

THORATEC CORP
Form 10-Q
August 12, 2004

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 July 3, 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 August 5, 2004 registrant had 50,143,386 shares of common stock outstanding.

THORATEC CORPORATION AND SUBSIDIARIES
TABLE OF CONTENTS

<u>Part I. Financial Information</u>	3
<u>Item 1. Condensed Consolidated Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets as of July 3, 2004 and January 3, 2004</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended July 3, 2004 and June 28, 2003</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended July 3, 2004 and June 28, 2003</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	15
<u>Item 3. Quantitative and Qualitative Disclosure of Market Risk</u>	34
<u>Item 4. Controls and Procedures</u>	35
<u>Part II. Other Information</u>	36
<u>Item 1. Litigation</u>	36
<u>Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities</u>	36
<u>Item 4. Submission of Matters to a Vote of Security Shareholders</u>	37
<u>Item 6. Exhibits and Reports on Form 8-K</u>	38
<u>Signatures</u>	39
<u>Exhibits</u>	40

PART I. FINANCIAL INFORMATION**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****THORATEC CORPORATION AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

(unaudited)
(in thousands)

	July 3, 2004	January 3, 2004
Assets		
Current Assets:		
Cash and cash equivalents	\$ 125,910	\$ 62,020
Short-term available-for-sale investments	42,566	
Restricted short-term investments	3,306	
Receivables, net of allowances of \$541 and \$486, respectively	27,694	27,969
Inventories	39,466	36,417
Deferred tax asset and other prepaid assets	12,287	12,796
Total Current Assets	251,229	139,202
Property, plant and equipment, net	28,861	28,492
Goodwill	94,535	96,065
Purchased intangible assets, net	159,004	164,865
Long-term available-for-sale investments		41,179
Restricted long-term investments	6,463	
Long-term deferred tax asset and other assets	12,032	6,328
Total Assets	\$ 552,124	\$ 476,131
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 24,038	\$ 22,772
Total Current Liabilities	24,038	22,772

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Senior subordinated convertible notes	143,750	
Long-term deferred tax liability and other liabilities	64,789	67,123
	<u> </u>	<u> </u>
 Total Liabilities	 232,577	 89,895
	<u> </u>	<u> </u>
 Shareholders' Equity:		
Common shares; 100,000 authorized; issued and outstanding 51,381 and 56,242, respectively	387,511	423,045
Deferred compensation	(2,175)	(2,630)
Accumulated deficit	(66,073)	(34,594)
Accumulated other comprehensive income:		
Unrealized gain (loss) on investments	(140)	51
Cumulative translation adjustments	424	364
	<u> </u>	<u> </u>
 Total accumulated other comprehensive income	 284	 415
	<u> </u>	<u> </u>
 Total Shareholders' Equity	 319,547	 386,236
	<u> </u>	<u> </u>
 Total Liabilities and Shareholders' Equity	 \$552,124	 \$476,131
	<u> </u>	<u> </u>

See notes to condensed consolidated financial statements.

THORATEC CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three Months Ended		Six Months Ended	
	July 3, 2004	June 28, 2003	July 3, 2004	June 28, 2003
Product sales	\$40,603	\$36,156	\$83,395	\$72,218
Cost of product sales	16,314	14,651	34,035	29,542
Gross profit	24,289	21,505	49,360	42,676
Operating expenses:				
Selling, general and administrative	13,774	11,169	26,787	21,229
Research and development	7,380	6,279	14,718	12,539
Amortization of purchased intangible assets	2,931	3,096	5,862	6,192
Legal settlement, restructuring and other costs		(67)	133	(124)
Total operating expenses	24,085	20,477	47,500	39,836
Income from operations	204	1,028	1,860	2,840
Interest and other income net	57	649	521	1,160
Income before income tax expense	261	1,677	2,381	4,000
Income tax expense	54	654	881	1,560
Net income	\$ 207	\$ 1,023	\$ 1,500	\$ 2,440
Net income per share, basic and diluted	\$ 0.00	\$ 0.02	\$ 0.03	\$ 0.04
Shares used to compute net income per share:				
Basic	53,722	55,394	54,907	55,226
Diluted	55,175	56,891	56,315	56,240

See notes to condensed consolidated financial statements.

