THORATEC CORP
Form 10-Q
May 11, 2005

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended April 2, 2005

or

o 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	**94588**
(Address of principal executive offices)	**(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 þ No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act): Yes þ No o

As of April 28, 2005 registrant had 48,266,917 shares of common stock outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

THORATEC CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS

(unaudited)
(in thousands)

	April 2, 2005	January 1, 2005
Assets		
Current assets:		
Cash and cash equivalents	$ 19,499	$ 16,017
Short-term available-for-sale investments	132,936	129,842
Restricted short-term investments	3,379	3,362
Receivables, net of allowances of $780 and $708 respectively	31,293	33,051
Inventories	37,389	39,141
Deferred tax asset	6,470	6,470
Prepaid expenses and other assets	4,563	3,873
Total current assets	235,529	231,756
Property, plant and equipment, net	27,517	27,584
Goodwill	94,097	94,097
Purchased intangible assets, net	150,337	153,141
Restricted long-term investments	4,836	4,845
Long-term deferred tax asset	6,489	6,381
Other assets	6,437	6,611
Total Assets	$ 525,242	$ 524,415
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable	6,176	7,699
Accrued compensation	8,060	9,507
Accrued income tax	4,502	2,299
Other accrued expenses	6,952	6,001
Total current liabilities	25,690	25,506
Senior subordinated convertible notes	143,750	143,750
Long-term deferred tax liability and other liabilities	62,129	63,051
Total liabilities	231,569	232,307

Shareholders Equity:		
Common shares; 100,000 authorized; issued and outstanding 48,207 and 48,375, respectively	363,674	364,775
Deferred compensation	(1,380)	(1,586)
Accumulated deficit	(68,864)	(71,514)
Accumulated other comprehensive income:		
Unrealized loss on investments	(382)	(325)
Cumulative translation adjustments	625	758
Total accumulated other comprehensive income	243	433
Total shareholders equity	293,673	292,108
Total Liabilities and Shareholders Equity	$ 525,242	$ 524,415

See notes to condensed consolidated financial statements.

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THORATEC CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended	
	April 2, 2005	April 3, 2004
Product sales	$ 50,488	$ 42,792
Cost of product sales	20,048	17,721
Gross profit	30,440	25,071
Operating expenses:		
Selling, general and administrative	14,817	13,013
Research and development	7,719	7,338
Amortization of purchased intangible assets	2,804	2,931
Litigation and other costs	178	133
Total operating expenses	25,518	23,415
Income from operations	4,922	1,656
Other income and (expense):		
Interest expense	(1,008)	
Interest income and other	836	465
Income before income tax expense	4,750	2,121
Income tax expense	(1,615)	(827)
Net income	$ 3,135	$ 1,294
Net income per share, basic	$ 0.07	$ 0.02
Net income per share, diluted	$ 0.06	$ 0.02
Shares used to compute net income per share:		
Basic	48,202	56,106
Diluted	49,009	57,458

See notes to condensed consolidated financial statements.

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THORATEC CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)
(in thousands)

	Three Months Ended	
	April 2, 2005	April 3, 2004
Cash flows from operating activities:		
Net income	$ 3,135	$ 1,294
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	4,453	4,641
Investment premium amortization	132	56
Non-cash interest and other expenses	1,008	
Tax benefit related to stock options	90	131
Amortization of deferred compensation	232	227
Change in net deferred tax liability	(1,183)	(68)
Changes in assets and liabilities:		
Receivables	1,757	(882)
Inventories	1,250	(541)
Prepaid expenses and other assets	(690)	(1,602)
Accounts payable and other liabilities	(512)	(3,899)
Other	119	(119)
Net cash provided by (used in) operating activities	9,791	(762)
Cash flows from investing activities:		
Purchases of available-for-sale investments	(15,370)	(19,100)
Sales of available-for-sale investments	8,900	26,750
Maturities of available-for-sale investments	3,070	5,844
Purchases of property, plant and equipment, net	(1,104)	(2,036)
Net cash provided by (used in) investing activities	(4,504)	11,458
Cash flows from financing activities:		
Proceeds from stock option exercises, net	541	715
Repurchase of common stock	(2,238)	(6,730)
Net cash provided by (used in) financing activities	(1,697)	(6,015)
Effect of exchange rate changes on cash and cash equivalents	(108)	71
Net increase in cash and cash equivalents	3,482	4,752
Cash and cash equivalents at beginning of period	16,017	18,270
Cash and cash equivalents at end of period	$ 19,499	$ 23,022

Supplemental disclosure of cash flow information:

Cash paid for taxes	$ 427	$ 217
Cash paid for interest	$	$
Supplemental disclosure of Non-cash investing and financing activities:		
Transfers of equipment from inventory	$ 502	$ 128

See notes to condensed consolidated financial statements.

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THORATEC CORPORATION AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(unaudited)
(in thousands)

	Three Months Ended	
	April 2, 2005	April 3, 2004
Net income	$ 3,135	$ 1,294
Other net comprehensive income :		
Unrealized loss on investments (net of taxes of $(108) and $(20) for the three months ended April 2, 2005 and April 3, 2004, respectively)	(382)	(31)
Foreign currency translation adjustments (net of taxes of $33 and $0 for the three months ended April 2, 2005 and April 3, 2004, respectively)	625	71
Comprehensive income	$ 3,378	$ 1,334

See notes to condensed consolidated financial statements.

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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 herein as 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 2004 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 2004 amounts to conform to the current presentation.

In prior years, auction rate securities were classified as cash and cash equivalents. These securities have been reclassified for all periods presented from cash and cash equivalents to short term available-for-sale investments. These auction rate securities have an underlying component of a long-term debt or equity instrument; however, they are traded or mature on a shorter term based on an auction bid that resets the interest rate over time intervals of 28 to 49 days. These resets allow for a much higher level of liquidity than typical long term investments. As of January 1, 2005, we reclassified $43.8 million of these securities to short-term available-for-sale investments from cash and cash equivalents based on the period from purchase date to the reset date and as they are not intended to be held to the maturity date.

