

THORATEC CORP  
Form 10-Q/A  
August 16, 2004

**Table of Contents**

---

---

**U.S. SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q/A**

**Amendment No. 1**

(Mark one)

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

**For the quarterly period ended April 3, 2004**

**or**

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

**for the transition period from            to**

**COMMISSION FILE NUMBER: 1-8145**

**THORATEC CORPORATION**

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

**California**

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

**94-2340464**

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

**6035 Stoneridge Drive, Pleasanton,  
California**

**(Address of principal executive offices)**

**94588**

**(Zip Code)**

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

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

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

As of May 7, 2004 registrant had 55,897,252 shares of common stock outstanding.

**Explanatory Note**

This Amendment No. 1 to the Quarterly Report on Form 10-Q of Thoratec Corporation for the quarter ended April 3, 2004 is being filed for the purpose of amending and revising Items 1 and 2 of Part I. This Form 10-Q/A is being filed in order to classify the Company's available-for-sale investments balance at January 3, 2004 as long-term, rather than short-term, on the Condensed Consolidated Balance Sheet. This classification is consistent with that shown on our Consolidated Balance Sheet as of January 3, 2004 on Form 10-K for the fiscal year ended January 3, 2004. As a result of this revision, we have deleted the reference to this reclassification of prior year amount in Note 1 to the Condensed Consolidated Financial Statements and revised the January 3, 2004 working capital and cash and cash equivalents and short-term available-for-sale investments amounts under the Liquidity and Capital Resources caption of Item 2.

Except as described above, no other significant amendments are being made to the Form 10-Q. This Form 10-Q/A does not reflect events occurring after April 3, 2004 or modify or update the disclosures contained in Form 10-Q other than as required to reflect the amendments discussed above.

**THORATEC CORPORATION AND SUBSIDIARIES  
TABLE OF CONTENTS**

<u>Part I. Financial Information</u>	3
<u>Item 1. Condensed Consolidated Financial Statements (unaudited)</u>	3
<u>Condensed Consolidated Balance Sheets as of April 3, 2004 and January 3, 2004</u>	3
<u>Condensed Consolidated Statements of Operations for the Three Months Ended April 3, 2004 and March 29, 2003</u>	4
<u>Condensed Consolidated Statements of Cash Flows for the Three Months Ended April 3, 2004 and March 29, 2003</u>	5
<u>Condensed Consolidated Statements of Comprehensive Income for the Three Months Ended April 3, 2004 and March 29, 2003</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosure of Market Risk</u>	20
<u>Item 4. Controls and Procedures</u>	21
<u>Part II. Other Information</u>	22
<u>Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities</u>	22
<u>Item 6. Exhibits and Reports on Form 8-K</u>	22
<u>Signatures</u>	23
Exhibits	24
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 32.1</u>	

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS****THORATEC CORPORATION AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**(unaudited)  
(in thousands)

	<b>April 3, 2004</b>	<b>January 3, 2004</b>
	<u>                    </u>	<u>                    </u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 48,022	\$ 62,020
Short-term available-for-sale investments	45,828	
Receivables, net of allowances of \$409 in 2004 and \$486 in 2003	28,851	27,969
Inventories	36,830	36,417
Deferred tax asset and other prepaid assets	13,193	12,796
	<u>                    </u>	<u>                    </u>
Total Current Assets	172,724	139,202
	<u>                    </u>	<u>                    </u>
Property, plant and equipment, net	28,948	28,492
Goodwill	95,116	96,065
Purchased intangible assets, net	161,934	164,865
Long-term available-for-sale investments		41,179
Long-term deferred tax asset and other assets	6,965	6,328
	<u>                    </u>	<u>                    </u>
Total Assets	\$465,687	\$476,131
	<u>                    </u>	<u>                    </u>
Liabilities and Shareholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 18,175	\$ 22,772
Total Current Liabilities	18,175	22,772
Long-term deferred tax liability and other liabilities	65,600	67,123
	<u>                    </u>	<u>                    </u>
Total Liabilities	83,775	89,895
	<u>                    </u>	<u>                    </u>

Shareholders' Equity:		
Common shares; 100,000 authorized; issued and outstanding 55,812 in 2004 and 56,242 in 2003	420,053	423,045
Deferred compensation	(2,403)	(2,630)
Accumulated deficit	(36,193)	(34,594)
Accumulated other comprehensive income:		
Unrealized gain on investments	20	51
Cumulative translation adjustments	435	364
	<u>          </u>	<u>          </u>
 Total accumulated other comprehensive income	 455	 415
	<u>          </u>	<u>          </u>
 Total Shareholders' Equity	 381,912	 386,236
	<u>          </u>	<u>          </u>
 Total Liabilities and Shareholders' Equity	 \$465,687	 \$476,131
	<u>          </u>	<u>          </u>

See notes to condensed consolidated financial statements.