THORATEC CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)
(in thousands)

Six Months Ended

	July 3, 2004	June 28, 2003
Cash flows from operating activities:		
Net income	\$ 1,500	\$ 2,440
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	9,393	8,701
Investment premium amortization	495	521
Amortization of deferred compensation	455	599
Loss on disposal of asset	1	25
Income tax expense	881	1,560
Non-cash compensation		4
Changes in assets and liabilities:		
Receivables	275	1,225
Inventories	(3,048)	1,499
Prepaid expenses and other assets	119	(274)
Accounts payable and other liabilities	772	(4,582)
Other	(993)	1,127
	<u>9,850</u>	<u>12,845</u>
Cash flows from investing activities:		
Purchases of available-for-sale and other investments	(29,084)	(4,439)
Maturities of available-for-sale investments	16,620	5,709
Purchases of property, plant and equipment	(3,836)	(2,831)
	<u>(16,300)</u>	<u>(1,561)</u>
Cash flows from financing activities:		
Net proceeds from issuance of convertible notes	139,181	
Proceeds from stock issued under employee stock purchase plan	788	578
Proceeds from stock option exercises	2,070	3,571
Repurchase of common stock	(71,759)	

	_____	_____
Net cash provided by financing activities	70,280	4,149
Effect of exchange rate changes on cash	60	68
	_____	_____
Net increase in cash and cash equivalents	63,890	15,501
Cash and cash equivalents at beginning of period	62,020	42,044
	_____	_____
Cash and cash equivalents at end of period	\$125,910	\$57,545
	_____	_____
Supplemental Cash Flow Disclosure:		
Cash paid for taxes	\$ 465	\$ 722
Cash paid for interest	\$	\$
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Tax benefit related to stock option exercises	\$ 387	\$ 911

See notes to condensed consolidated financial statements.

THORATEC CORPORATION AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

(in thousands, unless otherwise stated)

1. Basis of Presentation

The interim condensed consolidated financial statements of Thoratec Corporation, referred to as herein we, our, Thoratec, or the Company, have been prepared and presented in accordance with accounting principles generally accepted in the United States of America and the rules and regulations of the Securities and Exchange Commission, referred to as the SEC, without audit and reflect all adjustments necessary (consisting only of normal recurring adjustments) to present fairly our financial position, results of operations and cash flows. Certain information and footnote disclosures normally included in our annual financial statements, prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted. The accompanying financial statements should be read in conjunction with our fiscal 2003 consolidated financial statements filed with the SEC in our Annual Report on Form 10-K. The operating results for any interim period are not necessarily indicative of the results that may be expected for any future period.

The preparation of our condensed consolidated financial statements necessarily requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the consolidated balance sheet dates and the reported amounts of revenues and expenses for the periods presented.

We have made certain reclassifications of 2003 amounts to conform to the current presentation.

Debt Offering

On May 24, 2004 the Company completed the sale of senior subordinated convertible notes due 2034, referred to as the convertible notes. We received net proceeds from the sale, after underwriting discounts and other costs totaling \$4.6 million, of \$139.2 million. See note 9.

2. Stock Based Compensation

We account for stock-based compensation to employees using the intrinsic value method in accordance with APB No. 25, Accounting for Stock Issued to Employees. Accordingly, no accounting recognition is given to stock options granted at fair market value until they are exercised. Upon exercise, net proceeds, including tax benefits realized, are recorded in shareholders' equity. Similarly, no accounting recognition is given to our employee stock purchase plan until a purchase occurs. Upon purchase, net proceeds are recorded in common stock. Under the fair value recognition provisions of SFAS No. 123, the fair value of each option granted as a stock option or as an option to purchase shares under the employee stock purchase plan is estimated using the Black-Scholes option-pricing model. If compensation cost for our stock-based plans had been determined based on the fair value at the grant dates for awards under those plans, consistent with the method of SFAS No. 123, our reported net income would have been adversely affected, as shown in the following table:

	Three Months Ended		Six Months Ended	
	July 3, 2004	June 28, 2003	July 3, 2004	June 28, 2003
(in thousands, except per share data)				
Net income:				
As reported	\$ 207	\$ 1,023	\$ 1,500	\$ 2,440
Add: Stock-based compensation expense included in reported net income, net of related tax effects	148	183	287	368
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(3,354)	(1,849)	(5,397)	(3,878)
Pro forma	<u>\$ (2,999)</u>	<u>\$ (643)</u>	<u>\$ (3,610)</u>	<u>\$ (1,070)</u>
Basic earnings (loss) per share:				
As reported	\$ 0.00	\$ 0.02	\$ 0.03	\$ 0.04
Pro forma loss	\$ (0.06)	\$ (0.01)	\$ (0.07)	\$ (0.07)
Diluted earnings (loss) per share:				
As reported	\$ 0.00	\$ 0.02	\$ 0.03	\$ 0.04
Pro forma loss	\$ (0.05)	\$ (0.01)	\$ (0.06)	\$ (0.07)

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 consolidated statement of operations.