2. Stock Based Compensation

We account for stock-based compensation to employees using the intrinsic value method in accordance with Accounting Principals Board Opinion (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 Statement of Financial Accounting Standard (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:

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	Three Months Ended	
	April 2, 2005	April 3, 2004
	(in thousands, except per share data)	
		(Restated)
Net income (loss):		
As reported	$ 3,135	$ 1,294
Add: Stock-based compensation expense included in reported net income, net of related tax effects	47	139
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,917)	(1,896)
Pro forma income (loss)	$ 1,265	$ (463)
Basic earnings (loss) per share:		
As reported	$ 0.07	$ 0.02
Pro forma income (loss)	$ 0.03	$ (0.01)
Diluted earnings (loss) per share:		
As reported	$ 0.06	$ 0.02
Pro forma income (loss)	$ 0.03	$ (0.01)

Subsequent to the issuance of our condensed consolidated financial statements for the quarter ended October 2, 2004, management determined that total stock based employee compensation expense determined under the fair value based method, net of related tax effects, for the first three quarters of 2004 had been calculated incorrectly. Accordingly, such pro forma amounts presented above have been restated. The effect was to decrease pro forma stock-based compensation expense, net of tax and pro forma net loss by $0.1 million for the first quarter of 2004. Pro forma earnings per share had no effect on the same quarter. This correction did not impact the Company s consolidated financial position, results of operations, or cash flows for any of the periods presented.

3. New Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued statement 123R Share-Based Payment . This statement requires 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. Our adoption of this statement, which we expect to occur in the first quarter of 2006, will have a material, although non-cash, impact on our consolidated statements of operations.

4. Cash and cash equivalents

We consider highly liquid investments with original maturities of three months or less to be cash and cash equivalents.

5. Investments

Our investments are primarily held in auction rate securities, corporate and municipal bonds and U.S. government obligations and are classified as available-for-sale and are reported at fair value based upon quoted market price. All investments mature within two years or less from the date of purchase, except for some investments in U.S. Treasuries

held as restricted investments as collateral for future interest payments related to our convertible debt, which mature within three years from the date of purchase. Investments with maturities beyond one year may be classified as short-term, if they are intended for use in operations, based on their highly liquid nature or due to the frequency in which the interest rate is reset such as with auction rate securities. In addition these securities represent the investment of cash that is available and intended for current operations. Investments that are not intended for use in current operations are classified as long-term investments.

Securities classified as restricted are investments held in U.S. Treasuries as collateral for future interest payments related to our convertible debt and are reported at fair value based upon quoted market price. The investments that

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relate to interest payments due within one year have been classified as restricted short-term investments and the investments that relate to interest payments due after one year have been classified as restricted long-term investments. We determined that these investments had no impairments that were other-than temporary.

For all investments, temporary differences between cost and fair value is presented as a separate component of accumulated other comprehensive income. The specific identification method is used to determine realized gains and losses on investments.

6. Financial Instruments

We have a foreign currency exchange risk management program principally designed to mitigate the change in value of assets and liabilities (primarily assets and liabilities on our UK subsidiary s consolidated balance sheet that are denominated in UK pounds). Forward exchange contracts that generally have terms of three months or less are used to hedge these currency exposures on our books. The derivatives used in the foreign currency exchange risk management program are not designated as cash flow or fair value hedges under SFAS 133. These contracts are recorded on the condensed consolidated balance sheets at fair value in Deferred Tax Asset and Other Prepaid Assets current assets. Changes in the fair value of the contracts and the underlying exposures being hedged are included concurrently in Interest income and other. At April 2, 2005 and January 1, 2005, respectively, the Company had forward foreign currency contracts to exchange Pounds Sterling and Euros for U.S. Dollars with a notional value of $6.9 million and negligible fair value for the same periods. Net foreign currency exchange loss was $0.2 million and $0.1 as of April 2, 2005 and April 3, 2004, respectively.

7. Inventories

Inventories consist of the following:

	As of	
	April 2, 2005	**January 1, 2005**
	(in thousands)	
Finished goods	$ 15,744	$ 18,562
Work in process	7,432	4,582
Raw materials	14,213	15,997
Total	$ 37,389	$ 39,141

8. Property, Plant and Equipment

Property, plant and equipment consist of the following:

	As of	
	April 2, 2005	**January 1, 2005**
	(in thousands)	
Property, plant and equipment, at cost	$ 62,991	$ 61,670
Less accumulated depreciation	(35,474)	(34,086)

Total	$ 27,517	$ 27,584

9. Goodwill and Purchased Intangible Assets

The change in the carrying amount of goodwill, which is attributable to our Cardiovascular business segment, for the three and twelve month periods ended April 2, 2005 and January 1, 2005 was as follows:

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	As of April 2, 2005	As of January 1, 2005
	(in thousands)	
Beginning balance	$ 94,097	$ 96,065
Realization of acquired deferred tax asset		(1,153)
Reversal of accrual for securities registration costs		(815)
Ending balance	$ 94,097	$ 94,097

There were no adjustments to Goodwill in the first three months of 2005. In 2004, goodwill related to the merger of Thoratec with Thermo Cardiosystems, Inc. (TCA) was adjusted by $1.2 million to reflect the utilization of tax net operating loss (NOL) benefits related to our subsidiary in the United Kingdom (UK). At the time of the merger, a deferred tax asset related to these NOL tax benefits was established with a corresponding valuation allowance for the full amount. As our UK subsidiary more likely than not will begin utilizing a portion of this NOL benefit, a portion of the original valuation allowance has been reversed against goodwill .

