or**

**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: 1-8145**

**THORATEC CORPORATION**

**(Exact name of registrant as specified in its charter)**

**California**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**94-2340464**  
**(I.R.S. Employer Identification No.)**

**6035 Stoneridge Drive, Pleasanton, California**  
**(Address of principal executive offices)**

**94588**  
**(Zip Code)**

**Registrant's telephone number, including area code: (925) 847-8600**

*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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act):* Yes  No

As of November 8, 2004 registrant had 48,752,878 shares of common stock outstanding.

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**THORATEC CORPORATION AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(unaudited)**

	<b>October 2, 2004</b>	<b>January 3, 2004</b>
	<u>                    </u>	<u>                    </u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 76,920	\$ 62,020
Short-term available-for-sale investments	69,959	
Restricted short-term investments	3,318	
Receivables, net of allowances of \$527 and \$486 respectively	29,934	27,969
Inventories	41,386	36,417
Deferred tax asset and other prepaid assets	12,315	12,796
	<u>                    </u>	<u>                    </u>
Total Current Assets	233,832	139,202
	<u>                    </u>	<u>                    </u>
Property, plant and equipment, net	28,193	28,492
Goodwill	94,219	96,065
Purchased intangible assets, net	156,072	164,865
Long-term available-for-sale investments		41,179
Restricted long-term investments	6,509	
Long-term deferred tax asset and other assets	11,598	6,328
	<u>                    </u>	<u>                    </u>
Total Assets	\$530,423	\$476,131
	<u>                    </u>	<u>                    </u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 21,689	\$ 22,772
	<u>                    </u>	<u>                    </u>
Total Current Liabilities	21,689	22,772
	<u>                    </u>	<u>                    </u>
Senior subordinated convertible notes	143,750	
Long-term deferred tax liability and other liabilities	63,734	67,123
	<u>                    </u>	<u>                    </u>
Total Liabilities	229,173	89,895
	<u>                    </u>	<u>                    </u>

Shareholders' Equity:		
Common shares; 100,000 authorized; issued and outstanding 49,663 and 56,242, respectively	374,567	423,045
Deferred compensation	(1,947)	(2,630)
Accumulated deficit	(71,644)	(34,594)
Accumulated other comprehensive income:		
Unrealized gain (loss) on investments	(137)	51
Cumulative translation adjustments	411	364
	<u>          </u>	<u>          </u>
Total accumulated other comprehensive income	274	415
	<u>          </u>	<u>          </u>
Total Shareholders' Equity	301,250	386,236
	<u>          </u>	<u>          </u>
Total Liabilities and Shareholders' Equity	\$530,423	\$476,131
	<u>          </u>	<u>          </u>

See notes to condensed consolidated financial statements.

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**THORATEC CORPORATION AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

(unaudited)  
(in thousands, except per share data)

	Three Months Ended		Nine Months Ended	
	October 2, 2004	September 27, 2003	October 2, 2004	September 27, 2003
Product sales	\$40,661	\$ 35,250	\$124,055	\$107,469
Cost of product sales	17,646	14,256	51,680	43,799
	23,015	20,994	72,375	63,670
Gross profit				
Operating expenses:				
Selling, general and administrative	13,168	10,562	39,954	31,791
Research and development	6,970	6,100	21,689	18,640
Amortization of purchased intangible assets	2,931	3,096	8,793	9,288
Litigation, restructuring and other costs	310		443	(124)
	23,379	19,758	70,879	59,595
Total operating expenses				
Income (loss) from operations	(364)	1,236	1,496	4,075
Other income and (expense):				
Interest expense	(1,015)		(1,433)	
Interest income and other	693	218	1,633	1,379
	(686)	1,454	1,696	5,454
Income (loss) before income tax expense				
Income tax benefit (expense)	288	(567)	(594)	(2,127)
	\$ (398)	\$ 887	\$ 1,102	\$ 3,327
Net income (loss)				
Net income (loss) per share, basic and diluted	\$ (0.01)	\$ 0.02	\$ 0.02	\$ 0.06

Shares used to compute net income (loss) per share:

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Basic	50,114	55,704	53,304	55,386
Diluted	50,114	57,705	54,422	56,761

See notes to condensed consolidated financial statements.

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**THORATEC CORPORATION AND SUBSIDIARIES**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(unaudited)  
(in thousands)

	<b>Nine Months Ended</b>	
	<b>October 2, 2004</b>	<b>September 27, 2003</b>
<b>Cash flows from operating activities:</b>		
Net income	\$ 1,102	\$ 3,327
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	14,245	13,144
Investment premium amortization	667	796
Amortization of deferred compensation	682	903
Tax benefit related to stock option exercises	404	1,948
Loss on disposal of asset	57	25
Change in net deferred tax liability	(1,022)	1,424
Changes in assets and liabilities:		
Receivables	(1,965)	4,925
Inventories	(4,969)	2,356
Prepaid expenses and other assets	91	(1,720)
Accounts payable and other liabilities	(1,676)	(2,988)
Other	(145)	16
	7,471	24,156
<b>Cash flows from investing activities:</b>		
Purchases of available-for-sale and other investments	(66,712)	(14,138)
Maturities of available-for-sale investments	26,640	6,708
Purchases of property, plant and equipment	(4,968)	(4,169)
	(45,040)	(11,599)
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of convertible notes	139,453	
Proceeds from stock issued under employee stock purchase plan	775	578
Proceeds from stock option exercises	2,201	7,266
Repurchase of common stock	(90,008)	

	_____	_____
Net cash provided by financing activities	52,421	7,844
Effect of exchange rate changes on cash	48	50
	_____	_____
Net increase in cash and cash equivalents	14,900	20,451
Cash and cash equivalents at beginning of period	62,020	42,044
	_____	_____
Cash and cash equivalents at end of period	\$ 76,920	\$ 62,495
	_____	_____
<b>Supplemental Cash Flow Disclosure:</b>		
Cash paid for taxes	\$ 511	\$ 726
Cash paid for interest	\$	\$

See notes to condensed consolidated financial statements.

Table of Contents**THORATEC CORPORATION AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME****(unaudited)**  
**(in thousands)**

	<u>Three Months Ended</u>		<u>Nine Months Ended</u>	
	<u>October 2, 2004</u>	<u>September 27, 2003</u>	<u>October 2, 2004</u>	<u>September 27, 2003</u>
Net income (loss)	<u>\$ (398)</u>	<u>\$ 887</u>	<u>\$ 1,102</u>	<u>\$ 3,327</u>
Other net comprehensive income (loss):				
Unrealized gain (loss) on investments (net of taxes of \$9 and \$(28) for the three months ended and \$(113) and \$(15) for the nine months ended October 2, 2004 and September 27, 2003, respectively)	3	(37)	(188)	(18)
Foreign currency translation adjustments	<u>( 13)</u>	<u>29</u>	<u>48</u>	<u>85</u>
Comprehensive income (loss)	<u>\$ (408)</u>	<u>\$ 879</u>	<u>\$ 962</u>	<u>\$ 3,394</u>

See notes to condensed consolidated financial statements.



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Add: Stock-based compensation expense included in reported net income, net of related tax effects	132	183	443	551
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	<u>(3,010)</u>	<u>(2,163)</u>	<u>(9,006)</u>	<u>(6,040)</u>
Pro forma	<u>\$ (3,276)</u>	<u>\$ (1,093)</u>	<u>\$ (7,461)</u>	<u>\$ (2,162)</u>
Basic earnings (loss) per share:				
As reported	\$ (0.01)	\$ 0.02	\$ 0.02	\$ 0.06
Pro forma loss	\$ (0.07)	\$ (0.02)	\$ (0.14)	\$ (0.04)
Diluted earnings (loss) per share:				
As reported	\$ (0.01)	\$ 0.02	\$ 0.02	\$ 0.06
Pro forma loss	\$ (0.07)	\$ (0.02)	\$ (0.14)	\$ (0.04)

**Table of Contents****3. New Accounting Pronouncements**

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure* which amends FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements of the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We adopted the disclosure provisions of SFAS No. 148 at the beginning of fiscal 2002. On March 31, 2004, the FASB issued an exposure draft,

Share-Based Payment, an Amendment of FASB Statements No. 123 and 95. This proposed statement would require that stock-based compensation be recognized as a cost in the financial statements and that such cost be measured based on the fair value of the stock-based compensation. If issued in final form as proposed by the FASB, our adoption of this proposed statement would have a material, although non-cash, impact on our condensed consolidated statements of operations.

In March 2004, the Emerging Issues Task Force ( EITF ) reached a final consensus on Issue 03-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments* , to provide additional guidance in determining whether investment securities have an impairment which should be considered other-than-temporary. On September 15, 2004 the FASB issued proposed FSP EITF Issue 03-1-a to address the application of the EITF Issue 03-1 to debt securities that are affected by interest rate and/or sector-spread changes only. On September 30, 2004, the FASB issued FSP EITF Issue 03-1-1, which delayed the effective date of certain paragraphs of the EITF until EITF 03-1-a is issued. Management is still evaluating the potential effect that the adoption of EITF 03-1 and the related FASB Staff Position s ( FSP ) will have on the Company s operating results or financial condition.

In April 2004, the FASB issued FSP FASB Statement of Accounting Standards ( FAS ) No. 129-1, *Disclosure of Information about Capital Structure, Relating to Contingently Convertible Securities* to provide disclosure guidance for contingently convertible securities. We adopted the disclosure provisions in the second quarter of 2004 as they apply to the convertible notes. The 7.3 million shares underlying our convertible notes are reportable under this new disclosure are antidilutive and, therefore, have been excluded from the calculation of diluted net income per share.

In October 2004, EITF Issue No. 04-8, *Accounting Issues Related to Certain Features of Contingently Convertible Debt and the Effect on Diluted Earnings per Share* was issued. Issue No. 04-8 states that shares available under contingently convertible debt should be included in diluted earnings per share, or EPS, in all periods, since the notes were issued, except when inclusion is anti-dilutive, regardless of whether the contingency is met and regardless of whether the market price contingency is substantial. Our adoption of this proposed interpretation, which we expect to occur in the fourth quarter of 2004, would not have a material impact on our most recent consolidated results as the effect of the 7.3 million shares would be anti-dilutive. If in future periods the shares would be dilutive, then 7.3 million shares will be added to our share count used to calculate diluted earnings per share, and this inclusion could result in lower diluted EPS than if the existing guidance had not been changed by EITF 04-8.

**4. Cash and Investments**

We consider highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. Short-term investments consist of available-for-sale debt securities that are carried at fair value and generally mature between three months and two years from the purchase date. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature. We include any unrealized gains and losses on short-term investments, net of tax, in shareholders' equity as a component of other comprehensive income.

As required by the terms of the convertible notes during the second quarter of 2004 (See Note 9) we purchased an aggregate of \$9.8 million in U.S. government securities that were pledged to the trustee under the indenture. These funds are for the exclusive benefit of the holders of the convertible notes to provide for the payment, in full, of the first six semi-annual interest payments. The investments that relate to interest payments due in the first year have been classified as restricted short-term investments and the investments that relate to interest payments due after the first year have been classified as restricted long-term investments.