In March 2004, the 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. Management expects that the adoption of this Issue 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 the most recent Emerging Issues Task Force (EITF) meeting Issue No. 04-8, Accounting Issues Related to Certain Features of Contingently Convertible Debt and the Effect on Diluted Earnings per Share was discussed. The tentative conclusion was that shares available under contingently convertible debt should be included in diluted earnings per share, or EPS, in all periods, except when inclusion is anti-dilutive, regardless of whether the contingency is met and regardless of whether the market price contingency is substantial. If issued in final form as proposed by the EITF, adoption of this proposed interpretation 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 Issue No. 04-8 is adopted in final form, in periods when the shares would be dilutive, 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 was not changed as proposed 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 and to reflect management's intent that these investments be considered available for current operations. As a result of its reassessment during the quarter ended April 3, 2004, the Company has classified its investments as short-term at July 3, 2004. 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, 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.

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 balance sheet at fair value in Deferred Tax Asset and Other current assets. Changes in the fair value of the contracts and the underlying exposures being hedged are included concurrently in Interest and Other Income Net. At July 3, 2004, the notional value of outstanding contracts approximated \$9.6 million with negligible fair value.

6. Inventories

Inventories consist of the following:

	As of	
	July 3, 2004	January 3, 2004
	(in thousands)	
Finished goods	\$20,080	\$15,504
Work in process	5,862	9,089
Raw materials	13,524	11,824
	<u> </u>	<u> </u>
Total	\$39,466	\$36,417
	<u> </u>	<u> </u>

7. Property, Plant and Equipment

Property, plant and equipment consist of the following:

	As of	
	July 3, 2004	January 3, 2004
	(in thousands)	
Property, plant and equipment, at cost	\$ 61,820	\$ 58,023
Less accumulated depreciation	<u>(32,959)</u>	<u>(29,531)</u>
 Total	 <u>\$ 28,861</u>	 <u>\$ 28,492</u>

8. Goodwill and Other Intangible Assets

The change in the carrying amount of goodwill, which is attributable to our Cardiovascular business segment, for the six-month periods ended July 3, 2004 and June 28, 2003 was as follows:

	Six Months Ended	
	July 3, 2004	June 28, 2003
	(in thousands)	
Beginning balance	\$96,065	\$96,492
Realization of acquired deferred tax asset	(715)	
Reversal of accrual for securities registration costs	(815)	
	<u> </u>	<u> </u>
Ending balance	<u>\$94,535</u>	<u>\$96,492</u>

In the first half 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.

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:

	As of July 3, 2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
	(in thousands)		
Patents and Trademarks	\$ 37,815	\$(12,236)	\$ 25,579
Core Technology	37,485	(6,299)	31,186
Developed Technology	122,782	(20,623)	102,159

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Non-compete Agreement	90	(10)	80
	<u> </u>	<u> </u>	<u> </u>
Total Purchased Intangible Assets	\$198,172	\$(39,168)	\$ 159,004
	<u> </u>	<u> </u>	<u> </u>

As of January 3, 2004

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
	<u> </u>	<u> </u>	<u> </u>
		(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
	<u> </u>	<u> </u>	<u> </u>
Total Purchased Intangible Assets	\$198,172	\$(33,307)	\$ 164,865
	<u> </u>	<u> </u>	<u> </u>

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, 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 Diametrics Medical, Inc. (Diametrics). 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 July 3, 2004 and \$4.9 million for the six months ended July 3, 2004. Amortization expense related to identifiable intangible assets was \$3.1 million for the three months ended June 28, 2003 and \$6.2 million for the six months ended June 28, 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.

9. Long-term Debt

On May 24, 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. Total net proceeds to the Company from the sale were \$139.2 million, after debt issuance costs of \$4.6 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 \$4.6 million are included in other assets on the balance sheet. These 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 and Other Income Net on the Consolidated Statement of Operations.

	July 3, 2004
	(in thousands)
Long Term Debt Offering Proceeds:	
Principal amount of convertible notes at maturity	\$ 247.4
Original issue discount	(103.7)
Debt issuance costs	(4.6)
	<hr/>
Net proceeds	\$ 139.2
	<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 may 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 July 3, 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.

The convertible notes are subordinated, therefore, in the event of our bankruptcy, liquidation or dissolution and acceleration of or payment default on our senior indebtedness, holders of the convertible notes will not receive any payment until holders of any senior indebtedness we may have outstanding have been paid in full.

10. Common Stock

In February 2004, the Board of Directors authorized a stock repurchase program under which up to \$25 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 July 3, 2004, we had repurchased and retired 5.1 million shares with an aggregate purchase price of \$71.8 million under these combined programs.