In addition, goodwill was also adjusted by $0.8 million 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 agreement, we agreed to pay these costs should Thermo Electron Corporation (TCI) (the majority shareholder of 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 purchased intangible assets, net are as follows:

	As of April 2, 2005		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
		(in thousands)	
Patents and Trademarks	$ 37,815	$ (14,963)	$ 22,852
Core Technology	37,485	(7,622)	29,863
Developed Technology	122,782	(25,229)	97,553
Non-compete Agreement	90	(21)	69
Total Purchased Intangible Assets, net	$ 198,172	$ (47,835)	$ 150,337

	As of January 1, 2005		
	Gross Carrying Amount	Accumulated Amortization (in thousands)	Net Carrying Amount
Patents and Trademarks	$ 37,815	$ (14,051)	$ 23,764

Core Technology	37,485	(7,242)	30,243
Developed Technology	122,782	(23,721)	99,061
Non-compete Agreement	90	(17)	73
Total Purchased Intangible Assets, net	$ 198,172	$ (45,031)	$ 153,141

Effective January 1, 2005, the Company revised its estimate for the remaining useful lives for certain of its core and developed technology intangible assets. The effect of the change was to decrease amortization expense by $0.1 million during the three months ended April 2, 2005 and is expected to decrease amortization by $0.5 million during each of the next five years. Amortization expense related to purchased intangible assets, net was $2.8 million and $2.9 million for the three months ended April 2, 2005 and April 3, 2004, respectively. Amortization expense is expected to be approximately $11.2 million for each of the next five years. Patents and trademarks have useful lives of eight to twenty years, core and developed technology assets have useful lives ranging from nine to twenty four years and the useful life of the non-compete agreement is approximately six years.

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10. Long-Term Debt

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

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

The deferred debt issuance costs of $3.8 million, net of $0.5 million in amortization, are included in other assets on the condensed consolidated balance sheet. The deferred debt issuance costs are amortized on a straight line basis until May 2011 at which point the Company can redeem the debt. These charges are included in Interest expense on the condensed consolidated statement of operations.

Long Term Debt Offering Proceeds (in millions):	
Principal amount of convertible notes at maturity	$ 247.4
Original issue discount	(103.7)
Debt issuance costs	(4.3)
Net proceeds	$ 139.4

Holders of the convertible notes may convert their convertible notes into shares of our common stock at a conversion rate of 29.4652 shares per $1,000 principal amount of convertible notes, which represents a conversion price of $19.72 per share, subject to adjustments upon the occurrence of certain events. Holders were able to convert their convertible notes at any point after the close of business on September 30, 2004 if, as of the last day preceding the calendar quarter, the closing price of our common stock for at least 20 trading days in a period of 30 consecutive trading days ending on the last trading day of such preceding calendar quarter is more then 120% of the accreted conversion price per share of our common stock. Holders may surrender their convertible notes for conversion 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. As of the quarter ended April 2, 2005, no notes have been converted or called.

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 April 2, 2005 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

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accrued and unpaid interest and liquidated damages, if any for our failure to comply with our registration obligations regarding the convertible notes.

The convertible notes are subordinated to all of our senior indebtedness and structurally subordinated to all indebtedness of our subsidiaries. Therefore, in the event of a bankruptcy, liquidation or dissolution of us or one or more of our subsidiaries 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.

The aggregate fair value of the convertible notes at April 2, 2005, based on market quotes, was $129.3 million.

11. Common Stock

In February 2004 and again in July 2004, the Board of Directors authorized stock repurchase programs under which up to $50 million in the aggregate 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 April 2, 2005, we had repurchased and retired 8.5 million shares with an aggregate purchase price of $104.9 million under these combined programs.

12. Litigation and Other Costs

Litigation and other costs are comprised of:

	Three Months Ended	
	April 2, 2005	April 3, 2004
	(in thousands)	
Litigation	$ 178	$ 133

Litigation

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 comprised of additional legal expenses related to the settlement.

In June of 2004, MicroMed Technology, Inc., a potential competitor of the Company, sued the Company in Texas. MicroMed sought a temporary restraining order against the Company in connection with the Company s HeartMate II phase I clinical trial on the grounds that the Company had provided the HeartMate II VAD to clinical sites without charge and that doing so was a violation of Texas anti-trust law. In addition to injunctive relief, the plaintiff is seeking unspecified damages and fees, including those arising from potential sales of its VAD products which plaintiff alleges it lost due to the Company s HeartMate II clinical trial. We have successfully defended ourselves against MicroMed s requests for injunctive relief and will continue to vigorously defend any and all of the claims made by MicroMed in this action.

On August 3, 2004, a putative Federal securities law class action entitled *Johnson v. Thoratec Corporation, et al.* was filed in the United States District Court for the Northern District of California on behalf of purchasers of the publicly traded securities of the Company between April 28, 2004 and June 29, 2004. Subsequent to the filing of the Johnson complaint, additional complaints were filed in the same court alleging substantially similar claims. On November 24, 2004, the Court entered an order consolidating the various putative class action complaints into a single action entitled In re Thoratec Corp. Securities Litigation and thereafter entered an order appointing Craig Toby as Lead Plaintiff pursuant to the Private Securities Litigation Reform Act of 1995. On January 18, 2005, Lead Plaintiff filed a Consolidated Complaint. The Consolidated Complaint generally alleges violations of the Securities Exchange Act of 1934 by the Company, its chief executive officer, cardiovascular division president and

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former chief financial officer based upon, among other things, alleged false statements about the Company s expected sales and the market for HeartMate as a Destination Therapy treatment. The Consolidated Complaint seeks to recover unspecified damages on behalf of all purchasers of the Company s publicly traded securities during the putative class period. On March 4, 2005, defendants moved to dismiss the Consolidated Complaint and that motion currently is pending.

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

We believe that the claims asserted in both the Federal securities law putative class action and the state shareholder derivative actions are without merit. We have moved to dismiss the Federal action and will file a similar motion in the Wong action if necessary. We are unable to predict at this time the final outcome of these actions.