**Table of Contents****5. Financial Instruments**

We have a foreign currency exchange risk management program principally designed to mitigate the change in value of assets and liabilities that are denominated in non-functional currencies. Forward exchange contracts that generally have terms of three months or less are used to hedge these non-functional currency exposures on our books. The derivatives used in the foreign currency exchange risk management program are not designated as cash flow or fair value hedges under SFAS 133. These contracts are recorded on the condensed consolidated balance sheets at fair value in Deferred Tax Asset and Other Prepaid Assets current assets. Changes in the fair value of the contracts and the underlying exposures being hedged are included concurrently in Interest income and other . At October 2, 2004, the notional value of outstanding contracts approximated \$7.0 million with negligible fair value.

**6. Inventories**

Inventories consist of the following:

	<b>As of</b>	
	<b>October 2, 2004</b>	<b>January 3, 2004</b>
	<b>(in thousands)</b>	
Finished goods	\$21,133	\$15,504
Work in process	5,354	9,089
Raw materials	14,899	11,824
	<u>          </u>	<u>          </u>
Total	<u>\$41,386</u>	<u>\$36,417</u>

**7. Property, Plant and Equipment**

Property, plant and equipment consist of the following:

	<b>As of</b>	
	<b>October 2, 2004</b>	<b>January 3, 2004</b>
	<b>(in thousands)</b>	
Property, plant and equipment, at cost	\$ 61,131	\$ 58,023
Less accumulated depreciation	(32,938)	(29,531)
	<u>          </u>	<u>          </u>
Total	<u>\$ 28,193</u>	<u>\$ 28,492</u>

**8. Goodwill and Purchased Intangible Assets**

The change in the carrying amount of goodwill, which is attributable to our Cardiovascular business segment, for the nine month periods ended October 2, 2004 and September 27, 2003 was as follows:

	<b>Nine Months Ended</b>	
	<b>October 2, 2004</b>	<b>September 27, 2003</b>
	<b>(in thousands)</b>	
Beginning balance	\$96,065	\$ 96,492
Realization of acquired deferred tax asset	(1,031)	
Reversal of accrual for securities registration costs	(815)	
	<u>          </u>	<u>          </u>
Ending balance	<u>\$94,219</u>	<u>\$ 96,492</u>

In the first nine months of 2004, goodwill related to the 2001 merger of Thoratec and Thermo Cardiosystems, Inc. ( TCA ) was adjusted to reflect the utilization of tax net operating loss benefits. At the time of the merger, a deferred tax asset related to these tax benefits was established with a corresponding valuation allowance for the full amount. A portion of the original valuation allowance has been reversed against goodwill as we recognized benefits related to these tax assets.

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Goodwill was also adjusted in the first quarter of 2004 to reflect the reversal of an accrual, established at the time of the merger with TCA, for securities registration costs. Under the terms of the merger agreement, the Company committed to pay for securities registration related costs should Thermo Electron Corporation ( TCI ) (the majority shareholder in TCA prior to the merger) decide to sell its shares of the Company's common stock in a public offering. This commitment was enforceable until TCI's holdings in Thoratec fell below 10%, which occurred in the first quarter of 2004.

The components of identifiable intangible assets are as follows:

	<b>As of October 2, 2004</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
		(in thousands)	
Patents and Trademarks	\$ 37,815	\$(13,141)	\$ 24,674
Core Technology	37,485	(6,769)	30,716
Developed Technology	122,782	(22,177)	100,605
Non-compete Agreement	90	(13)	77
	<hr/>	<hr/>	<hr/>
Total Purchased Intangible Assets	\$198,172	\$(42,100)	\$ 156,072
	<hr/>	<hr/>	<hr/>
	<b>As of January 3, 2004</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
		(in thousands)	
Patents and Trademarks	\$ 37,815	\$(10,416)	\$ 27,399
Core Technology	37,485	(5,353)	32,132
Developed Technology	122,782	(17,535)	105,247
Non-compete Agreement	90	(3)	87
	<hr/>	<hr/>	<hr/>
Total Purchased Intangible Assets	\$198,172	\$(33,307)	\$ 164,865
	<hr/>	<hr/>	<hr/>

After fiscal 2003 year-end, the Company completed its assessment of the final results from its feasibility clinical trial for the Aria CABG graft which was ongoing through fiscal 2003. Based on the clinical trial results, the Company determined that it would not devote additional resources to the development of the Aria graft. Upon the decision to discontinue product development, the Company recorded an impairment charge of \$9.0 million in the fourth quarter of 2003 to write off purchased intangible assets related to the Aria graft which had been recorded as a result of the merger with TCA in 2001.

On September 30, 2003, we completed an asset purchase of the Immediate Response Mobile Analysis, or IRMA, point-of-care blood analysis system product line from Diagnostics Medical, Inc. ( Diagnostics ). We paid approximately \$5.2 million in cash and assumed trade payables. Approximately \$1.8 million of the total purchase price was allocated to purchased intangible assets.

Amortization expense related to identifiable intangible assets was \$2.9 million for the three months ended October 2, 2004 and \$8.8 million for the nine months ended October 2, 2004. Amortization expense related to identifiable intangible assets was \$3.1 million for the three months ended September 27, 2003 and \$9.3 million for the nine months ended September 27, 2003. Amortization expense is expected to be approximately \$11.7 million for each of the next five years. The purchased intangible assets have estimated useful lives of seven to twenty years.

**Table of Contents****9. Long-Term Debt**

In the second quarter of 2004, we completed the sale of \$143.8 million initial principal amount of senior subordinated convertible notes due 2034. The convertible notes were sold to Qualified Institutional Buyers pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Rule 144A thereunder. We used \$9.8 million of the net proceeds to purchase and pledge to the trustee under the indenture for the exclusive benefit of the holders of the convertible notes, U.S. government securities to provide for the payment, in full, of the first six scheduled interest payments. Additional net proceeds were used to repurchase 4.2 million shares of our outstanding common stock for \$60 million. The remaining net proceeds will be used for general corporate purposes, which may include additional stock repurchases, strategic investments or acquisitions. Total net proceeds to the Company from the sale were \$139.4 million, after debt issuance costs of \$4.3 million.

The convertible notes were issued at an issue price of \$580.98 per note, which is 58.098% of the principal amount at maturity of the notes. The convertible notes bear interest at a rate of 1.3798% per year on the principal amount at maturity, payable semi-annually in arrears in cash on May 16 and November 16 of each year, from November 16, 2004 until May 16, 2011. Beginning on May 16, 2011, the original issue discount will accrue daily at a rate of 2.375% per year on a semi-annual bond equivalent basis and, on the maturity date, a holder will receive \$1,000 per note. As a result, the aggregate principal amount of the notes at maturity will be \$247.4 million.

The deferred debt issuance costs of \$4.3 million are included in other assets on the condensed consolidated balance sheet. The deferred debt issuance costs are amortized on a straight line basis until May 2011 at which point the Company can redeem the debt. These charges are included in Interest expense on the consolidated statement of operations.

	<b>October 2, 2004</b>
	<b>(in thousands)</b>
<b>Long Term Debt Offering Proceeds:</b>	
Principal amount of convertible notes at maturity	\$ 247.4
Original issue discount	(103.7)
Debt issuance costs	(4.3)
	<hr/>
Net proceeds	\$ 139.4
	<hr/>

Holders of the convertible notes may convert their convertible notes into shares of our common stock at a conversion rate of 29.4652 shares per \$1,000 principal amount of convertible notes, which represents a conversion price of \$19.72 per share, subject to adjustments upon the occurrence of certain events. Holders were able to convert their convertible notes at any point after the close of business on September 30, 2004 if, as of the last day preceding the calendar quarter, the closing price of our common stock for at least 20 trading days in a period of 30 consecutive trading days ending on the last trading day of such preceding calendar quarter is more than 120% of the accreted conversion price per share of our common stock. Holders may surrender their convertible notes on or prior to May 16, 2029 during the five business day period after any five consecutive trading day period in which the trading price per note for each day of that period was less than 98% of the product of the closing sale price of our common stock and the conversion rate on each such day; provided that if on the day prior to any conversion the closing sale price of our common stock is greater than the accreted conversion price but less than or equal to 120% of the accreted conversion

price, then holders will receive upon conversion, in lieu of shares of common stock based on the conversion rate, cash or common stock, or a combination of cash and common stock, at our option, with a value equal to the accreted principal amount of the notes plus accrued but unpaid interest as of the conversion date. Additionally, holders may convert their convertible notes if we call them for redemption or if specified corporate transactions or significant distributions to holders of our stock have occurred.

Holders may require us to repurchase all or a portion of their convertible notes on each of May 16, 2011, 2014, 2019, 2024 and 2029 at a repurchase price equal to 100% of the issue price, plus accrued original issue discount, if any. In addition, if we experience a change in control or a termination of trading each holder may require us to purchase all or a portion of such holder's notes at the same price, plus, in certain circumstances, a make whole premium. The fair value of the make whole premium at October 2, 2004 was zero. We may redeem any of the convertible notes at any time beginning May 16, 2011, by giving the holders at least 30 days notice, either in whole or in part at a redemption price equal to the sum of the issue price and the accrued original issue discount, plus accrued and unpaid interest and liquidation damages, if any.



unspecified damages and fees, including those arising from potential sales of its VAD products which plaintiff alleges it lost due to the Company's HeartMate II clinical trial.

The Company has successfully defended itself against MicroMed's requests for injunctive relief and will continue to vigorously defend any and all of the claims made by MicroMed in this action.

On August 3, 2004, a putative Federal securities law class action entitled Johnson v. Thoratec Corporation, et al. was filed in the United States District Court for the Northern District of California on behalf of purchasers of the publicly traded securities of the Company between April 28, 2004 and June 29, 2004. The Johnson complaint generally alleges violations of the Securities Exchange Act of 1934 by the Company, its chief executive officer and chief financial officer based upon, inter alia, alleged false statements about the Company's expected sales and the market for HeartMate as a Destination Therapy treatment. The complaint seeks to recover unspecified damages on behalf of all purchasers of the Company's publicly traded securities during the class period. Subsequent to the filing of the Johnson complaint, additional complaints were filed in the same court alleging substantially similar claims. On October 4, 2004, a putative class member, Craig Toby, filed a motion to be appointed lead plaintiff pursuant to the Private Securities Litigation Reform Act of 1995 and to consolidate all of the pending class action litigations against Thoratec into a single proceeding. The Court has not yet ruled on those motions.

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On or about September 1, 2004, a shareholder derivative action entitled *Wong v. Grossman* was filed in the California Superior Court for Alameda County based upon essentially the same facts as the Federal securities class action suits. This action names the individual members of the Company's Board of Directors, including the Chief Executive Officer and our Chief Financial Officer as defendants and alleges that the defendants breached their fiduciary duties and wasted corporate assets, and that certain of the defendants traded in the Company's securities while in possession of material nonpublic information.

The Company believes that the claims asserted in both the Federal securities law putative class action and the state shareholder derivative action are without merit and the Company intends to move to dismiss both suits. However, we are unable to predict at this time the final outcome of these actions, or whether the resolution of the actions could materially affect our results of operations, cash flows or financial position.