In July 2004, the Board of Directors authorized a stock repurchase program under which Thoratec common stock with a market value of up to \$25 million may be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of such activity will be dependant on several conditions, including the price of Thoratec stock, general market conditions and other factors.

11. Legal Settlement, Restructuring and Other Costs

Legal settlement, restructuring and other costs are comprised of:

	Three Months Ended		Six Months Ended	
	July 3, 2004	June 28, 2003	July 3, 2004	June 28, 2003
	(in thousands)			
Legal Settlement	\$	\$	\$133	\$
Restructuring		(61)		(118)
Other		(6)		(6)
	—	—	—	—
Total	\$	\$(67)	\$133	\$(124)

Legal Settlement

In April 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D. This claim related to materials used in our 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. The expense recorded in the first quarter of 2004 is primarily composed of additional legal expenses related to the settlement.

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:

	Three Months Ended	Six Months Ended
	June 28, 2003	June 28, 2003
	(in thousands)	
Accrued Restructuring Costs:		
Beginning balance	\$ 97	\$ 679
Reduction of severance accrual	(61)	(122)
Payments of employee severance	(36)	(557)
	<u> </u>	<u> </u>
Ending balance	\$ <u> </u>	\$ <u> </u>

12. Income Taxes

Our effective tax rates were 21% and 39%, respectively, for the three months ended July 3, 2004 and June 28, 2003. The effective rate was 37% for the six months ended July 3, 2004 and 39% for the six months ended June 28, 2003. The reduction in our effective tax rate is due primarily to: (1) increased statutory research credits (both in dollars as well as a percentage of income before income taxes) and (2) 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.

At July 3, 2004 and January 3, 2004, we reported a net deferred tax liability of approximately \$ 49.6 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 Per Share

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

Three Months Ended		Six Months Ended	
July 3, 2004	June 28, 2003	July 3, 2004	June 28, 2003
<u> </u>	<u> </u>	<u> </u>	<u> </u>

	(in thousands)			
Net income	\$ 207	\$ 1,023	\$ 1,500	\$ 2,440
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Weighted average number of common shares-basic	53,722	55,394	54,907	55,226
Dilutive effect of stock options	1,453	1,497	1,408	1,014
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Weighted average number of common shares-diluted	55,175	56,891	56,315	56,240
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Net income per common share-basic and diluted	\$ 0.00	\$ 0.02	\$ 0.03	\$ 0.04
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Basic income per share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted income 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 July 3, 2004, options covering 3.8 million shares and 4.9 million shares of our common stock were excluded from the computation of the diluted income per share for the three-month and six-month periods ending July 3, 2004, respectively, as their inclusion would be antidilutive. Of the options to purchase shares of common stock outstanding as of June 28, 2003, those covering 3.5 million shares and 4.0 million shares of common stock were excluded from the computation of diluted income per share for the three and six months ended June 28, 2003, respectively, as their inclusion would be antidilutive.

If EITF Issue No. 04-8 is issued in final form as proposed by the EITF, our adoption of this proposed interpretation would not have a material impact on our most recent consolidated results as the effect of the convertible notes covering 7.3 million shares would be anti-dilutive. If Issue No. 04-8 is adopted in final form, in periods when the shares would be dilutive, 7.3 million shares will be added to our outstanding shares used to

calculate diluted earnings per share, and this inclusion could result in significantly lower diluted EPS than if the existing guidance was not changed as proposed.

Although we adopted the disclosure provisions of FASB FSP FAS No. 129-1 in the second quarter of 2004, the 7.3 million shares underlying our convertible notes were antidilutive. Therefore these shares were excluded from the calculation of diluted net income per share.

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:

	Three Months Ended		Six Months Ended	
	July 3, 2004	June 28, 2003	July 3, 2004	June 28, 2003
	(in thousands)			
Product sales:				
Cardiovascular	\$23,072	\$23,559	\$49,625	\$47,467
ITC	17,531	12,597	33,770	24,751
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total product sales	\$40,603	\$36,156	\$83,395	\$72,218
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Income before income taxes:				
Cardiovascular	\$ 2,000	\$ 3,453	\$ 6,283	\$ 7,242
ITC	2,388	2,138	4,720	4,487
Corporate (a)	(1,253)	(1,534)	(3,147)	(2,821)
Amortization of purchased intangibles	(2,931)	(3,096)	(5,862)	(6,192)
Legal settlement, restructuring and other costs (b)		67	(133)	124
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total income from operations	204	1,028	1,860	2,840
Interest and other income, net	57	649	521	1,160
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Income before income taxes	\$ 261	\$ 1,677	\$ 2,381	\$ 4,000
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

(a)

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

(b) Related solely to the Cardiovascular segment.