We carry sufficient insurance to cover what management believes to be any reasonable exposure on these actions; however, we cannot give assurance that our insurance will cover all costs or other exposures we may incur with respect to these actions.

13. Income Taxes

Our effective income tax expense rates were 34% and 39%, respectively, for the first quarters of 2005 and 2004. The reduction in our effective tax expense rate is due primarily to additional interest income from tax favorable investments and increased research tax credits. In addition, we have reserved amounts for anticipated tax audit adjustments in the U.S., state and other foreign tax jurisdictions based on our estimate of whether, and the extent to which, additional taxes and interest may be due.

At April 2, 2005 and January 1, 2005, we reported a net deferred tax liability of approximately $48.0 million and $49.2 million, respectively, comprised principally of temporary differences between the financial statement and income tax bases of intangible assets.

14. Net Income Per Share

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

	Three Months Ended	
	April 2, 2005	April 3, 2004
	(in thousands, except per share data)	
Net income	$ 3,135	$ 1,294
Weighted average number of common shares-basic	48,202	56,106
Dilutive effect of stock options & ESPP Shares	807	1,352
Weighted average number of common shares-diluted	49,009	57,458

Net income per common share-basic	$	0.07	$	0.02
Net income per common share-diluted	$	0.06	$	0.02

Basic earnings per share are computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted earnings per share reflect the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Options to purchase 5.9 million and 3.7 million shares of common stock were not included in the computation of diluted earnings and losses per share for the three months ended April 2, 2005 and April 3, 2004, respectively, as their inclusion would be antidilutive. In addition, the computation of diluted earnings per share excludes the effect of assuming the conversion of our convertible notes, which are convertible at $19.72 per share into 7.3 million shares of common stock, because their effect would have been antidilutive for the three months ended April 2, 2005. The

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convertible notes were not issued as of April 3, 2004 therefore there was no effect on the computation for diluted earnings per share for the three months then ended.

15. Business Segment and Geographical Data

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

Business Segments:

	Three Months Ended	
	April 2, 2005	April 3, 2004
	(in thousands)	
Product sales:		
Cardiovascular	$ 32,066	$ 26,553
ITC	18,422	16,239
Total product sales	$ 50,488	$ 42,792
Income before income taxes:		
Cardiovascular(a)	$ 6,128	$ 2,894
ITC(a)	3,151	2,292
Corporate (b)	(4,179)	(3,397)
Litigation and other costs (c)	(178)	(133)
Income from operations	4,922	1,656
Other income and (expense):		
Interest expense	(1,008)	
Interest income and other	836	465
Income before income tax expense	$ 4,750	$ 2,121

(a) Amortization expense of $2.8 million and $2.9 million for the three months ended April 2, 2005 and April 3, 2004, respectively, related to the Cardiovascular segment. The ITC segment had amortization expense of $40,000 and $39,000 for the same three month periods.

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

(c) Relates to expenses not specifically identified to a particular business segment.

Geographic Areas:

The geographic composition of our product sales were as follows:

	Three Months Ended	
	April 2, 2005	April 3, 2004
	(in thousands)	
Domestic	$ 39,204	$ 33,781
International	11,284	9,011
Total	$ 50,488	$ 42,792

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes 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 statements can be identified by the words expects, projects, hopes, believes, intends, should, estimate, will, would, may, anticip words of similar import and the negatives thereof. Actual results could differ materially from these forward-looking statements based on a variety of factors, many of which are beyond our control. Therefore, readers are cautioned not to put undue reliance on these statements. Investors are cautioned that all such statements involve risks and uncertainties, including risks related to the development of new markets such as Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of our products, changes in the mix of our product sales and the related gross margin for such product sales, the results of clinical trials including the HeartMate II, the ability to improve financial performance, regulatory approval processes, the effect of healthcare reimbursement and coverage policies, the effects of seasonality in our product sales, the effects of price competition from any of our competitors and the effects of any merger and acquisition related activities. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the Factors That May Affect Future Results section and in other documents we file with the Securities and Exchange Commission, or SEC. Actual results, events or performance may differ materially. These forward-looking statements speak only as of the date hereof. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

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 2004 filed with the SEC.

Overview

We are a leading manufacturer of circulatory support products for use by patients with congestive heart failure, or CHF. Our Ventricular Assist Devices, or VADs, are used primarily by 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 wholly-owned subsidiary, ITC, we design, develop, manufacture and market point-of-care diagnostic test systems and incision products that provide for fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes.

Our Business Model

Our business is comprised of two segments; Cardiovascular and ITC.

The major product lines within the Cardiovascular segment are:

Circulatory Support Products. Our circulatory support products include VADs for the short-term and long-term treatment of congestive heart failure.

Vascular Graft Products. We have developed small diameter grafts using our proprietary materials to address the vascular access market. Our grafts are sold in the United States and internationally for use in hemodialysis.

The major product lines of our ITC segment are:

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Point-of-Care Diagnostics. Our point-of-care products include coagulation diagnostic test systems that monitor a patient while being administered certain anticoagulants, blood gas/electrolyte and chemistry status, or anemia.

Incision. Our incision products include devices used to obtain a patient s blood sample for diagnostic testing and screening for platelet function.

Cardiovascular segment

We offer a broad product portfolio of implantable and external circulatory support product devices comprised of:

The Thoratec Ventricular Assist Device System is an external device for short to mid-term cardiac support, which is sold worldwide. The device is approved to assist the left and the right ventricle and is worn outside of the body. The Thoratec VAD is approved for use in bridge-to-transplant, or BTT.

The Thoratec Implantable Ventricular Assist Device, or IVAD, is the only bi-ventricular implantable blood pump approved for BTT and post-cardiotomy recovery. It can be used for left, right, or biventricular support. The IVAD utilizes the same internal working components as the Thoratec VAD System blood pump, but has an outer housing made of a titanium alloy that makes it more suitable for implantation.