Table of Contents**THORATEC CORPORATION AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

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

	<b>Three Months Ended</b>	
	<b>April 3, 2004</b>	<b>March 29, 2003</b>
Product sales	\$42,792	\$ 36,062
Cost of product sales	17,721	14,891
Gross profit	25,071	21,171
Operating expenses:		
Selling, general and administrative	13,013	10,060
Research and development	7,338	6,260
Amortization of purchased intangible assets	2,931	3,096
Legal settlement and restructuring costs	133	(57)
Total operating expenses	23,415	19,359
Income from operations	1,656	1,812
Interest and other income net	465	512
Income before income tax expense	2,121	2,324
Income tax expense	827	906
Net income	\$ 1,294	\$ 1,418
Net income per share:		
Basic and diluted	\$ 0.02	\$ 0.03

Shares used to compute net income per share:

Edgar Filing: THORATEC CORP - Form 10-Q/A

Basic	56,106	55,057
Diluted	57,458	55,534

See notes to condensed consolidated financial statements.

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

	<b>Three Months Ended</b>	
	<b>April 3, 2004</b>	<b>March 29, 2003</b>
<b>Cash flows from operating activities:</b>		
Net income	\$ 1,294	\$ 1,418
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	4,641	4,351
Amortization of deferred compensation	227	300
Investment premium amortization	282	275
Income tax expense	827	906
Changes in assets and liabilities:		
Receivables	(882)	3,003
Inventories	(413)	(344)
Prepaid expenses and other assets	(787)	(957)
Accounts payable and other liabilities	(5,294)	(3,205)
Other	(303)	437
	<hr/>	<hr/>
Net cash provided by (used in) operating activities	(408)	6,184
	<hr/>	<hr/>
<b>Cash flows from investing activities:</b>		
Purchases of available-for-sale and other investments	(11,325)	(4,439)
Sales of available-for-sale investments	5,844	5,709
Purchases of property, plant and equipment	(2,165)	(1,317)
	<hr/>	<hr/>
Net cash used in investing activities	(7,646)	(47)
	<hr/>	<hr/>
<b>Cash flows from financing activities:</b>		
Proceeds from stock option exercises	715	622
Repurchase of common stock	(6,730)	
	<hr/>	<hr/>
Net cash provided by (used in) financing activities	(6,015)	622



Edgar Filing: THORATEC CORP - Form 10-Q/A

Effect of exchange rate changes on cash	71	(56)
	<u>          </u>	<u>          </u>
Net increase (decrease) in cash and cash equivalents	(13,998)	6,703
Cash and cash equivalents at beginning of period	62,020	42,044
	<u>          </u>	<u>          </u>
Cash and cash equivalents at end of period	\$ 48,022	\$48,747
	<u>          </u>	<u>          </u>
<b>Supplemental Cash Flow Disclosure:</b>		
Cash paid for taxes	\$ 48	\$ 260
Cash paid for interest	\$	\$

See notes to condensed consolidated financial statements.

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

	<b>Three Months Ended</b>	
	<b>April 3, 2004</b>	<b>March 29, 2003</b>
Net income	\$ 1,294	\$ 1,418
Other net comprehensive income (loss):		
Unrealized gain (loss) on investments (net of taxes of \$(20) and \$14 in 2004 and 2003, respectively)	(31)	22
Foreign currency translation adjustments	71	(28)
Comprehensive income	\$ 1,334	\$ 1,412

See notes to condensed consolidated financial statements.