***Restructuring Costs***

We completed consolidation of our VAD manufacturing operations in the second quarter of 2003. Total costs related to this consolidation were \$1.5 million. Following is a summary of restructuring cost activity relating to the consolidation:

	<b>Nine Months Ended</b>
	<b>September 27, 2003</b>
	<b>(in thousands)</b>
<b>Accrued Restructuring Costs:</b>	
Beginning balance	\$ 679
Reduction of severance accrual	(122)
Payments of employee severance	(557)
	<hr/>
Ending balance	\$ <hr/>

**12. Income Taxes**

Our effective tax rates were 42% and 39% for the three months ended October 2, 2004 and September 27, 2003, respectively. The effective rate was 35% for the nine months ended October 2, 2004 and 39% for the nine months ended September 27, 2003. The reduction in our effective tax rate is due primarily to: (1) a reduction of our projected annual profit before tax; (2) additional interest income from tax favorable investments; and (3) a lower effective state tax rate due to increased statutory tax credits. The effective income tax rate for both quarters differed from the statutory federal income tax rate primarily due to the impact of state taxes.

At October 2, 2004 and January 3, 2004, we reported a net deferred tax liability of approximately \$ 48.6 million and \$51.3 million, respectively, comprised principally of temporary differences between the financial statement and income tax bases of intangible assets.

**13. Net Income (Loss) Per Share**

Basic and diluted net income (loss) per share were calculated as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>October 2, 2004</b>	<b>September 27, 2003</b>	<b>October 2, 2004</b>	<b>September 27, 2003</b>
	<b>(in thousands, except per share data)</b>			
Net income (loss)	\$ (398)	\$ 887	\$ 1,102	\$ 3,327
Weighted average number of common shares-basic	50,114	55,704	53,304	55,386
Dilutive effect of stock options	—	2,001	1,118	1,375
Weighted average number of common shares-diluted	50,114	57,705	54,422	56,761
Net income (loss) per common share-basic and diluted	\$ (0.01)	\$ 0.02	\$ 0.02	\$ 0.06

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Basic net income (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Of the options to purchase shares of our common stock outstanding as of October 2, 2004, options covering 10.5 million shares and 4.7 million shares of our common stock were excluded from the computation of the diluted net income (loss) per share for the three month and nine month periods ending October 2, 2004, respectively, as their inclusion would be antidilutive. Of the options to purchase shares of common stock outstanding as of September 27, 2003, those covering 0.2 million shares and 3.2 million shares of common stock were excluded from the computation of diluted net income (loss) per share for the three and nine months ended September 27, 2003, respectively, as their inclusion would be antidilutive.

**14. Business Segment and Geographical Data**

We organize and manage our business by functional operating entities. Our functional entities operate in two segments: (1) Cardiovascular and (2) ITC. The Cardiovascular segment develops, manufactures and markets proprietary medical devices used for circulatory support and vascular graft applications. The ITC segment develops, manufactures and markets point-of-care diagnostic test systems.

## Business Segments:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>October 2, 2004</b>	<b>September 27, 2003</b>	<b>October 2, 2004</b>	<b>September 27, 2003</b>
	(in thousands)			
Product sales:				
Cardiovascular	\$22,919	\$ 21,331	\$ 72,544	\$ 68,799
ITC	17,742	13,919	51,511	38,670
Total product sales	<u>\$40,661</u>	<u>\$ 35,250</u>	<u>\$124,055</u>	<u>\$107,469</u>
Income before income taxes:				
Cardiovascular	\$ 2,330	\$ 2,920	\$ 8,649	\$ 10,161
ITC	2,058	2,967	6,778	7,454
Corporate (a)	(1,511)	(1,555)	(4,695)	(4,376)
Amortization of purchased intangibles	(2,931)	(3,096)	(8,793)	(9,288)
Litigation, restructuring and other costs (b)	<u>(310)</u>	<u>          </u>	<u>(443)</u>	<u>124</u>
Total income (loss) from operations	(364)	1,236	1,496	4,075
Other income and (expense):				
Interest expense	(1,015)		(1,433)	
Interest income and other	693	218	1,633	1,379

	_____	_____	_____	_____
Income (loss) before income taxes	\$ (686)	\$ 1,454	\$ 1,696	\$ 5,454
	_____	_____	_____	_____

(a) Represents primarily general and administrative expenses not specifically identified to any particular business segment.

(b) In 2004, relates to expenses not specifically identified to any particular business segment. In 2003, this amount related solely to the Cardiovascular segment.

Geographic Areas:

The geographic composition of our product sales were as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>October 2, 2004</b>	<b>September 27, 2003</b>	<b>October 2, 2004</b>	<b>September 27, 2003</b>
	_____	_____	_____	_____
	<b>(in thousands)</b>			
Domestic	\$30,774	\$28,662	\$ 95,946	\$ 88,913
International	9,887	6,588	28,109	18,556
	_____	_____	_____	_____
Total	\$40,661	\$35,250	\$124,055	\$107,469
	_____	_____	_____	_____

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

**Forward-Looking Statements**

*With the exception of historical facts, the statements contained in this Form 10-Q are forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements generally can be identified by use of statements that include words such as believe, expect, anticipate, intend, plan, foresee, may, hope, will, estimates, potential, continue, or phrases. Similarly, statements that describe our objectives, plans or goals also are forward-looking statements. All of these forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statement. See Factors Affecting Future Results for the principal risk factors that could cause our actual performance and future actions to differ materially from the forward-looking statements. Readers are urged to consider these factors carefully in evaluating the forward-looking statements. The forward-looking statements included in this Form 10-Q are made only as of the date of this report and we undertake no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances. In addition, quantitative projections of 2004 revenue and gross margins, as well as projections regarding our market share and the status of our competition, clinical trials and product acceptance set forth in our Annual Report on Form 10-K for fiscal 2003 and our Quarterly Report on Form 10-Q for the first quarter of fiscal 2004, and any amendments thereto, should no longer be relied upon. See our Interim Report on Form 8-K furnished on June 29, 2004, which describes changes to our revenue projections for fiscal 2004.*

*The following presentation of management's discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements included in this Form 10-Q, and our Annual Report on Form 10-K for 2003 filed with the SEC.*

**Table of Contents****Overview**

We are a leading manufacturer of circulatory support products for use by patients with congestive heart failure, or CHF. According to the American Heart Association, 4.9 million patients in the United States suffer from CHF and an additional 550,000 patients are diagnosed with this disease annually. We were the first company to receive approval from the United States Food and Drug Administration, or FDA, to commercially market a ventricular assist device, referred to as VADs, to treat patients with late-stage heart failure, which comprises approximately 5% to 10% of the CHF patient population. Our VADs are used primarily by these CHF patients to perform some or all of the pumping function of the heart and we currently offer the widest range of products to serve this market. We believe that our long-standing reputation for quality and innovation and our excellent relationships with leading cardiovascular surgeons worldwide position us to capture growth opportunities in the expanding congestive heart failure market. Through our ITC subsidiary we design, develop, manufacture and market point-of-care diagnostic test systems that provide fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes.

**Our Business Model**

The two product lines that represent the majority of our revenues are VADs and point-of-care diagnostic test systems and services. Historical annual revenue mix has been as follows:

VAD pumps including associated products and services	60-62%
Point-of-care diagnostic test systems	34-38%
Grafts/Other	2-4%

**Acquisitions and Strategic Developments**

On September 30, 2003, we completed an asset purchase of the Immediate Response Mobile Analysis, or IRMA, point-of-care blood analysis system product line from Diagnostics Medical, Inc. ( Diagnostics ). We paid approximately \$5.2 million in cash and assumed trade payables. The purchase price was allocated based on the fair value of assets acquired as determined by an independent valuation firm. There was no goodwill recorded with the transaction. As a result of the acquisition, \$0.2 million relating to in-process research and development was expensed in the fourth quarter of 2003.

On March 30, 2004, we made an investment in BioCardia, Inc. Under the terms of the investment documents, we (i) will assist BioCardia in exploring opportunities for developing devices for the surgical delivery of biotherapeutics, (ii) have limited exclusive rights to negotiate the distribution, licensing or purchase of surgical delivery technology developed by BioCardia and (iii) through an observational board seat, will be able to review relevant clinical data accumulated by BioCardia through its multiple trials. We have accounted for this investment on the cost basis as we do not have the ability to exercise significant influence over BioCardia's operating and financial policies. This investment is included on our condensed consolidated balance sheet in other long-term assets.

**Restructuring Plan**

In June 2001, following the merger with Thermo Cardiosystems, Inc., we initiated a restructuring plan to consolidate all of our VAD manufacturing operations to our facilities in Pleasanton, California. Through April 2003, the completion date of the restructuring plan, we recorded a total of \$1.5 million in restructuring charges. These charges represent estimated employee severance costs and stock option acceleration charges.

**Critical Accounting Policies and Estimates**

We have identified certain accounting policies as critical to our business operations and the understanding of our results of operations. This section should be read in conjunction with the section entitled Critical Accounting Policies in our annual report on Form 10-K for fiscal 2003.

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations are discussed

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below. Preparation of financial statements in accordance with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities. There can be no assurance that actual results will not differ from those estimates.

***Evaluation of Goodwill and Purchased Intangibles for Impairment***

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, we periodically evaluate the carrying value of long-lived assets to be held and used including intangible assets, when events or circumstances warrant such a review. The carrying value of a long-lived asset to be held and used is considered impaired when the anticipated separately identifiable undiscounted cash flows from such an asset are less than the carrying value of the asset. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. Management must make estimates of these future cash flows and the approximate discount rate, and if these estimates prove incorrect, the carrying value of these assets on our condensed consolidated balance sheet could significantly misstate their true value.

As of the beginning of fiscal year 2002, we adopted SFAS No. 142, *Goodwill and Other Intangible Assets*, and ceased the amortization of purchased goodwill. In addition, we reevaluated the useful lives of our identifiable intangible assets and determined that the remaining useful lives were appropriate. Each year we complete an impairment test of goodwill as required by SFAS No. 142. Upon completion of our impairment tests as of the end of fiscal 2003, we determined that our goodwill was not impaired.

***Revenue Recognition***

We recognize revenue from product sales when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectibility is reasonably assured. Sales to distributors are recorded when title transfers upon shipment. One of our distributors has certain limited product return rights. A limited number of our other distributors have certain rights of return upon termination of their distribution agreement. A reserve for sales returns is recorded for these customers applying reasonable estimates of product returns based upon significant historical experience. No other direct sales customers or distributors have return rights or price protection.

Sales of certain Cardiovascular segment products to first-time customers are recognized when it has been determined that the customer has the ability to use such products. These sales frequently include the sale of products and training services under multiple element arrangements. For most customers, training is not essential to the functionality of the products as the customers already possess sufficient expertise and experience to use the products. In these situations, training is provided as a best practice to optimize the use and success of the products. The amount of revenue under these arrangements allocated to training is based upon fair market value of the training, which is performed principally by third party providers. The amount of product sales allocated to the Cardiovascular segment products is done on a residual method basis. Under this method, the total value of the arrangement is allocated first to the undelivered training element based on the fair market value, with the remainder being allocated to the Cardiovascular segment products. The amount of product sales allocated to training is recorded as deferred revenue and is recognized when the training is completed. As of the nine months ended October 2, 2004, all products that had been delivered and recorded as product sales were delivered to customers for which training had been completed. There was no amount of product sales deferred related to this training not yet completed at the nine months ended October 2, 2004; however, \$20,000 of such product sales were deferred at the end of 2003 and \$100,000 at the end of 2002.