Geographic Areas:

The geographic composition of our product sales were as follows:

	Three Months Ended		Six Months Ended	
	July 3, 2004	June 28, 2003	July 3, 2004	June 28, 2003
	(in thousands)			
Domestic	\$31,392	\$30,247	\$65,173	\$60,251
International	9,211	5,909	18,222	11,967
Total	\$40,603	\$36,156	\$83,395	\$72,218

15. Litigation and Claims

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.

In June of 2004, MicroMed Technology, Inc., a potential competitor of the Company, sued the Company in Texas. MicroMed sued for 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 provides the HeartMate II VAD to clinical sites without charge. MicroMed has asked the court to prevent Thoratec from providing the HeartMate II to the clinical sites without charge by claiming that such practices violate Texas anti-trust law. In addition to a temporary restraining order, the plaintiff is seeking unspecified damages and fees, including those resulting from lost sales of its VAD products (which are in clinical trials in the U.S. only and not yet commercially approved) due to the Company's HeartMate II clinical trial.

The Company defeated MicroMed's motion for a temporary restraining order and intends to mount a vigorous defense to all of the claims made by MicroMed.

16. Subsequent Events

On July 29, 2004 the company announced that the board of directors authorized a stock repurchase program under which Thoratec common stock with a market value of up to \$25 million may be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of such activity will be dependant on several conditions, including the price of Thoratec stock, general market conditions and other factors.

On August 3, 2004, a putative 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 plaintiffs' law firms issued press releases indicating that additional similar complaints have been filed in the same court, alleging essentially the same claims, on behalf of the same putative class of purchasers of Thoratec securities. The Company has not been served with any of those complaints. Based on the facts known to date, Thoratec believes that the claims asserted in this action and the related actions are without merit and intends to vigorously defend this suit. However, we are unable to predict at this time the final outcome of the various shareholder actions, or whether the resolution of the actions could materially affect our results of operations, cash flows or financial position. No amount in respect of this matter has been accrued in our consolidated financial statements.

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 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.

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 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 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*, which we adopted as of the beginning of fiscal year 2002, 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 balance sheet could significantly overstate 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 distributor has certain limited product return rights. A limited number of 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 in accordance with SFAS No. 48, *Revenue Recognition when Right of Return Exists*. 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 revenues under these arrangements allocated to training is based upon fair market value of the training, 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 six months ended July 3, 2004 all products that had been delivered and recorded as product sales were delivered to customers for which training had been completed. There were no amount of product sales deferred related to this training not yet completed at the six months ended July 3, 2004, however, there were \$20,000 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 six months ended July 3, 2004, the years ended 2003, and 2002 are \$3.1 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 a one-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.

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, we approved a Restructuring Plan to consolidate all of our VAD manufacturing operations to our manufacturing facilities and headquarters in Pleasanton, California. Through the completion date of the Restructuring Plan in April 2003, we recorded \$1.5 million of restructuring charges in accordance with Emerging Issues Task Force 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity* and Staff Accounting Bulletin 100, *Restructuring and Impairment Charges*. These charges represent estimated employee severance costs and stock option acceleration charges. We completed the relocation of the Woburn, Massachusetts manufacturing operations to our Pleasanton facility in the first quarter of 2003 and in February 2003 the FDA inspected the Pleasanton facility related to this transfer. We received FDA approval in April 2003. As of the completion date of the Restructuring Plan, we had paid approximately \$1.3 million in severance payments to 78 employees.

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 consolidated statement of operations.

In March 2004, the 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. Management expects that the adoption of this Issue 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 debt we issued on May 24, 2004. The 7.3 million shares underlying our convertible notes that are reportable under this new disclosure are antidilutive. Therefore, these shares have been excluded from the calculation of diluted net income per share.

In the most recent Emerging Issues Task Force (EITF) meeting Issue No. 04-8, *Accounting Issues Related to Certain Features of Contingently Convertible Debt and the Effect on Diluted Earnings per Share* was discussed. The

tentative conclusion was that shares available under contingently convertible debts should be included in diluted earnings per share in all periods, except when inclusion is anti-dilutive, regardless of whether the contingency is met and regardless of whether the market price contingency is substantive. If issued in final form as proposed by the EITF, adoption of this proposed interpretation would not have had a material impact on our consolidated results as the effect of the 7.3 million shares would be anti-dilutive. In periods when the shares would be dilutive 7.3 million shares will be added to our share count used to calculate diluted earnings per share.