The HeartMate Left Ventricular Assist System, also called the HeartMate XVE, is an implantable device for mid to long-term cardiac support and the only device approved in the United States, Europe and Canada for permanent support of those patients ineligible for heart transplantation. The HeartMate XVE is approved for use in both BTT and Destination Therapy, or permanent support for patients suffering from end-stage heart failure who are not eligible for heart transplantation.

The HeartMate II, which is currently in clinical trials for BTT and Destination Therapy, is an implantable LVAS consisting of a miniature rotary blood pump that is designed to provide long-term support. Its design is intended to be not only smaller, but also simpler, quieter, and longer lasting than current generation assist devices.

The *Vectra* vascular access graft is designed for use as a shunt between an artery and a vein, primarily to provide access to the bloodstream for renal hemodialysis patients requiring frequent needle punctures during treatment.

The primary markets for our VAD products are those patients suffering from heart failure and, in particular, from CHF. CHF is a chronic disease that occurs when degeneration of the heart muscle reduces the pumping power of the heart, causing the heart to become too weak to pump blood at a level sufficient to meet the body s demands. CHF can be caused by artery or valve diseases or a general weakening of the heart muscle itself. Other conditions, such as high blood pressure or diabetes, can also lead to CHF.

In the United States, there are currently two FDA-approved indications for the use of VADs in patients with CHF as a bridge to heart transplant and as Destination Therapy. We are currently pursuing one additional indication for our Thoratec VAD products for therapeutic recovery of the heart. Beyond the CHF markets, VADs are also approved for use during recovery following cardiac surgery.

We currently market VADs that may be implanted or worn outside the body and that are suitable for treatments for different durations for patients of varying sizes and ages. We estimate that doctors have implanted over 9,500 of our devices in patients suffering from heart failure. Our devices are currently used primarily for patients awaiting a heart transplant or Destination Therapy implants. On November 6, 2002, the United States Food and Drug Administration, or FDA, approved the HeartMate VAD as the first heart assist device for Destination Therapy. On April 7, 2003, the

FDA approved the HeartMate XVE, an enhanced version of the HeartMate VAD, for Destination Therapy. Thoratec is the only company to have a ventricular assist device approved for Destination Therapy in the United States. In August 2004, we received FDA approval in the U.S. to market the IVAD for use in bridge-to-transplantation and post-cardiotomy recovery patients who are unable to be weaned from cardiopulmonary bypass. This makes the IVAD the only currently approved implantable cardiac assist device that can provide left, right or biventricular support.

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ITC Segment

The major product lines of diagnostic test systems and incision device products are:

The Hemochron Point of Care, or POC, coagulation system is used to monitor a patient s coagulation while being administered anticoagulants in various settings, including in the cardiovascular operating room to monitor the drug Heparin and in an anticoagulation clinic to monitor the drug Coumadin. Hemochron is considered a moderately complex device and must be used by professionally trained personnel. The system consists of a small, portable analytical instrument and disposable test cuvettes.

The Immediate Response Mobile Analysis, or IRMA, POC blood gas/electrolyte and chemistry system is used to monitor a patient s blood gas/electrolyte and chemistry status. It is considered moderately complex and its use requires supervision by professionally trained personnel. The system consists of a small, portable analytical instrument and disposable test cartridges.

The ProTime coagulation monitoring system is used to monitor a patient s coagulation while they are taking oral anticoagulants such as Coumadin, and can be prescribed to be used by patients at home or can be used in the physician s office or clinic. The system consists of a small, portable analytical instrument and disposable test cuvettes.

The Hemoglobin Pro System (Hgb Pro) is used by professionals, mainly in the doctor s office to test

for anemia; providing quick results on a very small blood sample. The system consists of a small, hand held test meter and disposable test strips.

Tenderfoot, Tenderlett and Surgicutt incision products are used by professionals to obtain a patient s blood sample for diagnostic testing. The tenderfoot is a heel stick used for infant testing, Tenderlett is used for finger incisions and the Surgicutt is used to perform screening tests to determine platelet function. All products feature permanently retracting blades for safe, virtually pain-free incision.

The Hemochron and IRMA products are primarily sold into the Hospital POC segment of the market. The ProTime and Hemoglobin Pro products are sold into the Alternate Site POC market comprising physicians offices, long-term care facilities, clinics, visiting nurse associations, and home healthcare companies.

Our incision products are sold to both the Hospital POC market and the Alternate Site POC. Our most successful incision product is the Tenderfoot. Although we market this product based on its high-end features, we believe that, in the long-term, customers will increasingly make purchasing decisions on these types of products based on price. Therefore, we expect a gradual erosion of market share over time.

Critical Accounting Policies and Estimates

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. For a more detailed discussion on the application of these and other accounting policies, see the notes to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for fiscal 2004 filed with the SEC. 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 Purchased Intangibles and Goodwill for Impairment

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, we periodically evaluate the carrying value of long-lived assets to be held and used, including intangible assets subject to amortization, 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

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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 any of these estimates proves incorrect, the carrying value of these assets on our consolidated balance sheet could become significantly impaired.

As of the beginning of fiscal year 2002, we adopted SFAS No. 142, Goodwill and Other Intangible Assets, and ceased amortizing purchased goodwill. Since then, we complete an annual impairment test of goodwill and other intangible assets subject to amortization as required by SFAS No. 142 and SFAS No. 144. Upon completion of our impairment tests as of the end of the year 2004, we determined that neither goodwill nor intangible assets were impaired. Based on changes in business conditions, we did modify the economic useful lives of certain components of our core and developed technology assets which had an immaterial impact on our results of operations for the three months ended April 2, 2005.