We also rent certain medical devices to customers on a month-to-month or as-used basis. Rental income is based on utilization and is included in product sales as earned. Included in product sales for the nine months ended October 2, 2004, the years ended 2003, and 2002 are \$4.4 million, \$4.6 million, and \$3.8 million, respectively, of income earned from the rental of these medical devices.

The majority of our products are covered by up to a two-year limited manufacturer's warranty from the date of installation. Estimated contractual warranty obligations are recorded when related sales are recognized and any additional amounts are recorded when such costs are probable and can be reasonably estimated.

**Table of Contents*****Reserves***

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make payments owed to us for product sales. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

In June 2001, following the merger with Thermo Cardiosystems, Inc., we initiated a restructuring plan to consolidate all of our VAD manufacturing operations. Through April 2003, the completion date of the restructuring plan, we recorded a total of \$1.5 million in restructuring charges. These charges represent estimated employee severance costs and stock option acceleration charges

***Accounting Pronouncements***

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure* which amends FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements of the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We adopted the disclosure provisions of SFAS No. 148 at the beginning of fiscal 2002. On March 31, 2004, the FASB issued an exposure draft,

Share-Based Payment, an Amendment of FASB Statements No. 123 and 95. This proposed statement would require that stock-based compensation be recognized as a cost in the financial statements and that such cost be measured based on the fair value of the stock-based compensation. If issued in final form as proposed by the FASB, our adoption of this proposed statement would have a material, although non-cash, impact on our condensed consolidated statements of operations.

In March 2004, the Emerging Issues Task Force ( EITF ) reached a final consensus on Issue 03-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments* , to provide additional guidance in determining whether investment securities have an impairment which should be considered other-than-temporary. On September 15, 2004 the FASB issued proposed FSP EITF Issue 03-1-a to address the application of the EITF Issue 03-1 to debt securities that are affected by interest rate and/or sector-spread changes only. On September 30, 2004, the FASB issued FSP EITF Issue 03-1-1, which delayed the effective date of certain paragraphs of the EITF until EITF 03-1-a is issued. Management expects that the adoption of this Issue and the related FSP s will not have a significant effect on the Company s operating results or financial condition.

In April 2004, the FASB issued FSP FAS No. 129-1, *Disclosure of Information about Capital Structure, Relating to Contingently Convertible Securities* to provide disclosure guidance for contingently convertible securities. We adopted the disclosure provisions in the second quarter of 2004 as they apply to the convertible notes. The 7.3 million shares underlying our convertible notes are reportable under this new disclosure are antidilutive and, therefore, have been excluded from the calculation of diluted net income per share. See note 13.

In October 2004, EITF Issue No. 04-8, *Accounting Issues Related to Certain Features of Contingently Convertible Debt and the Effect on Diluted Earnings per Share* was issued. Issue No. 04-8 states that shares available under contingently convertible debt should be included in diluted earnings per share, or EPS, in all periods, since the notes were issued, except when inclusion is anti-dilutive, regardless of whether the contingency is met and regardless of whether the market price contingency is substantial. Our adoption of this proposed interpretation, which we expect to occur in the fourth quarter of 2004, would not have a material impact on our most recent consolidated results as the effect of the 7.3 million shares would be anti-dilutive. If in future periods the shares would be dilutive, then 7.3 million shares will be added to our share count used to calculate diluted earnings per share, and this inclusion

could result in lower diluted EPS than if the existing guidance had not been changed by EITF 04-8.

**Table of Contents****Results of Operations**

The following table sets forth selected condensed consolidated statements of operations data for the periods indicated as a percentage of total product sales:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>October 2, 2004</b>	<b>September 27, 2003</b>	<b>October 2, 2004</b>	<b>September 27, 2003</b>
Product sales	100%	100%	100%	100%
Cost of sales	43	40	42	41
Gross profit	57	60	58	59
Operating expenses:				
Selling, general & administrative	33	30	32	30
Research & development	17	17	18	17
Amortization of purchased intangible assets	7	9	7	8
Litigation, restructuring and other costs	1	0	0	0
Total operating expenses	58	56	57	55
Income (loss) from operations	(1)	4	1	4
Other income and (expense):				
Interest expense	(3)	0	(1)	0
Interest income and other	2	1	1	1
Income (loss) before income taxes	(2)	5	1	5
Income tax benefit (expense)	1	2	0	2
Net income (loss)	(1)%	3%	1%	3%

See Note 14 to our unaudited condensed consolidated interim financial statements in this report for data presented by business segment.

**Three months ended October 2, 2004 and September 27, 2003*****Product Sales***

Product sales in the third quarter of 2004 were \$40.7 million compared to \$35.3 million in the third quarter of 2003. The primary components of the \$5.4 million increase in product sales were the following:

Point-of-care diagnostic sales increased \$2.8 million, including \$1.4 million in revenue from the IRMA product line acquired in the fourth quarter of 2003.

Alternate site sales of the Protime product line increased \$0.9 million.

Other sales, (drivers, cannulae, service, rentals and spares) increased \$1.5 million, including an increase in TLC II driver revenue principally from Home Discharge, which was approved by the FDA toward the end of the second quarter 2004.

Our sales of Destination Therapy implants were lower year to date than we had originally anticipated, and we expect product sales to increase more slowly than we had originally projected.

### ***Gross Profit***

Gross profit in the third quarter of 2004 was 57% compared to 60% in the third quarter of 2003. The change in margins were due to the following fluctuations:

A higher margin resulting from higher average sales prices on IVAD and PVAD products internationally, offset by

A lower margin on point-of-care products, primarily related to the IRMA product line, plus higher distribution costs associated with the shift in mix from distributor to direct channels.

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***Selling, General and Administrative***

Selling, general and administrative expenses in the third quarter of 2004 were \$13.2 million, or 33% of product sales, compared to \$10.6 million, or 30% of product sales, in the third quarter of 2003. Underlying the \$2.6 million increase in spending were the following:

Increased headcount from 164 at the end of the third quarter of 2003 to 203 at the end of the third quarter of 2004, together with annual salary.

Higher spending on marketing and related activities, primarily associated with our HeartHope Center Program, Destination Therapy, and costs associated with the IRMA product line.

We anticipate that selling, general and administrative costs will generally increase each year as our business grows, with some quarterly and annual significant increases in spending in connection with particular events such as product development or enhancements. Spending as a percentage of revenue is expected to decrease assuming revenue from current products increases, particularly if we realize increasing revenue generated by Destination Therapy implants.

***Research and Development***

Research and development expenses in the third quarter of 2004 were \$7.0 million compared to \$6.1 million in the third quarter of 2003, representing 17% of product sales for both periods. Research and development costs are largely project driven, and the level of spending depends on the level of project activity planned and subsequently approved and conducted. The primary component of our research and development costs is employee salaries and benefits. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations.

We anticipate that research and development costs will generally increase each year assuming our business grows, with some quarterly and annual significant increases in spending in connection with particular events such as product introductions and regulatory approvals. We expect research and development spending as a percentage of revenue to trend downward as revenue from current products increase, in particular if we realize increasing revenue related to sales of Destination Therapy implants.

***Amortization of Purchased Intangible Assets***

Amortization of purchased intangible assets in the third quarter of 2004 was \$2.9 million compared to \$3.1 million in the third quarter of 2003. The decrease of \$0.2 million is primarily due to the write-off of purchased intangible assets related to the Aria CABG graft in the fourth quarter of 2003.

***Income Taxes***

Our effective tax rates were 42% and 39% for the third quarters of 2004 and 2003, respectively. The change in our effective tax rate over these quarters was due primarily to a reduction of our projected annual profit before tax and additional interest income from tax favorable investments. The effective income tax rate for both quarters differed from the statutory federal income tax rate primarily due to the impact of state taxes, research and experimental tax credits and tax favorable investments.

**Nine months ended October 2, 2004 and September 27, 2003**

***Product Sales***

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Product sales in the first nine months of 2004 were \$124.1 million compared to \$107.5 million in the first nine months of 2003. The primary components of the \$16.6 million increase in product sales were as follows:

\$8.1 million higher revenue from sales of point-of-care diagnostic test systems, including \$4.7 million generated by the IRMA product line;

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\$4.7 million higher revenue from sales of alternate site and incision products, including a \$3.5 million increase in the ProTime product line;

\$5.2 million higher VAD revenue; partially offset by

\$1.4 million lower graft revenue.

***Gross Profit***

Gross profit as a percentage of sales in the first nine months of 2004 and 2003 was 58% and 59%, respectively. Within these essentially flat margins were the following fluctuations:

A 3% higher margin on cardiovascular products resulting from a shift in mix from lower to higher margin products, partially offset by higher manufacturing costs.

A 4% lower margin on point-of-care revenue, primarily related to the IRMA product line, plus higher distribution costs associated with the shift in mix from distributor to direct channels.

***Selling, General and Administrative***

Selling, general and administrative expenses in the first nine months of 2004 were \$40.0 million, or 32% of product sales, compared to \$31.8 million, or 30% of product sales, in the first nine months of 2003. Underlying the \$8.2 million increase in these expenses were the following drivers:

Increased headcount from 164 at the end of the first nine months of 2003 to 203 at the end of the first nine months of 2004, together with annual salary increases.

Higher spending on marketing and related activities, primarily associated with our HeartHope Center Program, Destination Therapy, and costs associated with the IRMA product line.

Higher professional fees, including legal, audit and financial consulting services relating primarily to our compliance with the Sarbanes-Oxley Act of 2002.

***Research and Development***

Research and development expenses in the first nine months of 2004 were \$21.7 million compared to \$18.6 million in the first nine months of 2003, representing 18% and 17% of product sales, respectively. The primary component of our research and development costs is employee salaries and benefits. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations

***Amortization of Purchased Intangible Assets***

Amortization of purchased intangible assets in the first nine months of 2004 was \$8.8 million compared to \$9.3 million in the first nine months of 2003. The decrease of \$0.5 million is primarily due to the write-off of purchased intangible assets related to the Aria CABG graft in the fourth quarter of 2003.

***Income Taxes***

Our effective tax rates were 35% and 39% for the nine month periods ended October 2, 2004 and September 27, 2003, respectively. The reduction in our effective tax on a comparative basis was due primarily to a reduction of our projected annual profit before tax and additional interest income from tax favorable investments. The effective income tax rate for both quarters differed from the statutory federal income tax rate primarily due to the impact of state taxes,

research and experimental tax credits and tax favorable investments.

**Liquidity and Capital Resources**

At October 2, 2004, we had working capital of \$212.1 million compared with \$116.4 million at January 3, 2004. Cash and cash equivalents and short-term available-for-sale investments at October 2, 2004 were \$146.9 million

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compared to \$62 million at January 3, 2004. The increase is due primarily to proceeds from our convertible debt offering in the second quarter of 2004.