Results of Operations

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

	Three Months Ended		Six Months Ended	
	July 3, 2004	June 28, 2003	July 3, 2004	June 28, 2003
Product sales	100%	100%	100%	100%
Cost of sales	40	41	41	41
Gross profit	60	59	59	59
Operating expenses:				
Selling, general & administrative	34	31	32	29
Research & development	18	17	18	17
Amortization of purchased intangible assets	7	9	7	8
Legal settlement, merger, restructuring and other costs	0	0	0	0
Total operating expenses	59	57	57	54
Income from operations	1	3	2	4
Interest and other income net	0	2	1	1
Income before income taxes	1	5	3	5
Income tax expense	0	2	1	2
Net income	1%	3%	2%	3%

Three months ended July 3, 2004 and June 28, 2003***Product Sales***

Product sales in the second quarter of 2004 were \$40.6 million compared to \$36.2 million in the second quarter of 2003. The primary components of the \$4.4 million increase in product sales were the following:

Point-of-care diagnostic sales increased \$4.9 million, including \$1.6 million in revenue from the IRMA product line acquired in the fourth quarter of 2003.

This increase in point-of-care diagnostics was offset by lower sales of grafts, with VAD sales essentially flat.

Our sales of Destination Therapy implants were lower in the second quarter than we originally anticipated, and we expect product sales to increase more slowly than we originally projected, partly because we believe customers delayed purchasing Destination Therapy implants until the proposed increase in the Medicare reimbursement rate becomes effective on October 1, 2004.

Gross Profit

Gross profit in the second quarter of 2004 was 60% compared to 59% in 2003. Within these essentially flat margins were the following fluctuations:

A 4% higher margin on VAD products resulting from a shift in mix to higher margin lines, offset by

A 3% lower margin on point-of-care products, primarily related to the lower margin IRMA product line acquired in the fourth quarter of 2003, plus higher distribution costs associated with the shift in mix from distributor to direct channels.

If we recognize higher revenue for our current Destination Therapy initiatives, we anticipate that margins will increase as the higher margin VAD products represent a larger portion of our overall revenues.

Selling, General and Administrative

Selling, general and administrative expenses in the second quarter of 2004 were \$13.8 million, or 34% of product sales, compared to \$11.2 million, or 31% of product sales, in the second quarter of 2003. Underlying the \$2.6 million increase in spending were the following:

Increased SG&A headcount from 138 at the end of the second quarter of 2003 to 198 at the end of the second quarter of 2004, together with annual salary increases aggregating approximately 4.5% effective January 2004.

Higher spending on marketing and related activities, primarily associated with Destination Therapy, and costs associated with the IRMA product line acquired in the fourth quarter of 2003.

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 increase, particularly if we realize increasing revenue generated by Destination Therapy implants.

Research and Development

Research and development expenses in the second quarter of 2004 were \$7.4 million compared to \$6.3 million in the second quarter of 2003, representing 18% and 17% of product sales, respectively. 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 as 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 second quarter of 2004 was \$2.9 million compared to \$3.1 million in the second 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 21% and 39%, respectively, for the second quarters of 2004 and 2003. The reduction in our effective tax rate over the two 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.

Six months ended July 3, 2004 and June 28, 2003

Product Sales

Product sales in the first six months of 2004 were \$83.4 million compared to \$72.2 million in the first six months of 2003. The primary components of the \$11.2 million increase in product sales were as follows:

\$9.0 million higher revenue from sales of point-of-care diagnostic test systems, including \$3.3 million generated by the IRMA product line acquired in the fourth quarter of 2003;

\$3.0 million higher VAD sales; and

\$0.8 million lower graft sales.

Gross Profit

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

A 4% higher margin on cardiovascular products resulting from a shift in mix from lower to higher margin products, offset by higher manufacturing costs.

A 4% lower margin on point-of-care revenues, primarily related to the lower margin IRMA product line acquired in the fourth quarter of 2003, 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 six months of 2004 were \$26.8 million, or 32% of product sales, compared to \$21.2 million, or 29% of product sales, in the first six months of 2003. Underlying the \$5.6 million increase in these expenses were the following drivers:

Increased SG&A headcount from 138 at the end of the first six months of 2003 to 198 at the end of the first six months of 2004, together with annual salary increases aggregating 4.5% effective January 2004.

Higher spending on marketing and related activities, primarily associated with Destination Therapy, and costs associated with the IRMA product line acquired in the fourth quarter of 2003.

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 six months of 2004 were \$14.7 million compared to \$12.5 million in the first six 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 six months of 2004 was \$5.9 million compared to \$6.2 million in the first six months of 2003. The decrease of \$0.3 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 rates were 37% for the six months ended July 3, 2004 and 39% for the six months ended June 28, 2003. 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 July 3, 2004, we had working capital of \$227.2 million compared with \$116.4 million at January 3, 2004. Cash and cash equivalents and short-term available-for-sale investments at July 3, 2004 were \$168.5 million compared to \$62 million at January 3, 2004.