**Table of Contents**

**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**(Unaudited)**

**(in thousands, unless otherwise stated)**

**1. Basis of Presentation**

The interim condensed consolidated financial statements of Thoratec Corporation, referred to as 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, or the SEC, without audit and reflect all adjustments necessary (consisting only of normal recurring adjustments) to present fairly our financial position at April 3, 2004 and January 3, 2004, our results of operations for the three-month periods ended April 3, 2004 and March 29, 2003 and cash flows for the three-month periods ended April 3, 2004 and March 29, 2003. Certain information and footnote disclosures normally included in our annual financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. The accompanying financial statements should be read in conjunction with our fiscal 2003 consolidated financial statements filed with the SEC in our Annual Report on Form 10-K. The operating results for any interim period are not necessarily indicative of the results that may be expected for any future period.

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

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

**Stock Based Compensation**

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

**Table of Contents**

	<b>Three Months Ended</b>	
	<b>April 3, 2004</b>	<b>March 29, 2003</b>
Net income:		
As reported	\$ 1,294	\$ 1,418
Add: Stock-based compensation expense included in reported net income, net of related tax effects	139	185
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	<u>(2,043)</u>	<u>(2,029)</u>
Pro forma	<u>\$ (610)</u>	<u>\$ (426)</u>
Basic and diluted earnings (loss) per share:		
As reported	\$ 0.02	\$ 0.03
Pro forma loss	\$ (0.01)	\$ (0.01)

**2. New Accounting Pronouncements**

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

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

**3. Cash and Investments**

We consider highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. Short-term investments consist of available-for-sale debt securities that are carried at fair value and generally mature between three months and two years from the purchase date. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature and to reflect management's intent that these investments be considered available for current operations. As a result of its reassessment during the quarter ended April 3, 2004, the Company has classified its investments as short-term at April 3, 2004. We include any unrealized gains and losses on short-term investments, net of tax, in shareholders' equity as a component of other comprehensive income.

**4. Financial Instruments**

We have a foreign currency exchange risk management program principally designed to mitigate the change in value of assets and liabilities that are denominated in non-functional currencies. Forward exchange contracts that generally have terms of three months or less are used to hedge these non-functional currency exposures on the Company's books. The derivatives used in the foreign currency exchange risk management program are not designated as cash flow or fair value hedges under SFAS 133. These contracts are recorded on the balance sheet at fair value in

Deferred Tax Asset and Other current assets. Changes in the fair value of the contracts and the underlying exposures being hedged are included concurrently in Interest and Other Income Net . At April 3, 2004, the notional value of outstanding contracts approximated \$10.3 million with a fair value of approximately \$0.1 million.

**Table of Contents****5. Inventories**

Inventories consist of the following:

	<b>As of</b>	
	<b>April 3, 2004</b>	<b>January 3, 2004</b>
Finished goods	\$17,660	\$15,504
Work in process	5,893	9,089
Raw materials	13,277	11,824
	<u>          </u>	<u>          </u>
Total	\$36,830	\$36,417
	<u>          </u>	<u>          </u>

**6. Property, Plant and Equipment**

Property, plant and equipment consist of the following:

	<b>As of</b>	
	<b>April 3, 2004</b>	<b>January 3, 2004</b>
Property, plant and equipment, at cost	\$ 60,183	\$ 58,023
Less accumulated depreciation	(31,235)	(29,531)
	<u>          </u>	<u>          </u>
Total	\$ 28,948	\$ 28,492
	<u>          </u>	<u>          </u>

**7. Goodwill and Other Intangible Assets**

The change in the carrying amount of goodwill, which is attributable to our Cardiovascular business segment, for the three-month periods ended April 3, 2004 and March 29, 2003 was as follows:

<b>Three Months Ended</b>	
<b>April 3, 2004</b>	<b>March 29, 2003</b>
<u>          </u>	<u>          </u>

Edgar Filing: THORATEC CORP - Form 10-Q/A

Beginning balance	\$96,065	\$96,492
Realization of acquired foreign deferred tax asset	(134)	
Reversal of accrual for securities registration costs	(815)	
	<u>          </u>	<u>          </u>
Ending balance	\$95,116	\$96,492
	<u>          </u>	<u>          </u>

In the first quarter of 2004, goodwill related to the 2001 merger of Thoratec and Thermo Cardiosystems, Inc. ( TCA ) was adjusted to reflect the utilization of tax net operating loss benefits related to our subsidiary in the United Kingdom. At the time of the merger, a deferred tax asset related to these tax benefits was established with a corresponding valuation allowance for the full amount. As our UK subsidiary more likely than not will begin utilizing a portion of this benefit, a portion of the original valuation allowance has been reversed against goodwill.