Cash provided by operating activities for the nine months ended October 2, 2004 was \$7.5 million, after payments for litigation and annual bonuses accrued at January 3, 2004 totaling \$5.2 million. In addition, investing activities used \$45 million, with \$40.1 million net purchases of investments and \$5.0 million to acquire property, plant and equipment. Of the net investment activity, \$9.8 million was used to purchase U.S. Government securities that were pledged in relation to the issuance of our convertible notes. The purchases of property, plant and equipment were comprised of \$4.3 million for equipment and \$0.7 million for leasehold improvements. Cash provided by financing activities for the first nine months of 2004 was \$52.4 million, including \$139.4 million net proceeds from the issuance of our convertible notes and an additional \$3.0 million from proceeds related to stock option exercises and our Employee Stock Purchase Plan, partially offset by \$90.0 million paid to repurchase 6.9 million shares of stock under our stock repurchase programs.

A portion of the debt offering proceeds were used to purchase and pledge \$9.8 million to the trustee under the indenture for the exclusive benefit of the holders of the convertible notes, U.S. government securities to provide for the payment, in full, of the first six scheduled interest payments. Additional net proceeds were used to repurchase 4.2 million shares of our outstanding common stock for \$60 million. The remaining net proceeds will be used for general corporate purposes, which may include additional stock repurchases, strategic investments or acquisitions. The convertible notes were issued at an issue price of \$580.98 per note, which is 58.098% of the principal amount at maturity of the notes. The convertible notes bear interest at a rate of 1.3798% per year on the principal amount at maturity, payable semi-annually in arrears in cash on May 16 and November 16 of each year, from November 16, 2004 until May 16, 2011. Beginning on May 16, 2011, the original issue discount will accrue daily at a rate of 2.375% per year on a semi-annual bond equivalent basis and, on the maturity date, a holder will receive \$1,000 per note. As a result, the aggregate principal amount of the notes at maturity will be \$247.4 million.

In February 2004 and July 2004, the Board of Directors authorized stock repurchase programs under which up to an aggregate of \$50 million of our common stock could be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of purchases were based on several conditions, including the price of our stock, general market conditions and other factors. In May 2004, in conjunction with our convertible notes offering, the Board of Directors authorized the repurchase of an additional \$60 million of our common stock. As of October 2, 2004, we had repurchased and retired 6.9 million shares with an aggregate purchase price of \$90.0 million under these combined programs.

We believe that cash and cash equivalents, short-term available-for-sale investments on hand and expected cash flows from operations, will be sufficient to fund our operations, capital requirements and stock repurchase programs for at least the next twelve months.

The impact of inflation on our financial position and the results of operations was not significant during any of the periods presented.

**Contractual Obligations**

As of October 2, 2004, we had the following contractual obligations (in millions):

<u>Total</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>Thereafter</u>
\$ 167.6	2.1	3.4	3.4	3.4	3.4	151.9

Long-Term Debt Obligations (includes interest)(a)							
Operating Lease Obligations	20.3	.6	2.5	2.5	2.4	2.1	10.2
Purchase Obligations	15.4	.2	2.0	2.0	2.0	2.0	7.2
	<u>          </u>	<u>      </u>	<u>      </u>	<u>      </u>	<u>      </u>	<u>      </u>	<u>      </u>
Total	\$203.3	2.9	7.9	7.9	7.8	7.5	169.3
	<u>          </u>	<u>      </u>	<u>      </u>	<u>      </u>	<u>      </u>	<u>      </u>	<u>          </u>

Our purchase obligations of \$15.4 million were comprised of supply agreements in effect at October 2, 2004.

(a) See Note 9 to our unaudited consolidated interim financial statements in this report for data on interest related to long-term debt.

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**Off-Balance Sheet Items**

In the third quarter of 2004 we obtained an Irrevocable Standby Letter of Credit for \$390,000 as part of our worker's compensation insurance program. The Letter of Credit is not collateralized. The Letter of Credit expires on June 30, 2005 and is scheduled to automatically renew each year on June 30.

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**FACTORS THAT MAY AFFECT FUTURE RESULTS**

*Our business faces many risks. Such risks include those related to the development of new markets including Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of Thoratec products, changes in the mix of Thoratec product sales, and the related gross margin for such product sale, the results of clinical trials including the HeartMate II, the ability to improve financial performance, regulatory approval processes, the effect of healthcare reimbursement and coverage policies, the effects of seasonality in Thoratec products sales, the effects of price competition from any Thoratec competitors and the effects of any merger and acquisition related activities. The risks described below are what we believe to be the material risks facing our company. However, the risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risk factors actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline significantly. Investors should consider the following risks, as well as the other information included in this Quarterly Report and our Annual Report on Form 10-K for fiscal 2003, before deciding to invest in our company.*

***We have a history of net losses.***

We were founded in 1976 and we have a history of incurring losses from operations. As of October 2, 2004, our accumulated deficit was approximately \$71.6 million. We anticipate that our expenses will increase as a result of increased pre-clinical and clinical testing, research and development and selling, general and administrative expenses. We could also incur significant additional costs in connection with our business development activities and the development and marketing of new products and indicated uses for our existing products as well as litigation costs. Such costs could prevent us from achieving or maintaining profitability in future periods.

***Since our physician and hospital customers depend on third party reimbursement, if third party payors fail to provide appropriate levels of reimbursement for our products, our results of operations will be harmed.***

Significant uncertainty exists as to the reimbursement status of newly approved health care products such as VADs and vascular grafts, which can delay or prevent adoption in volume by hospitals. Government and other third party payors are increasingly attempting to contain health care costs. Payors are attempting to contain costs by, for example, limiting coverage and the level of reimbursement of new therapeutic products. Payors are also attempting to contain costs by refusing, in some cases, to provide any coverage for uses of approved products for disease indications other than those for which the FDA has granted marketing approval.

To date, a majority of private insurers with whom we have been involved and the Centers for Medicare and Medicaid, referred to as CMS, have determined to reimburse some portion of the cost of our VADs and our diagnostic and vascular graft products, but we cannot estimate what portion of such costs will be reimbursed and our products may not continue to be approved for reimbursement. In addition, changes in the health care system may affect the reimbursability of future products. If coverage is not expanded or if the reimbursement levels are not increased or are partially or completely reduced, our revenues would be reduced.

***If we fail to obtain approval from the FDA and from foreign regulatory authorities, we cannot market and sell our products under development in the United States and in other countries, and if we fail to adhere to ongoing FDA Quality System Regulations, the FDA may withdraw our market clearance or take other action.***

Before we can market new products in the United States, we must obtain clearance from the FDA. This process is lengthy and uncertain. In the United States, one must obtain clearance from the FDA of a 510(k) premarket notification or approval of a more extensive submission known as a pre-market approval, or PMA, application. If the

FDA concludes that any of our products does not meet the requirements to obtain clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, then we would be required to file a PMA application. The process for a PMA application is lengthy, expensive and typically requires extensive pre-clinical and clinical trial data.

We may not obtain clearance of a 510(k) notification or approval of a PMA application with respect to any of our products on a timely basis, if at all. If we fail to obtain timely clearance or approval for our products, we will not be able to market and sell our products, harming our ability to generate revenue. The FDA may also limit the claims that we can make about our products. We may also be required to obtain clearance of a 510(k) notification or PMA

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Supplement from the FDA before we can market products that have been cleared, but we have since modified or that we subsequently wish to market for new disease indications.

The FDA also requires us to adhere to Quality System Regulations, which include production design controls, testing, quality control, storage and documentation procedures. The FDA may at any time inspect our facilities to determine whether we have adequate compliance. Compliance with Quality System Regulations for medical devices is difficult and costly. In addition, we may not be found to be compliant as a result of future changes in, or interpretations of, regulations by the FDA or other regulatory agencies. If we do not achieve compliance, the FDA may withdraw marketing clearance, require product recall or take other enforcement action, which in each case would harm our business. Any change or modification to a device is required to be made in compliance with Quality System Regulations, which compliance may cause interruptions or delays in the marketing and sale of our products. The FDA also requires device manufacturers to submit reports regarding deaths, serious injuries and certain malfunctions relating to use of their products.

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer or shorter than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements.

The federal, state and foreign laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties, which in each case would harm our business.

***Certain lawsuits have been filed against us***

On August 3, 2004, a putative Federal securities law class action entitled Johnson v. Thoratec Corporation, et al. was filed in the United States District Court for the Northern District of California on behalf of purchasers of the publicly traded securities of the Company between April 28, 2004 and June 29, 2004. The complaint seeks to recover unspecified damages on behalf of all purchasers of the Company's publicly traded securities during the class period. Subsequent to the filing of the Johnson complaint, additional complaints were filed in the same court alleging substantially similar claims.

On or about September 1, 2004, a shareholder derivative action entitled Wong v. Grossman was filed in the California Superior Court for Alameda County based upon essentially the same facts as the Federal securities class action suits. This action names the individual members of the Company's Board of Directors, including our Chief Executive Officer, and our Chief Financial Officer as defendants.

We intend to move to dismiss both suits. However, we are unable to predict at this time the final outcome of these actions, or whether the resolution of the actions could materially affect our results of operations, cash flows or financial position.

In June of 2004, MicroMed Technology, Inc., a potential competitor of the Company, sued the Company in Texas. MicroMed sought a temporary restraining order against the Company in connection with the Company's HeartMate II phase I clinical trial on the grounds that the Company had provided the HeartMate II VAD to clinical sites without charge and that doing so was a violation of Texas anti-trust law. In addition to injunctive relief, the plaintiff is seeking unspecified damages and fees, including those arising from potential sales of its VAD products which plaintiff alleges it lost due to the Company's HeartMate II clinical trial.

The Company has successfully defended itself against MicroMed's requests for injunctive relief and will continue to vigorously defend any and all of the claims made by MicroMed in this action.

***Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.***

We have a substantial level of debt. As of October 2, 2004, we had \$143.8 million of outstanding indebtedness. The terms of our convertible notes do not restrict our ability to incur additional indebtedness, including indebtedness senior to the notes. The level of our indebtedness, among other things, could:

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- make it difficult for us to make payments on our debt;
- make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, acquisitions or general corporate purposes;
- limit our flexibility in planning for or reacting to changes in our business;
- reduce funds available for use in our operations;
- impair our ability to incur additional debt because of financial and other restrictive covenants proposed for any such additional debt;
- make us more vulnerable in the event of a downturn in our business or an increase in interest rates; or
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources.

If we experience a decline in product sales due to any of the factors described in this section or otherwise, we could have difficulty paying interest or principal amounts due on our indebtedness. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, including the convertible notes, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under our other indebtedness. Any default under our indebtedness could have a material adverse effect on our business, operating results and financial condition.

***If hospitals do not conduct Destination Therapy procedures using our VAD, our product sales will be diminished.***

The use of our VADs as long-term therapy in patients who are not candidates for heart transplantation (Destination Therapy) was approved by the FDA in 2002, and was approved for reimbursement by the CMS in late 2003.