Cash provided by operating activities was \$ 9.9 million, after payments for legal settlement and annual bonuses accrued at January 3, 2004 totaling \$5.2 million. In addition, investing activities used \$16.3 million, with \$12.5 million used for investments and \$3.8 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 \$3.2 million for equipment and \$0.6 million for leasehold improvements. Cash provided by financing activities was \$70.3 million, as we received \$139.2 million net proceeds from the issuance of our convertible notes and an additional \$2.1 million from proceeds related to stock option exercises, offset by \$71.8 million paid during the first and second quarters of 2004 to repurchase 5.1 million shares of stock under our stock repurchase programs.

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.

On February 11, 2004, the Board of Directors authorized a stock repurchase program under which up to \$25 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 are 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 July 3, 2004, we had repurchased and retired 5.1 million shares with an aggregate of \$71.8 million under these combined programs. On July 28, 2004, the Board of Directors authorized up to an additional \$25 million for the repurchase of our common stock on the open market or in privately negotiated transactions.

We believe that cash and cash equivalents and 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 program 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 July 3, 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>
Long-Term Debt Obligations (includes interest)	\$167.6	2.1	3.4	3.4	3.4	3.4	151.9
Operating Lease Obligations	21.0	1.3	2.5	2.5	2.4	2.1	10.2
Purchase Obligations	15.8	.6	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	\$204.4	4.0	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 \$15.8 million were comprised of supply agreements in effect at July 3, 2004.

FACTORS THAT MAY AFFECT FUTURE RESULTS

Our business faces many risks. 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 July 3, 2004, our accumulated deficit was approximately \$66.1 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. 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 in turn 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. Pre-clinical data may need to be obtained in accordance with FDA good laboratory practices.

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 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.

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 July 3, 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:

- 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; and 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 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.

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 or unfavorable reimbursement from health care payors. Also, economic, psychological, ethical and other concerns may limit general acceptance of our ventricular assist, graft and other products.

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

A significant amount of our current products 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.

As a result of the Merger, the number of our employees increased significantly, and has continued to grow. The number of our employees increased from 183 on December 30, 2000 to 899 on July 3, 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.

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 July 3, 2004, we had \$253.5 million of net intangible assets, representing 45.9% of our total assets and 79.3% of our shareholders' equity. These intangible assets consist primarily of goodwill and other intangible assets arising from the Merger and our trademarks and patented technology. Amortization expense relating to these intangible assets for the first half and second quarter of 2004 were \$5.9 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 in the event 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 the Merger.

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 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 use up 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.

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 Metronic, Inc., iSTAT, Radiometer, Bayer, Inc., 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 Holding AG and Hemo-Sense.

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, which may make it difficult for holders to resell our common stock issuable upon conversion of the convertible notes when desired or at attractive prices.

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. 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 the Merger;

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

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.

In the past, shareholders have often instituted securities class action litigation after periods of volatility in the market price of a company's securities. If a shareholder or convertible note holder files a securities class action suit against us, we would 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.

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. We transferred the manufacturing operations for the HeartMate from Woburn, Massachusetts to Pleasanton, California and, in the first half of 2003, received clearance from the FDA to begin manufacturing the HeartMate in this new location. 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 amount of the domestic operations of our ITC subsidiary are conducted through distributors. For the six months ended July 3, 2004, 19% 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 recent 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 \$3.9 million of our sales in the second quarter of 2004.

This transition will include 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. We expect our sales, general and administrative costs to increase. We expect the transition process to conclude in early 2005 when the last distributor will have been converted and the United States 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

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

If we fail to build an effective direct sales force for our Hemochron and IRMA product lines, our revenues may fail to increase as expected or could decrease, which could adversely affect our results of operations and financial condition.

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 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. 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 six months ended July 3, 2004 and the year ended 2003, sales originating outside the United States and U.S. export sales accounted for approximately 21% 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 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 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, which could seriously harm our business and operations, 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.

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.

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.

If the ETIF adopts Issue No. 04-8 as proposed, we would be required to include all shares available upon conversion of our convertible notes in our diluted EPS if the effect would be dilutive, regardless of whether the notes are then convertible. This inclusion could result in a significantly lower diluted EPS number than would otherwise have been the case.

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE OF MARKET RISK

Interest Rate Risk

Our investment portfolio is made up of cash equivalent and marketable security 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 debt issuance however, does not have interest rate risk associated 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 July 3, 2004, the Company had forward foreign currency contracts in Pounds Sterling and Euros with a notional value of \$9.6 million and with a negligible fair value. There were no such contracts outstanding at June 28, 2003. The impact of foreign currency revaluation, net of forward foreign currency contracts, was a loss of \$0.1 million for the quarter ending July 3, 2004 and a gain of \$0.2 million for the quarter ending June 28, 2003.