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

The components of identifiable intangible assets, consisting primarily of patents and trademarks, core technology and developed technology, which are included in purchased intangible assets on the consolidated balance sheets, are as follows:

**Table of Contents**

<b>As of April 3, 2004</b>			
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Patents and Trademarks	\$ 37,815	\$(11,326)	\$ 26,489
Core Technology	37,485	(5,826)	31,659
Developed Technology	122,782	(19,079)	103,703
Non-compete Agreement	90	(7)	83
<b>Total Purchased Intangible Assets</b>	<b>\$198,172</b>	<b>\$(36,238)</b>	<b>\$ 161,934</b>
<b>As of January 3, 2004</b>			
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Patents and Trademarks	\$ 37,815	\$(10,416)	\$ 27,399
Core Technology	37,485	(5,353)	32,132
Developed Technology	122,782	(17,535)	105,247
Non-compete Agreement	90	(3)	87
<b>Total Purchased Intangible Assets</b>	<b>\$198,172</b>	<b>\$(33,307)</b>	<b>\$ 164,865</b>

Subsequent to fiscal 2003 year-end, the Company completed its assessment of the final results from its feasibility clinical trial for the Aria CABG graft which was ongoing through fiscal 2003. Based on the clinical trial results, the Company determined that it would not devote additional resources to the development of the Aria graft. Upon the decision to discontinue product development, the Company recorded an impairment charge of \$8,987 in the fourth quarter of 2003 to write off purchased intangible assets related to the Aria graft, which were recorded as a result of the merger with TCA in 2001.

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

Amortization expense related to identifiable intangible assets for the three month periods ended April 3, 2004 and March 29, 2003 was \$2,931 and \$3,096, respectively. Amortization expense is expected to be approximately



\$11.7 million for each of the next five years. The purchased intangible assets have estimated useful lives of seven to twenty years.

### 8. Common Stock

In February 2004, the Board of Directors authorized a stock repurchase program under which up to \$25.0 million of our common stock could be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of purchases were based on several conditions, including the price of our stock, general market conditions and other factors. As of April 3, 2004, we have repurchased and retired 510 thousand shares with an aggregate purchase price of \$6,730 under this program. For each share repurchased, we reduced the common stock account by the average value per share reflected in the account prior to the repurchase with the excess allocated to accumulated deficit. As of April 3, 2004 the reduction to common stock and the excess allocated to accumulated deficit was \$3,837 and \$2,893, respectively.

### 9. Legal Settlement and Restructuring Costs

Legal settlement and restructuring costs were recorded in the condensed consolidated statements of operations as follows:

	Three Months Ended	
	April 3, 2004	March 29, 2003
Legal Settlement	\$133	\$
Restructuring	—	(57)
	—	—
Total	\$133	\$(57)

**Table of Contents*****Legal Settlement***

In April 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004, the Company settled the claim and recorded a charge of \$2,256 in the fourth quarter of 2003 for the settlement and related legal costs. The expense recorded in the first quarter of 2004 is primarily composed of additional legal expenses related to the settlement.

***Restructuring Costs***

All restructuring activities and related expenses were completed in the second quarter of 2003. From the inception of our plan to consolidate all of our ventricular assist device, or VAD, manufacturing operations, which we call the Restructuring Plan, through the completion date in April 2003, we recorded \$1,495 of restructuring charges. These charges represented employee severance costs and stock option acceleration charges. Total severance payments under the Restructuring Plan were \$1,297 paid to 78 employees. Following is a summary of our accrued restructuring costs activity:

	<b>Three Months Ended March 29, 2003</b>
Accrued Restructuring Costs:	
Beginning balance	\$ 679
Reduction of severance accrual	(61)
Payments of employee severance	(521)
	<hr/>
Ending balance	\$ 97
	<hr/>

**10. Income Taxes**

Our effective tax rate was 39% for both the three-month periods ending April 3, 2004 and March 29, 2003. The effective income tax expense rate for both quarters differed from the statutory federal income tax rate primarily due to the impact of state taxes.