The number of Destination Therapy procedures actually performed is dependent on many factors, most of which are out of our direct control, including:

- the number of CMS sites approved for Destination Therapy;
- the clinical outcomes of Destination Therapy procedures;
- cardiology and referring physician education, and their commitment to Destination Therapy;
- the economics of the Destination Therapy procedure for individual hospitals, which includes the costs of the VAD and related pre- and post- operative procedures and their reimbursement;
- the impact of changes in reimbursement rates on the timing of purchases of VADs for Destination Therapy; and
- the economics for individual hospitals of not conducting a Destination Therapy procedure, including the costs and related reimbursements of long-term hospitalization.

The different outcomes of these and other factors, and their timing, will have a significant impact on our future operating results. Sales of our VADs for Destination Therapy have proved slower than we had originally anticipated, and we are unable to predict when, if ever, these sales will generate significant revenue for us.



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***The long and variable sales and deployment cycles for our VAD systems may cause our revenue and operating results to vary significantly, which increases the risk of an operating loss for any given fiscal quarter.***

Our VAD systems have lengthy sales cycles and we may incur substantial sales and marketing expenses and expend significant effort without making a sale. Even after making the decision to purchase our VAD systems, our customers often deploy our products slowly. For example, the length of time between initial contact with cardiac surgeons and the purchase of our VAD systems is generally between nine and eighteen months. In addition, the cardiac centers that buy the majority of our products are usually led by cardiac surgeons who are heavily recruited by competing centers or by centers looking to increase their profiles. When one of these surgeons moves between centers we sometimes experience a temporary but significant reduction in purchases by the departed center while it replaces its lead surgeon. As a result, it is difficult for us to predict the quarter in which our customers may purchase our VAD systems and our revenue and operating results may vary significantly from quarter to quarter, which increases the risk of an operating loss for us for any given quarter. In particular, sales of our VADs for Destination Therapy have been lower than we had originally anticipated, and we cannot predict when, if ever, sales of our VADs for this indication will generate significant revenue.

***Physicians may not accept or continue to accept our products and products under development.***

The success of our current and future products will require acceptance or continued acceptance by cardiovascular and vascular surgeons and other medical professionals. Such acceptance will depend on clinical results and the conclusion by these professionals that our products are safe, cost-effective and acceptable methods of treatment. Even if the safety and efficacy of our future products are established, physicians may elect not to use them for a number of reasons. These reasons could include the high cost of our VAD systems, restrictions on coverage, unfavorable reimbursement from health care payors, or use of alternative therapies. Also, economic, psychological, ethical and other concerns may limit general acceptance of our ventricular assist, graft and other products.

***Our future product sales will be affected by the number of heart transplants conducted.***

A significant amount of our current product sales is generated by our VADs implanted temporarily in patients awaiting heart transplants. The number of heart transplants conducted worldwide depends on the number of hearts available to transplant, which number in turn depends on the death rate of otherwise healthy people from events such as automobile accidents. To the extent that public safety measures and technological improvements, such as automobile air bags and anti-lock brakes, are successfully implemented, the availability of these hearts to transplant may not grow significantly, and may trend downward.

***We have experienced rapid growth and changes in our business, and our failure to manage this and any future growth could harm our business.***

The number of our employees increased from 183 on December 30, 2000 to 905 on October 2, 2004. We expect to continue increasing the number of our employees, and we may suffer if we do not manage and train our new employees effectively. Our product sales may not continue to grow at a rate sufficient to support the costs associated with an increasing number of employees. Any future periods of rapid growth may place significant strains on our managerial, financial and other resources. The rate of any future expansion, in combination with our complex technologies and products, may demand an unusually high level of managerial effectiveness in anticipating, planning, coordinating and meeting our operational needs as well as the needs of our customers.

***If we fail to successfully introduce new products, our future growth may suffer.***

As part of our growth strategy, we intend to develop and introduce a number of new products and product improvements. We also intend to develop new indications for our existing products. For example, we are currently developing updated versions of our HeartMate products. If we do not introduce these new products, product improvements and new indications on a timely basis, or if they are not well accepted by the market, our future growth may suffer.

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***Amortization of our intangible assets, which represent a significant portion of our total assets, will adversely affect our net income and we may never realize the full value of our intangible assets.***

As of October 2, 2004, we had \$250.3 million of net intangible assets, representing 47% of our total assets and 83% of our shareholders' equity. Amortization expense relating to these intangible assets for the first nine months and third quarter of 2004 were \$8.8 million and \$2.9 million, respectively. Ongoing amortization of purchased intangibles will reduce our net income or increase our net loss.

We may not receive the recorded value for our intangible assets if we sell or liquidate our business or assets. The material concentration of intangible assets increases the risk of a large charge to earnings if that the revenue from, and recoverability of, these intangible assets is impaired. In the event of such a charge to net income, the market price of our common stock could be adversely affected. For example, in the first quarter of 2004, we completed an assessment of the final results from the feasibility clinical trial for the Aria CABG graft, which was ongoing through fiscal 2003. Based on the clinical trial results, we determined not to devote additional resources to development of the Aria graft. Upon the decision to discontinue product development, we recorded an impairment charge of approximately \$9 million as of January 3, 2004 to write off purchased intangible assets related to the Aria graft, recorded as a result of our merger with TCA.

***We rely on specialized suppliers for certain components and materials in our products and alternative suppliers may not be available.***

We depend on a number of custom-designed components and materials supplied by other companies including, in some cases, single source suppliers for components and materials used in our VAD products and blood testing products. For example, a single source currently manufactures and supplies the heart valves used in our HeartMate products. We do not have long-term written agreements with most of our vendors and from these vendors receive components on a purchase order basis only. If we need alternative sources for key raw materials or component parts for any reason, such alternative sources may not be available and our inventory may not be sufficient to fill orders before we find alternative suppliers or begin manufacturing these components or materials ourselves. Cessation or interruption of sales of circulatory support products would seriously harm our business, financial condition and results of operations.

Alternative suppliers, if available, may not agree to supply us. In addition, we may need to obtain FDA approval before using new suppliers or manufacturing our own components or materials. Existing suppliers could also be subject to an FDA enforcement action, which could also disrupt our supplies. If alternative suppliers are not available, we may not have the expertise or resources necessary to produce these materials or component parts internally.

Because of the long product development cycle in our business, suppliers may discontinue components upon which we rely before the end of life of our products. In addition, the timing of the discontinuation may not allow us time to develop and obtain FDA approval for a replacement component before we exhaust our inventory of the legacy component.

If suppliers discontinue components on which we rely, we may have to:

pay premium prices to our suppliers to keep their production lines open or to alternative suppliers;

buy substantial inventory to take us through the scheduled end of life of our product, or through such time that we will have a replacement product developed and approved by the FDA; or

stop shipping the product in which the legacy component is used once our inventory of the discontinued component is exhausted.

Any of these interruptions in the supply of our materials could result in substantial reductions in revenue and increases in our production costs.

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***If we fail to compete successfully against our existing or potential competitors, our product sales or operating results may be harmed.***

Competition from medical device companies and medical device subsidiaries of health care and pharmaceutical companies is intense and is expected to increase. Competitors for the VAD system include World Heart Corporation and ABIOMED, Inc. Principal competitors in the vascular graft market include W.L. Gore, Inc., C.R. Bard and Boston Scientific Corporation. Principal competitors in the hospital coagulation and blood gas monitoring equipment market include the Cardiac Surgery Division of Medtronic, Inc., iSTAT, Radiometer, Abbott Diagnostics, and Instrument Laboratories. Our primary competitor in the skin incision device market is Becton, Dickson and Company. Competitors in the alternate site (non-hospital) point-of-care diagnostics market include Roche Diagnostics and HemoSense.

Many of our competitors have substantially greater financial, technical, distribution, marketing and manufacturing resources than we have. Accordingly, our competitors may be able to develop, manufacture and market products more efficiently and at a lower cost than we can. We expect that the key competitive factors will include the relative speed with which we can:

develop products;

complete clinical testing;

receive regulatory approvals; and

manufacture and sell commercial quantities of products.

Additionally, our competitors may succeed in developing and marketing technologies and products that are more effective than ours. Any such products may render our technology and products obsolete or noncompetitive. In addition, new surgical procedures and medications could be developed that replace or reduce the importance of current procedures that use our products.

***The price of our common stock may fluctuate significantly.***

The price of our common stock has been, and is likely to continue to be, highly volatile, which means that it could decline substantially within a short period of time. For example our stock price has ranged from \$8.46 to \$15.95 in the ten months ended October 30, 2004. The price of our common stock could fluctuate significantly for many reasons, including the following:

future announcements concerning us or our competitors;

timing and reaction to the publication of clinical trial results;

quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;

charges, amortization and other financial effects relating to our merger with TCA;

introduction of new products or changes in product pricing policies by us or our competitors;

acquisition or loss of significant customers, distributors or suppliers;

business acquisitions or divestitures;

changes in earnings estimates by analysts;

changes in third party reimbursement practices;

regulatory developments, enforcement actions bearing on advertising, marketing or sales, and disclosure regarding completed ongoing or future clinical trials; and

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fluctuations in the economy, world political events or general market conditions.

In addition, stock markets in general, and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years, which fluctuations have frequently been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our stock may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

Shareholders have often instituted securities class action litigation after periods of volatility in the market price of a company's securities. Some securities class action suits have been filed against us, and if other such suits are filed against us in the future, we may incur substantial legal fees and our management's attention and resources would be diverted from operating our business in order to respond to the litigation. See Certain lawsuits have been filed against us. above.

***We may encounter problems manufacturing our products.***

We may encounter difficulties manufacturing our products. We do not have experience in manufacturing some of our products in the commercial quantities that might be required if we receive FDA approval of several or all of the products and indications currently under development, including the HeartMate II VAD currently commencing. If we have difficulties manufacturing our products, our business will be harmed.

***Since we depend upon distributors, if we lose a distributor or a distributor fails to perform, our operations will be harmed.***

With the exception of Canada and the larger countries in Europe, we sell our VAD and HeartMate systems in foreign markets through distributors. In addition, we sell our vascular access graft products through the Bard Peripheral Vascular division of C.R. Bard Corporation in the United States, Europe and selected countries in Scandinavia, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan. Substantially all of the international operations and a large portion of the Alternate Site domestic operations of our ITC subsidiary are conducted through distributors. For the nine months ended October 2, 2004, 21% of our total product sales were through Cardinal Healthcare, a distributor of our blood coagulation testing equipment and skin incision devices.

To the extent we rely on distributors, our success will depend upon the efforts of others, over which we may have little control. If we lose a distributor or a distributor fails to perform to our expectations, our revenues will be harmed.

***Changes we make to our method of distributing and selling our products could hurt our relationship with distributors and their customers.***

Following our acquisition of the IRMA product line of blood gas analyzers, commencing in March 2004, we changed our manner of distributing our Hemochron and IRMA product lines to our hospital point-of-care customers in the United States from a distributor model to a direct sales model. Sales of these products represented approximately \$4.7 million of our sales in the first nine months of 2004.

This transition includes expanding the sales, technical service, customer service and shipping headcount at our ITC subsidiary in order to provide our customers with the support and service that they historically obtained from our distributors, resulting in an increase in our sales and general and administrative costs. We expect the transition process to conclude in early 2005 when the last distributor will have been converted and the United States hospital point-of-care market will be served exclusively by ITC on a direct basis. This transition and its execution involve significant risks, including:

the alienation of distributors when they are informed of our plans;

the promotion by our former distributors of products from competitors rather than our products;

the potential loss of customers who prefer to deal with a particular distributor; and

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the challenges and costs associated with building an effective direct sales force.