Revenue Recognition

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

Sales of certain Cardiovascular segment products to first-time customers are recognized when it has been determined that the customer has the ability to use such products. These sales frequently include the sale of products and training services under multiple element arrangements. Training is not considered essential to the functionality of our products. The amount of revenue under these arrangements allocated to training is based upon the fair market value of the training, which is typically performed on behalf of the Company by third party providers. The amount of product sales allocated to the Cardiovascular segment products is done on a fair value basis. Under this basis, the total value of the arrangement is allocated to the training and the Cardiovascular segment products based on the relative fair market value of the training and the 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 end of the fiscal quarter ended April 2, 2005, all products that had been delivered and recorded as product sales were delivered to customers for which training had been completed. There was no amount of product sales deferred related to this training not yet completed at the end of the three months ended April 2, 2005 and none at the 2004 fiscal year end.

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

In determining when to recognize revenue, management makes decisions on such matters as the relative fair values of the product and training elements when sold together, customer credit worthiness and warranty reserves. If these decisions prove incorrect, the carrying value of these assets and liabilities on our consolidated balance sheet could be significantly different.

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.

Management must make judgments to determine the amount of reserves to accrue. If management estimates prove incorrect, our financial statements could be adversely affected.

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Accounting Pronouncements

In December 2004, the FASB issued statement 123® Share-Based Payment . This statement requires 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. Our adoption of this statement, which we expect to occur in the first quarter of 2006, will have a material, although non-cash, impact on our consolidated statements of operations.

Results of Operations

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

	Three Months Ended	
	April 2, 2005	April 3, 2004
Product sales	100%	100%
Cost of sales	40	41
Gross profit	60	59
Operating expenses:		
Selling, general and administrative	30	31
Research and development	15	17
Amortization of purchased intangible assets	6	7
Litigation and other costs		
Total operating expenses	51	55
Income from operations	9	4
Other income and (expense):		
Interest expense	(2)	
Interest income and other	2	1
Income before income tax expense	9	5
Income tax expense	3	2
Net income	6%	3%

See Note 15 to our unaudited condensed consolidated interim financial statements in this report for data presented by business segment.

Three months ended April 2, 2005 and April 3, 2004

Product Sales

Product sales in the first quarter of 2005 were $50.5 million compared to $42.8 million in the first quarter of 2004. The Cardiovascular segment increased sales by $5.5 million and the ITC segment increased sales by $2.2 million.

Product sales increases are due to an increase in volume unless otherwise noted. The primary components of the total $7.7 million increase in product sales were the following:

VAD product sales increased $4.4 million. The majority of this increase came from higher sales of the IVAD product line of $4.1 million.

Other ancillary product sales, (drivers, cannulae, service, rentals and spares) increased $0.9 million, including an increase in TLC II driver revenue principally from Home Discharge , which was approved by the FDA toward the end of the second quarter of 2004.

Graft product sales increased by $0.2 million due to a higher average selling price.

Point-of-care diagnostic product sales increased $2.7 million, due primarily to a $1.1 million increase in sales in our Hemochron product line coupled with modest increases in sales of our IRMA, ProTime and Hemoglobin products quarter over quarter.

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Incision product sales decreased by $0.5 million due in part to lower volume offset by higher average selling prices.

For the three months ended April 2, 2005 and April 3, 2005, sales originating ourside of the United Staes and U.S. export sales accounted for approximately 22% and 23%, respectively, of our total product sales.

Gross Profit

Gross profit in the first quarter of 2005 was 60% compared to 59% in the first quarter of 2004. The change in gross profit was due to the following fluctuations:

The Cardiovascular segment increased gross profit by 1% due to higher incremental revenue in conjunction with higher margin VAD product sales offset by an increase in manufacturing costs;

The ITC segment increased gross profit by 3%, due to higher incremental revenue in higher margin products and increased margins in the point-of-care market related to the shift in mix from distributor to direct channels sales.

Selling, General and Administrative

Selling, general and administrative expenses in the first quarter of 2005 were $14.8 million, or 30% of product sales, compared to $13.0 million, or 31% of product sales, in the first quarter of 2004. The $1.8 million increase in spending resulted from:

Increased personnel costs associated with higher product sales in both the Cardiovascular and ITC segments totaling $0.7 million.

Higher spending on marketing and related activities, primarily associated with our HeartHope Center Program, Destination Therapy, and costs associated with the IRMA product line totaling $0.3 million.

Higher professional fees, including legal, audit and financial consulting services relating to our compliance with the Sarbanes-Oxley Act of 2002 and project related business development activities of an additional $0.8 million.

Research and Development

Research and development expenses in the first quarter of 2005 were $7.7 million compared to $7.3 million in the first quarter of 2004, representing 15% and 17% of product sales for the respective periods. Our Cardiovascular and ITC segment each incurred $0.2 million of the increase in expenses quarter over quarter. 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 .

Amortization of Purchased Intangible Assets

Amortization of purchased intangible assets in the first quarter of 2005 was $2.8 million compared to $2.9 million in the first quarter of 2004. The decrease of $0.1 million is the result of changes in business conditions which caused us to modify the remaining economic useful lives of certain of our core and developed technology assets. These changes were made in accordance with our periodic valuation of the useful lives of our identifiable intangible assets under FAS 144 as of January 1, 2005.

Interest Expense

Interest expense for the first quarter 2005 was $1.0 million compared to none in the first quarter of 2004. This expense in first quarter of 2005 includes $0.8 million in interest payments and $0.2 million in amortization of the

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debt issuance costs related to our convertible notes issued in May 2004. We did not have these notes or any other debt instrument in the first quarter of 2004.

Interest Income and Other

Interest income and other for the three months ended April 2, 2005 was $0.8 million compared to $0.5 million in the three months ended April 3, 2004. This increase was primarily due to higher interest income earned on our portfolio based on increased cash balances, as a result of the convertible notes issuance, in the first quarter of 2005 compared to the first quarter of 2004, before the notes were issued.