At April 3, 2004 and January 3, 2004, we reported a net deferred tax liability of approximately \$51,263 and \$51,332, respectively, comprised principally of temporary differences between the financial statement and income tax bases of intangible assets.

**11. Net Income Per Share**

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

	<b>Three Months Ended</b>	
	<b>April 3, 2004</b>	<b>March 29, 2003</b>
Net income	\$ 1,294	\$ 1,418
Weighted average number of common shares-basic	56,106	55,057
Dilutive effect of stock options	1,352	477
Weighted average number of common shares-diluted	57,458	55,534
Net income per common share-basic and diluted	\$ 0.02	\$ 0.03

Basic income per share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted income per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Of the options to purchase shares of common stock outstanding as of April 3, 2004 and March 29, 2003, 3,675 and 5,531 shares of common stock, respectively, were not included in the computation of the diluted income per share as their inclusion would be antidilutive.

**Table of Contents****12. Business Segment and Geographical Data**

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

Business Segments:

	<b>Three Months Ended</b>	
	<b>April 3, 2004</b>	<b>March 29, 2003</b>
Product sales:		
Cardiovascular	\$26,553	\$23,908
ITC	16,239	12,154
	<hr/>	<hr/>
Total product sales	\$42,792	\$36,062
	<hr/>	<hr/>
Income before income taxes:		
Cardiovascular	\$ 4,028	\$ 3,788
ITC	2,332	2,349
Corporate (a)	(1,640)	(1,286)
Amortization of purchased intangibles (b)	(2,931)	(3,096)
Legal settlement and restructuring costs (b)	(133)	57
	<hr/>	<hr/>
Total operating income	1,656	1,812
Interest and other income, net	465	512
	<hr/>	<hr/>
Income before income taxes	\$ 2,121	\$ 2,324
	<hr/>	<hr/>

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

(b) Related to the Cardiovascular segment.

Geographic Areas:

	<b>Three Months Ended</b>	
	<b>April 3,</b>	<b>March 29,</b>

Edgar Filing: THORATEC CORP - Form 10-Q/A

	<u>2004</u>	<u>2003</u>
Product sales:		
Domestic	\$33,781	\$30,028
International	9,011	6,034
	<u>          </u>	<u>          </u>
Total	\$42,792	\$36,062
	<u>          </u>	<u>          </u>

**Table of Contents****ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****Forward-Looking Statements**

*With the exception of historical facts, the statements contained in this Form 10-Q/A are forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements generally can be identified by use of statements that include phrases such as believe, expect, anticipate, intend, plan, foresee, may, hope, will, estimates, potential, or other similar words or phrases. Similarly, statements that describe our objectives, plans or goals also are forward-looking statements. All of these forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statement. The principal risk factors that could cause actual performance and future actions to differ materially from the forward-looking statements include, but are not limited to, the ability to achieve and maintain profitability; the ability of third party payors to cover and provide appropriate levels of reimbursement for our products; the ability to receive Food and Drug Administration, or FDA, and foreign regulatory authorities approval to manufacture, market and sell our products; the ability to direct and manage current and future growth, including the growth of the number of Destination Therapy, or DT, procedures performed and the integration of any current and future acquisitions of companies or technologies; new product development and introduction, including FDA approval and market receptiveness; the ability to realize the full value of our intangible assets; the reliance on specialized suppliers; competition from other products; the ability to manufacture products on an efficient and timely basis and at a reasonable cost and in sufficient volume, including the ability to obtain timely deliveries of parts from suppliers; the dependence upon distributors and any changes made to our method of distribution; the ability to protect our proprietary technologies or an infringement of others' patents; product liability or other claims; our ability to identify and correct quality issues in a timely manner and at a reasonable cost; the ability to maintain compliance with changing federal and state regulations; the long and variable sales and deployment cycle of our ventricular assist device ( VAD ) products; worldwide demand for circulatory support and graft products and blood coagulation testing and skin incision devices and the management of risks inherent in selling in foreign countries; claims relating to the handling, storage or disposal of hazardous chemicals and biomaterials; stock price volatility due to general economic conditions or future issuances and sales of our stock; the occurrence of natural catastrophic disasters; foreign currency fluctuations; the ability to attract and retain talented employees; and other factors identified in our Annual Report on Form 10-K for 2003 which we filed with the Securities and Exchange Commission, or the SEC. Readers are urged to consider these factors carefully in evaluating the forward-looking statements. The forward-looking statements included in this Form 10-Q/A are made only as of the date of this report and we undertake no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances.*