If we fail to build an effective direct sales force for our hospital point-of-care product lines, our revenues may fail to increase as expected or could decrease, which could adversely affect our results of operations and financial condition. As we end the third quarter of 2004, over 95% of our U.S. hospital point-of-care business has been converted to the direct sales model with no material adverse event.

***Our inability to protect our proprietary technologies or an infringement of others' patents could harm our competitive position.***

We rely on patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not adequately protect our rights. In addition, we cannot assure you that any of our pending patent applications will issue. The Patent and Trademark Office, or PTO, may deny or significantly narrow claims made under patent applications and the issued patents, if any, may not provide us with commercial protection. We could incur substantial costs in proceedings before the PTO or in any future litigation to enforce our patents in court. These proceedings could result in adverse decisions as to the validity and/or enforceability of our patents. In addition, the laws of some of the countries in which our products are or may be sold may not protect our products and intellectual property to the same extent as U.S. laws, if at all. We may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries.

Our commercially available VAD products, which account for a significant portion of our sales, generally are not protected by any patents. We rely principally on trade secret protection and, to a lesser extent, patents to protect our rights to the HeartMate. We rely principally on patents to protect our coagulation testing equipment, skin incision devices, Hemochron disposable cuvettes, IRMA analyzer, IRMA disposable cartridges, and Hgb Pro disposable test strips.

We seek to protect our trade secrets and unpatented proprietary technology, in part, with confidentiality agreements with our employees and consultants. Although it is our policy to require that all employees and consultants sign such agreements, we cannot assure you that every person who gains or has gained access to such information has done so. Moreover, these agreements may be breached and we may not have an adequate remedy.

Our products may be found to infringe prior or future patents owned by others. We may need to acquire licenses under patents belonging to others for technology potentially useful or necessary, and such licenses may not be available to us. We could incur substantial costs in defending suits brought against us on such patents or in bringing suits to protect our patents or patents licensed by us against infringement.

For example, in 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004, the Company settled the claim and recorded a charge of \$2.3 million in the fourth quarter of 2003 for the settlement and related legal costs.

***Product liability claims could damage our reputation and hurt our financial results.***

Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing and sale of human medical devices. We maintain only a limited amount of product liability insurance. Our insurance policies generally must be renewed on an annual basis. We may not be able to maintain or increase such insurance on acceptable terms or at reasonable costs, and such insurance may not provide us with adequate coverage against potential liabilities. A successful claim brought against us in excess of, or outside of, our insurance coverage could seriously harm our financial condition and results of operations. Claims against us, regardless of their merit or

potential outcome, may also reduce our ability to obtain physician endorsement of our products or expand our business.

***Identified quality problems can result in substantial costs and write-downs.***

FDA regulations require us to track materials used in the manufacture of our products, so that any problems identified in a finished product can easily be traced back to other finished products containing the defective

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materials. In some instances, identified quality issues require scrapping or expensive rework of the affected lot(s), not just the tested defective product and could also require us to stop shipments.

In addition, since some of our products are used in situations where a malfunction can be life threatening, identified quality issues can result in the recall and replacement, generally free of charge, of substantial amounts of product already implanted or otherwise in the marketplace.

Any quality issue identified can therefore result in substantial costs and write offs, which could materially harm our financial results.

***If we make acquisitions or divestitures, we could encounter difficulties that harm our business.***

We may acquire companies, products or technologies that we believe to be complementary to our business. If we do so, we may have difficulty integrating the acquired personnel, operations, products or technologies and we may not realize the expected benefits of any such acquisition. In addition, acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees and increase our expenses, which could harm our business. We may also sell businesses or assets as part of our strategy or if we receive offers from third parties. If we do so, we may sell an asset or business for less than its full value.

***Our non-U.S. sales present special risks.***

During the nine months ended October 2, 2004 and the year ended 2003, sales originating outside the United States and U.S. export sales accounted for approximately 23% and 19%, respectively, of our total product sales. We anticipate that sales outside the United States and U.S. export sales will continue to account for a significant percentage of our product sales and we intend to continue to expand our presence in international markets. Non-U.S. sales are subject to a number of special risks. For example:

we generally sell many of our products at a lower price outside the United States;

sales agreements may be difficult to enforce;

receivables may be difficult to collect through a foreign country's legal system;

foreign customers may have longer payment cycles;

foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;

U.S. export licenses may be difficult to obtain;

intellectual property rights may be more difficult to enforce in foreign countries;

terrorist activity or war may interrupt distribution channels or adversely impact our customers or employees; and

fluctuations in exchange rates may affect product demand and adversely affect the profitability, in U.S. dollars, of products sold in foreign markets where payments are made in local currencies.

Any of these events could harm our operations or operating results.

*Any claims relating to improper handling, storage or disposal of hazardous chemicals and biomaterials could be time consuming and costly.*

Producing our products requires the use of hazardous materials, including chemicals and biomaterials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials.

We could be subject to both criminal liability and civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us for injury or

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contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts or harm our operating results.

***The occurrence of a catastrophic disaster or other similar events could cause damage to our facilities and equipment, which would require us to cease or curtail operations.***

We are vulnerable to damage from various types of disasters, including earthquake, fire, terrorist acts, flood, power loss, communications failures and similar events. For example, in October 1989, a major earthquake that caused significant property damage and a number of fatalities struck near the area in which our Pleasanton, California facility is located. If any such disaster were to occur, we may not be able to operate our business at our facilities, in particular because our premises require FDA approval, which could result in significant delays before we can manufacture product from a replacement facility. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Therefore, any such catastrophe could seriously harm our business and results of operations.

***If we are unable to favorably assess the effectiveness of our internal control over financial reporting, or if our independent auditors are unable to provide an unqualified attestation report on our assessment, our stock price could be adversely affected.***

Under the Sarbanes-Oxley Act of 2002, we are required to assess the effectiveness of our internal controls for financial reporting and assert that such internal controls are effective. Our independent auditors must evaluate management's assessment of the effectiveness of our internal controls over financial reporting and render an opinion on management's assessment and the effectiveness of our internal controls over financial reporting. To prepare for compliance with this requirement of the Sarbanes-Oxley Act, we have undertaken certain actions including the adoption of an internal plan which includes a timeline and schedule of activities for the evaluation, testing and remediation, if necessary, of internal controls. These actions have resulted in and are likely to continue to result in increased expenses, and have required and are likely to continue to require significant efforts by management and other employees. Although we believe that our efforts will enable us to provide the required report and enable our independent auditors to provide the required attestation as of our fiscal year end, we can give no assurance that such efforts will be completed in a timely manner and on a successful basis. If this were to occur, we may be unable to assert that the internal controls over financial reporting are effective, or our independent auditors may not be able to render the required attestation concerning our assessment and the effectiveness of the internal controls over financial reporting, which in either event could adversely effect investor confidence and the market price of our common stock.

***Fluctuations in foreign currency exchange rates could result in declines in our reported sales and earnings.***

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign exchange rates. At present, we use forward foreign currency contracts to hedge the gains and losses created by the remeasurement of non-functional currency denominated assets and liabilities. However, we do not engage in hedge exposures that will arise from future sales. As a result, sales occurring in the future that are denominated in foreign currencies may be translated into U.S. dollars at a less favorable rate than our current exchange rate environment resulting in reduced revenues and earnings.

***The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.***

Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, sales, marketing, managerial and financial personnel, and attracting and retaining additional

highly qualified personnel in these areas. We face intense competition for such personnel, and we may not be able to attract and retain these individuals. We compete with numerous companies, as well as universities and nonprofit research organizations, throughout all our locations. The loss of key personnel for any reason or our inability to hire and retain additional qualified personnel in the future could prevent us from sustaining or growing our business. Our success will depend in large part on the continued services of our research, managerial and manufacturing personnel. We cannot assure you that we will continue to be able to attract and retain sufficient qualified personnel.

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***We may be unable to repay or repurchase our convertible notes or our other indebtedness.***

At maturity, the entire outstanding principal amount of our convertible notes will become due and payable. Holders of the convertible notes may also require us to repurchase the convertible notes on May 16 in each of 2011, 2014, 2019, 2024 and 2029. In addition, if certain fundamental changes to our company occur, the holders of the convertible notes may require us to repurchase all or a portion of their convertible notes. We may not have sufficient funds or may be unable to arrange for additional financing to pay the principal amount due at maturity or the repurchase price of the convertible notes. Any such failure would constitute an event of default under the indenture, which could, in turn, constitute a default under the terms of our other indebtedness. Any default under our indebtedness could have a material adverse effect on our business, operating results and financial condition.

***Conversion of the convertible notes or other future issuances of our stock will dilute the ownership interests of existing shareholders.***

The conversion of some or all of the convertible notes will dilute the ownership interest of our existing shareholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. Further, the existence of the convertible notes may encourage short selling by market participants because the conversion of the convertible notes could depress the price of our common stock. In addition, future sales of substantial amounts of our stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our stock. Sales of our shares and the potential for such sales could cause our stock price to decline.

In addition, our adoption of ETIF Issue No. 04-8, expected to occur in the fourth quarter of 2004, which requires the inclusion of all shares available upon conversion of our convertible notes in our diluted EPS regardless of whether the notes are then convertible, would not have a material impact on our consolidated results for the periods in which the notes were outstanding as the effect of the 7.3 million shares would be anti-dilutive. If in future periods the shares would be dilutive, then 7.3 million shares will be added to our share count used to calculate diluted earnings per share, and this inclusion could result in significantly lower diluted EPS than if the existing guidance had not been changed by EITF 04-8.

***Anti-takeover defenses in our governing documents could prevent an acquisition of our company or limit the price that investors might be willing to pay for our common stock.***

Our governing documents could make it difficult for another company to acquire control of our company. For example:

Our Articles of Incorporation allow our Board of Directors to issue, at any time and without shareholder approval, preferred stock with such terms as it may determine. No shares of preferred stock are currently outstanding. However, the rights of holders of any of our preferred stock that may be issued in the future may be superior to the rights of holders of our common stock.

We have a rights plan, commonly known as a poison pill, which would make it difficult for someone to acquire our company without the approval of our Board of Directors.

All or any one of these factors could limit the price that certain investors would be willing to pay for shares of our common stock and could delay, prevent or allow our Board of Directors to resist an acquisition of our company, even if the proposed transaction was favored by a majority of our independent shareholders.

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**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE OF MARKET RISK**

**Interest Rate Risk**

Our investment portfolio is made up of cash equivalent and marketable investments in money market funds and debt instruments of government agencies and high quality corporate issuers. All investments are carried at market value and are treated as available-for-sale. All investments mature within two years or less from the date of purchase. The holdings of any one issuer, except government agencies, do not exceed 10% of the portfolio. If interest rates rise, the market value of our investments may decline which could result in a loss if we are forced to sell an investment before the scheduled maturity. We do not utilize derivative financial instruments to manage interest rate risks.