Income Taxes

Our effective income tax expense rates were 34% and 39%, respectively, for the first quarters of 2005 and 2004. The reduction in our effective tax expense rate is due primarily to additional interest income from tax favorable investments and increased research tax credits. In addition, we have provided adequate amounts for anticipated tax audit adjustments in the U.S., state and other foreign tax jurisdictions based on our estimate of whether, and the extent to which, additional taxes and interest may be due. If events occur which indicate payment of these amounts are unnecessary or the liability proves to be more than anticipated, the reversal of the liabilities would result in tax benefits being recognized or a further charge to expense would result in the period the event occurs.

Our effective tax rate is calculated based on the statutory tax rate imposed on projected annual pre-tax income or loss in various jurisdictions. Since relatively small changes in our forecasted profitability for 2005 can significantly affect our projected annual effective tax rate, we believe our quarterly tax expense rate of 34% is the most reliable estimate of our effective tax expense rate. Accordingly, our quarterly tax rate for the second quarter and the remainder of 2005 will be largely dependent on our profitability and could fluctuate significantly.

Liquidity and Capital Resources

At April 2, 2005, we had working capital of $209.8 million compared with $206.3 million at January 1, 2005. Cash and cash equivalents and short-term available-for-sale investments at April 2, 2005 were $152.4 million compared to $145.9 million at January 1, 2005. The increase is due primarily to cash generated from operations, offset in part by net purchases of property, plant and equipment and repurchases of our common stock.

Cash provided by operating activities for the three months ended April 2, 2005 was $9.8 million. Investing activities used $4.5 million, with $3.4 million net purchases of investments and $1.1 million to acquire property, plant and equipment, net of $0.5 million in inventory transfers of product for demonstration purposes. The purchases of property, plant and equipment consisted of equipment purchases of $1.6 million, of which $1.0 million of the purchases relates to the Cardiovascular segment and $0.6 million relates to the ITC segment. Cash used in financing activities for the quarter was $1.7 million, including $2.2 million paid to repurchase 0.2 million shares of stock under our stock repurchase programs, partially offset by $0.5 million from proceeds related to stock option exercises and our Employee Stock Purchase Plan.

In March 2005, we agreed to purchase a new enterprise resource planning software system (ERP system) for our ITC segment. The estimated cost of the purchased software licenses, hardware, implementation costs and consulting for the ERP system is approximately $0.8 million over the 2005 fiscal year.

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

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FACTORS THAT MAY AFFECT FUTURE RESULTS

Our business faces many risks. These risks include those related to the development of new products and markets including Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of our products, changes in the mix of our product sales, and the related gross margin for such product sales, the results of clinical trials, including those for the HeartMate II, the ability to improve financial performance, regulatory approval processes, the effect of healthcare reimbursement and coverage policies, our product sales, the effects of price competition from any of our competitors and the effects of any merger and acquisition related activities. The risks described below are what we believe to be the material risks facing our company. However, the risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risk factors actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline significantly. Investors should consider the following risks, as well as the other information included in this Quarterly Report and our Annual Report on Form 10-K, and other documents we file from time to time with the SEC, such as our current reports on Form 8-K and any public announcements we make from time to time.

We have a history of net losses.

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

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

Significant uncertainty exists as to the reimbursement status of newly approved health care products such as VADs and vascular grafts, which uncertainty 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 Medicine & Medicaid Services, or the 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) pre-market

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

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

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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.

Certain lawsuits have been filed against us.

Commencing on or about August 3, 2004, several Federal securities law putative class action suits were 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. These suits were consolidated in a consolidated complaint filed on or about January 18, 2005. The complaint seeks to recover unspecified damages on behalf of all purchasers of our publicly traded securities during the class period.

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

In June of 2004, MicroMed Technology, Inc., a potential competitor of ours, sued us in Texas. MicroMed sought injunctive relief against us in connection with our HeartMate II Phase I clinical trial on the grounds that we had provided the HeartMate II VAD to clinical sites without charge and that doing so was a violation of Texas anti-trust law. In addition to injunctive relief, the plaintiff is seeking unspecified damages and fees, including those arising from potential sales of its VAD products which plaintiff alleges it lost due to our HeartMate II clinical trial. We have successfully defended ourselves against MicroMed s requests for injunctive relief and will continue to vigorously defend any and all of the claims made by MicroMed in this action.

We believe that the claims asserted in the MicroMed action, and both the Federal securities law putative class action and the state shareholder derivative action are without merit. We have filed a motion to dismiss in the Federal securities law putative class action and the shareholder suit currently is stayed through to at least early July 2005.

We are unable to predict at this time the final outcome of these actions.

We carry sufficient insurance to cover what management believes to be any reasonable exposure on these actions; however, we cannot give assurance that our insurance will cover all costs or other exposures we may incur with respect to these actions.

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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. The terms of our convertible notes do not restrict our ability to incur additional indebtedness, including indebtedness senior to the convertible 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; 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 (i.e., they are Destination Therapy patients) 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 depends 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;
- cardiologists and referring physicians education, and their commitment to Destination Therapy;
- the economics of the Destination Therapy procedure for individual hospitals, which include 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

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operating results. Sales of our VADs for Destination Therapy have proved slower than we had originally anticipated, and we are unable to predict when, if ever, these sales will generate significant revenue for us.

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

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 customers may purchase our VAD systems and our product sales 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 the level of revenues we expect.

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

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

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

A significant amount of our current product sales is generated by our VADs implanted temporarily in patients awaiting heart transplants. The number of heart transplants conducted worldwide depends on the number of hearts available to transplant, which number in turn depends on the death rate of otherwise healthy people from events such as automobile accidents.

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

The number of our employees has substantially increased during the past several years. We expect to continue increasing the number of our employees, and our business 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 fail to commercialize these new products, product improvements and new indications on a timely basis, or if they are not well accepted by the market, our future growth may suffer.