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 July 3, 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 done 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 July 3, 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 July 3, 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 review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis 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.

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 sued for 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 provides the HeartMate II VAD to clinical sites without charge. MicroMed has asked the court to prevent Thoratec from providing the HeartMate II to the clinical sites without charge by claiming that such practices violate Texas anti-trust law. In addition to a temporary restraining order, the plaintiff is seeking unspecified damages and fees, including those resulting from lost sales of its VAD products (which are in clinical trials in the U.S. only and not yet commercially approved) due to the Company's HeartMate II clinical trial.

The Company defeated MicroMed's motion for a temporary restraining order and intends to mount a vigorous defense to all of the claims made by MicroMed.

On August 3, 2004, a putative 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 plaintiffs' law firms issued press releases indicating that additional similar complaints have been filed in the same court, alleging essentially the same claims, on behalf of the same putative class of purchasers of Thoratec securities. The Company has not been served with any of those complaints. Based on the facts known to date, Thoratec believes that the claims asserted in this action and the related actions are without merit and intends to vigorously defend this suit. However, we are unable to predict at this time the final outcome of the various shareholder actions, or whether the resolution of the actions could materially affect our results of operations, cash flows or financial position. No amount in respect of this matter has been accrued in our consolidated financial statements.

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

(c) Recent Unregistered Sales of Equity Securities.

On May 24, 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 \$139.2 million, after debt issuance costs of \$4.6 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.

Holder 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 may 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.*

	Total Number Of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part Of Publicly Announced Program	Maximum Dollar Value Of Shares That May Yet Be Purchased Under The Program (in millions)
January 4, 2004 to January 31, 2004		\$		\$ 25.0
February 1, 2004 to February 28, 2004	185,000	\$13.59	185,000	\$ 25.0
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
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
Total	5,149,100	\$13.94	5,149,100	

(1) Our stock repurchase program, which authorizes the Company to repurchase up to \$85 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. On July 29, 2004 we announced that the Board of Directors authorized the Company to repurchase up to an additional \$25 million shares. These programs do not have an expiration date.

(2)

Includes 250,000 shares which were purchased from Thermo Electron Corporation in a privately arranged transaction executed through a third party broker at the then current market price.

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

The annual meeting of shareholders was held on May 21, 2004. The following item was voted upon and approved at the meeting:

To elect directors to serve for the ensuing year until their successors are elected,

	Number of Votes	
	For	Withheld
Howard E. Chase	52,924,625	1,001,777
J. Daniel Cole	52,663,177	1,263,225
Neil F. Dimick	52,065,580	1,860,822
D. Keith Grossman	52,562,093	1,364,309
J. Donald Hill	52,093,268	1,833,134
William M. Hitchcock	52,625,153	1,301,249
George W. Holbrook, Jr.	52,241,999	1,684,403
Daniel M. Mulvena	52,243,119	1,683,283

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits:

- 4.1 Indenture, dated as of May 24, 2004, by and between the Registrant and U.S. Bank, National Association, as Trustee.
- 4.2 Pledge Agreement, dated as of May 24, 2004, between the Registrant and U.S. Bank, National Association, and Pledge Agreement Supplement, dated as of June 7, 2004.
- 4.3 Control Agreement, dated as of May 24, 2004, between the Registrant and U.S. Bank, National Association, and Control Agreement Amendment, dated as of June 7, 2004.
- 4.4 Registration Rights Agreement, dated May 24, 2004, by and among the Registrant and Merrill Lynch Pierce Fenner & Smith Incorporated as Initial Purchaser of the Senior Subordinated Convertible Notes due 2034.
- 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.

(b) Reports on Form 8-K:

On June 29, 2004, the Company furnished a Current Report on Form 8-K, reporting under item 12, providing an update on our business activities and outlook for the remainder of 2004.

On June 8, 2004, the Company furnished a Current Report on Form 8-K, reporting under item 9, announcing that the initial purchaser for our initial offering of \$125 million initial principal amount of senior convertible notes due 2023, exercised its option to purchase an additional \$18.7 million initial principal amount of such senior subordinated convertible notes.

On May 20, 2004, the Company furnished a Current Report on Form 8-K, reporting under item 9, announcing our intention to commence an offering of \$125 million in aggregate initial principal amount of senior convertible notes as well as the pricing of the note offering.

On April 27, 2004, the Company furnished a Current Report on Form 8-K, reporting under item 12, announcing our fiscal 2004 first quarter results.

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: August 12, 2004

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

Date: August 12, 2004

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

39

EXHIBIT INDEX

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