Our convertible notes do not bear interest rate risk as the notes were issued at a fixed rate of interest.

**Foreign Currency Rate Fluctuations**

We conduct business in foreign countries. Our international operations consist primarily of sales and service personnel for our ventricular assist products, who report into our U.S. sales and marketing group and are internally reported as part of that group. All assets and liabilities of our non-U.S. operations are translated into U.S. dollars at the period-end exchange rates and the resulting translation adjustments are included in comprehensive income. The period-end translation of the non-functional currency assets and liabilities (primarily assets and liabilities on our UK subsidiary consolidated balance sheet that are not denominated in UK Pounds) at the period-end exchange rates result in foreign currency gains and losses, which are included in Interest and Other Income-Net.

We use forward foreign currency contracts to hedge the gains and losses generated by the revaluation of these non-functional currency assets and liabilities. These derivatives are not designated as cash flow or fair value hedges under SFAS No. 133. As a result, changes in the fair value of the forward foreign currency contracts are included as incurred in Interest and Other Income Net. The change in the fair value of the forward foreign currency contracts typically offsets the change in value from revaluation of the non-functional currency assets and liabilities. These contracts typically have maturities of three months or less. At October 2, 2004 and September 27, 2003, the Company had forward foreign currency contracts in Pounds Sterling and Euros with a notional value of \$7.0 million and \$4.6 million, respectively. The impact of foreign currency revaluation, net of forward foreign currency contracts, was negligible for the quarter ending October 2, 2004 and a loss of \$0.2 million for the quarter ending September 27, 2003.

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**ITEM 4. CONTROLS AND PROCEDURES**

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of October 2, 2004.

Disclosure controls and procedures are designed to reasonably assure that the information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our disclosure controls and procedures include components of our internal control over our financial reporting, which consists of control processes designed to provide reasonable assurance regarding the reliability of financial reporting and permitting the preparation of our financial statements in conformity with generally accepted accounting principles. To the extent that components of our internal control over our financial reporting are included within our disclosure controls and procedures, they are included in the scope of our quarterly controls evaluation.

The evaluation of our disclosure controls and procedures included a review of our processes and implementation and the effect on the information generated for use in this Quarterly Report. In the course of this evaluation, we sought to identify any significant deficiencies or material weaknesses in our controls, to determine whether we had identified any acts of fraud involving personnel who have significant roles in internal controls and to confirm that any necessary corrective action, including process improvements, were being undertaken. This type of evaluation is performed every fiscal quarter so that our conclusions concerning the effectiveness of these controls can be reported in our periodic reports filed with the SEC. The overall goals of these evaluations activities are to monitor our disclosure controls and procedures and to make modifications as necessary.

Based on the evaluation, subject to the limitations described below, our management, including the Chief Executive Officer and Chief Financial Officer, concluded that as of October 2, 2004 the Company's disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. There have been no changes in our internal controls during the fiscal quarter ended October 2, 2004 that have materially affected or are reasonably likely to materially affect the Company's internal control over financial reporting.

Our management, including the Chief Executive Officer and the Chief Financial Officer, do not expect that the disclosure controls and procedures or internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can only provide reasonable, not absolute, assurances that the objectives of the control system are met. The design of a control system reflects resource constraints; the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of error or fraud, if any, within the Company have been or will be detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns occur because of simple error or mistake. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events. There can be no assurance that any design will succeed in achieving its stated goals under all future conditions; over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We intend to continuously review and evaluate the design and effectiveness of our disclosure controls and procedures and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. Our senior management has timely access to all material financial and non-financial information concerning our business. While we believe the present design of our disclosure controls and procedures is effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

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**PART II. OTHER INFORMATION**

**ITEM 1. LITIGATION**

In June of 2004, MicroMed Technology, Inc., a potential competitor of the Company, sued the Company in Texas. MicroMed sought a temporary restraining order against the Company in connection with the Company's HeartMate II phase I clinical trial on the grounds that the Company had provided the HeartMate II VAD to clinical sites without charge and that doing so was a violation of Texas anti-trust law. In addition to an injunctive relief, the plaintiff is seeking unspecified damages and fees, including those arising from potential sales of its VAD products which plaintiff alleges it lost due to the Company's HeartMate II clinical trial.

The Company has successfully defended itself against MicroMed's requests for injunctive relief and will continue to vigorously defend any and all of the claims made by MicroMed in this action.

On August 3, 2004, a putative Federal securities law class action entitled Johnson v. Thoratec Corporation, et al. was filed in the United States District Court for the Northern District of California on behalf of purchasers of the publicly traded securities of the Company between April 28, 2004 and June 29, 2004. The Johnson complaint generally alleges violations of the Securities Exchange Act of 1934 by the Company, its chief executive officer and chief financial officer based upon, inter alia, alleged false statements about the Company's expected sales and the market for HeartMate as a Destination Therapy treatment. The complaint seeks to recover unspecified damages on behalf of all purchasers of the Company's publicly traded securities during the class period. Subsequent to the filing of the Johnson complaint, additional complaints were filed in the same court alleging substantially similar claims. On October 4, 2004, a putative class member, Craig Toby, filed a motion to be appointed lead plaintiff pursuant to the Private Securities Litigation Reform Act of 1995 and to consolidate all of the pending class action litigations against Thoratec into a single proceeding. The Court has not yet ruled on those motions.

On or about September 1, 2004, a shareholder derivative action entitled Wong v. Grossman was filed in the California Superior Court for Alameda County based upon essentially the same facts as the Federal securities class action suits. This action names the individual members of the Company's Board of Directors, including our Chief Executive Officer and our Chief Financial Officer as defendants and alleges that the defendants breached their fiduciary duties and wasted corporate assets, and that certain of the defendants traded in the Company's securities while in possession of material nonpublic information.

The Company believes that the claims asserted in both the Federal securities law putative class action and the state shareholder derivative action are without merit and the Company intends to move to dismiss both suits. However, we are unable to predict at this time the final outcome of these actions, or whether the resolution of the actions could materially affect our results of operations, cash flows or financial position.

While we believe we carry sufficient insurance to cover what management believes to be any reasonable exposure on these actions, we cannot give you any assurance that our insurance will cover any costs or other exposures we may have with respect to these actions.

**ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES**

*(c) Recent Unregistered Sales of Equity Securities.*

In the second quarter of 2004 we completed the sale of \$143.8 million initial principal amount of senior subordinated convertible notes due 2034. The convertible notes were sold in a private placement to Qualified Institutional Buyers pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Rule 144A thereunder. Total proceeds to the Company from the sale were \$139.4 million, after debt issuance costs of \$4.3 million.

The convertible notes were issued at an issue price of \$580.98 per note, which is 58.098% of the principal amount at maturity of the notes. The convertible notes bear interest at a rate of 1.3798% per year on the principal amount at maturity, payable semi-annually in arrears in cash on May 16 and November 16 of each year, from November 16, 2004 until May 16, 2011. Beginning on May 16, 2011, the original issue discount will accrue daily at

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a rate of 2.375% per year on a semi-annual bond equivalent basis and, on the maturity date, a holder will receive \$1,000 per note. As a result, the aggregate principal amount of the notes at maturity will be \$247.4 million.

Holders of the convertible notes may convert their convertible notes into shares of our common stock at a conversion rate of 29.4652 shares per \$1,000 principal amount of convertible notes, which represents a conversion price of \$19.72 per share, subject to adjustments upon the occurrence of certain events. Holders were able to convert their convertible notes at any point after the close of business on September 30, 2004 if, as of the last day preceding the calendar quarter, the closing price of our common stock for at least 20 trading days in a period of 30 consecutive trading days ending on the last trading day of such preceding calendar quarter is more than 120% of the accreted conversion price per share of our common stock. Holders may surrender their convertible notes on or prior to May 16, 2029 during the five business day period after any five consecutive trading day period in which the trading price per note for each day of that period was less than 98% of the product of the closing sale price of our common stock and the conversion rate on each such day; provided that if on the day prior to any conversion the closing sale price of our common stock is greater than the accreted conversion price but less than or equal to 120% of the accreted conversion price, then holders will receive upon conversion, in lieu of shares of common stock based on the conversion rate, cash or common stock, or a combination of cash and common stock, at our option, with a value equal to the accreted principal amount of the notes plus accrued but unpaid interest as of the conversion date. Additionally, holders may convert their convertible notes if we call them for redemption or if specified corporate transactions or significant distributions to holders of our stock have occurred.

The debt offering proceeds were used to purchase and pledge \$9.8 million to the trustee under the indenture for the exclusive benefit of the holders of the convertible notes, U.S. government securities to provide for the payment, in full, of the first six scheduled interest payments. Additional net proceeds were used to repurchase 4.2 million shares of our outstanding common stock for \$60 million. The remaining net proceeds will be used for general corporate purposes, which may include additional stock repurchases, strategic investments or acquisitions.

*(e) Purchases of Equity Securities by the Issuer.*

	<b>Total Number Of Shares Purchased</b>	<b>Average Price Paid Per Share</b>	<b>Total Number of Shares Purchased as Part Of Publicly Announced Program</b>	<b>Maximum Dollar Value Of Shares That May Yet Be Purchased Under The Program (in millions)</b>
January 4, 2004 to January 31, 2004		\$		\$ 25.0
February 1, 2004 to February 28, 2004	185,000	\$13.59	185,000	\$ 22.5
February 29, 2004 to April 3, 2004	325,000(2)	\$12.97	325,000	\$ 18.3
April 4, 2004 to May 1, 2004	0	\$ 0	0	\$ 18.3

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May 2, 2004 to May 29, 2004	4,234,100	\$14.33	4,234,100	\$ 17.6
May 30, 2004 to July 3, 2004	405,000	\$10.76	405,000	\$ 13.2
July 4, 2004 to July 31, 2004	1,240,000	\$10.67	1,240,000	\$ 25.0
August 1, 2004 to August 28, 2004	162,000	\$10.10	162,000	\$ 23.4
August 29, 2004 to October 2, 2004	332,000	\$10.21	332,000	\$ 20.0
	<u>          </u>	<u>      </u>	<u>          </u>	
Total	6,883,100	\$13.08	6,883,100	

- (1) Our stock repurchase programs, which authorizes the Company to repurchase up to \$110 million of shares, was announced on February 11, 2004 as a \$25 million of shares program and increased on May 12, 2004 to an \$85 million shares program, and again was increased to \$110 million of shares on July 29, 2004. These programs do not have an expiration date.
- (2) Includes 250,000 shares purchased from Thermo Electron Corporation in a privately arranged transaction executed through a third party broker at the then current market price.

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**ITEM 6. EXHIBITS**

(a) Exhibits:

31.1 Section 302 Certifications of Chief Executive Officer and Chief Financial Officer.

32.1 Section 906 Certifications of Chief Executive Officer and Chief Financial Officer.

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**SIGNATURES**

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

THORATEC CORPORATION

Date: November 12, 2004

/s/ D. Keith Grossman  
D. Keith Grossman,  
Chief Executive Officer

Date: November 12, 2004

/s/ M. Wayne Boylston  
M. Wayne Boylston,  
Senior Vice President, Chief  
Financial Officer and Secretary  
(Principal Financial and Accounting  
Officer)