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

A substantial portion of our assets are comprised of goodwill and purchased intangible assets. We may not receive the recorded value for our intangible assets if we sell or liquidate our business or assets. The material concentration of intangible assets increases the risk of a large charge to earnings if the revenue from, and recoverability of, these intangible assets is impaired. We completed an assessment of the current values of our intangible assets at the year ended 2004 and determined that no impairment exists, however the lives have been modified on several components of these identified assets. In the event, however, of such a charge to net income, the market price of our common stock could be adversely affected. For example, in the first quarter of 2004, we completed an assessment of the final results from the feasibility clinical trial for the Aria CABG graft, which was ongoing through fiscal 2003. Based on the clinical trial results, we determined not to devote additional resources to development of the Aria graft. Upon the decision to discontinue product development, we recorded an impairment charge of approximately $9 million as of January 3, 2004 to write off purchased intangible assets related to the Aria graft, recorded as a result of our merger with TCA.

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

We depend on a number of custom-designed components and materials supplied by other companies including, in some cases, single source suppliers for components, instruments and materials used in our VAD products and blood testing products. For example, single sources currently manufacture and supply our ProTime and Hemoglobin instruments and the heart valves used in our HeartMate products. The suppliers of our ProTime and Hemoglobin products are located in China and Germany, respectively. We do not have long-term written agreements with most of our vendors and from these vendors receive components on a purchase order basis only. If we need alternative sources for key raw materials or component parts for any reason, such alternative sources may not be available and our inventory may not be sufficient to fill orders before we find alternative suppliers or begin manufacturing these components or materials ourselves. Cessation or interruption of sales of circulatory support products and or our point-of-care 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 require FDA approval before using new suppliers or manufacturing our own components or materials. Existing suppliers could also become subject to an FDA enforcement action, which could also disrupt our supplies. If alternative suppliers are not available, we may not have the expertise or resources necessary to produce these materials or component parts internally.

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

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

- pay premium prices to our suppliers to keep their production lines open or to obtain alternative suppliers;
- buy substantial inventory to last 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 product sales and increases in our production costs.

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

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

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

develop products;

complete clinical testing;

receive regulatory approvals; and

manufacture and sell commercial quantities of products.

Large medical device companies dominate the markets in which ITC competes. We expect that any growth in this market will come from expanding our market share at the expense of other companies, and from testing being shifted away from central laboratories to the point-of-care. However, this market segment is very competitive, and includes the following potential drivers:

New drug therapies under development may not require the intense monitoring of a patient s coagulation that the current anti-coagulation drug of choice (Heparin) requires.

New competitors might enter the market with broader test menus.

Any of the devices of our competitors in clinical trials and in development could prove to be clinically superior, easier to implant, and/or less expensive than current commercialized devices, thereby impacting Thoratec s marketshare.

The price of our common stock may fluctuate significantly.

The price of our common stock has been, and is likely to continue to be, highly volatile, which means that it could decline substantially within a short period of time. For example our stock price has ranged from $8.46 to $14.99 in the 12 months ended April 2, 2005. The price of our common stock could fluctuate significantly for many reasons, including the following:

future announcements concerning us or our competitors;

timing and reaction to the publication of clinical trial results;

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

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

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

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- 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.

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

We may encounter problems manufacturing our products.

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

With the exception of Canada and the larger countries in Europe, we sell our Thoratec 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 (which is also a competitor of ours) in the United States,

and selected countries in Europe, the Middle East and Northern Africa, and through Goodman Co. Ltd. in Japan. Substantially all of the international operations and a large portion of the Alternate Site domestic operations of ITC are conducted through distributors. For the quarter ended April 2, 2005, 16% of ITC s 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 or no control. If we lose a distributor or a distributor fails to perform to our expectations, our product sales may be harmed.

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

In March 2004, we began changing our manner of distributing our Hemochron product line to our hospital point-of-care customers in the United States from a distributor model to a direct sales model.

This transition to a direct sales model necessitated expanding the sales, technical service, customer service and

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shipping headcount at ITC in order to provide our customers with the support and service that they historically obtained from our distributors, resulting in an increase in our sales and general and administrative costs. This transition process concluded in the first quarter of 2005, which resulted in the United States hospital point-of-care market now being served directly and exclusively by ITC. This transition and its execution involve significant risks, including:

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 hospital point-of-care product lines, our revenues may fail to increase as expected or could decrease, which could adversely affect our results of operations and financial condition.

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 majority 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 our HeartMate product line. 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 us by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004, we 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 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

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against potential liabilities. A successful claim brought against us in excess 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 acceptance 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 and we may not realize the expected benefits of any such acquisition. In addition, acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees and increase our expenses, which could harm our business. We may also sell businesses or assets as part of our strategy or if we receive offers from third parties. If we do so, we may sell an asset or business for less than its full value.

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

A substaintial portion of our total sales occurs outside the United States. We anticipate that sales outside the United States and U.S. export sales will continue to account for a significant percentage of our product sales and we intend to continue to expand our presence in international markets. Non-U.S. sales are subject to a number of special risks. For example:

- we generally sell many of our products at a lower price outside the United States;
- sales agreements may be difficult to enforce;
- receivables may be difficult to collect through a foreign country s legal system;
- foreign customers may have longer payment cycles;

- foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;
- U.S. export licenses may be difficult to obtain;
- intellectual property rights may be more difficult to enforce in foreign countries;
- terrorist activity or war may interrupt distribution channels or adversely impact our customers or employees; and
- fluctuations in exchange rates may affect product demand and adversely affect the profitability, in U.S. dollars, of products sold in foreign markets where payments are made in local currencies.

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

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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, in particular because our premises require FDA approval, which could result in significant delays before we can manufacture product from a replacement facility. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Therefore, any such catastrophe could seriously harm our business and results of operations.

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

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