*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/A, and our Annual Report on Form 10-K for 2003 filed with the SEC.*

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

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

**Our Business Model**

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

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

**Ventricular Assist Devices**

The VAD is a mechanical device to assist a failing heart pump blood, both as a temporary measure until a failing heart recovers or is replaced in a heart transplant (Bridge to Transplant BTT), and as a permanent implant to supplement the efforts of the heart to pump blood (Destination Therapy DT). We derive the majority of our VAD revenue from two different VAD products as follows:

The HeartMate VAD was acquired in our 2001 merger with Thermo Cardiosystems, Inc. a subsidiary of Thermo Electron Corporation. This VAD is made of titanium, contains an electrically powered pump, provides a safe interface with blood through a sintering process applied to the titanium, and has an average selling price that is typically approximately \$65 thousand per unit. The HeartMate VAD is only approved to assist the left ventricle, and is implanted inside the body cavity. It is currently approved for use in BTT and DT.

The Thoratec VAD is made of polymers, is powered pneumatically, provides a safe interface with blood through our proprietary Thoralon coating, and has an average selling price that is approximately \$35 thousand per unit. The Thoratec VAD is approved to assist the left and the right ventricle, and is worn outside the body cavity. It is currently approved for use in BTT.

VAD revenue historically has been split approximately equally between the HeartMate and the Thoratec VAD, while unit sales volume has historically been weighted around 2:1 in favor of the Thoratec VAD. As DT becomes a more significant element of our business, we expect unit shipments and revenue for the HeartMate VAD to grow to exceed that of the Thoratec VAD.

We estimate we have in excess of 90% of the VAD market domestically and more than 50% internationally. Domestic revenue growth will come from expanding the market through new indications for our current products, in particular the recent approval of Destination Therapy, and from the development and approval of new, generally

smaller and longer lasting products, that can be used in a broader range of patients. Internationally we expect growth to come by taking market share from our competitors and from expanding the market.



## Table of Contents

We believe that potential competitors are at least 3 years away from completion of DT clinical trials required before their products will become commercially available and compete with our products in the United States. In addition, unless our competitor's products result in significantly better outcomes than our products, we believe that absent any compelling reasons, cardiac centers will not generally change suppliers.

The use of our VADs for Destination Therapy in patients who are not candidates for heart transplantation was approved by the FDA in 2002, and was approved for reimbursement by CMS in late 2003. We estimate that there are approximately 100,000 people who could be candidates for Destination Therapy, of which we believe between 5,000 and 15,000 are treatable using current technologies. Our future revenue growth is dependent in large part on the successful adoption and sale of our products for Destination Therapy.

### Point-Of-Care Diagnostic Test Systems Business

Through our ITC subsidiary, we design, develop, manufacture and market point-of-care diagnostic test systems that provide fast, accurate blood test results, to monitor a patient's coagulation while they are being administered anticoagulants, and to monitor a patient's blood gas/electrolyte and chemistry status. These products are sold into Hospitals, Physician's offices, long-term care facilities, clinics, visiting nurse associations, and home healthcare companies.

Large medical device companies dominate these markets and we estimate our products hold anywhere from 2% to 20% market share. Growth in this market will come from taking market share away from other companies, and from the shifting of diagnostic testing from the central laboratory 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 requires.

New competitors that might enter the market with broader test menus. To address this risk, in late 2003 we acquired the IRMA (Immediate Response Mobile Analysis) product line of blood gas/electrolyte and chemistry tests, which has significantly increased our test menu offering, and also offers us the opportunity to develop the next generation system that combines coagulation, blood gas and electrolyte testing in one machine.

Overall, we are planning for sales of our point-of-care diagnostic test systems to grow at an annual growth rate of up to 10% for the next several years. This growth assumes increased patient testing, better patient outcomes, and increased decentralization of testing from central laboratories to point-of-care. We expect our international sales to increase from 26% currently and could range up to 30% of ITC's total annual sales by 2007.

### Vascular Graft Products

The *Vectra* vascular access graft was approved for sale in the United States in December 2000 and in Europe in January 1998. It 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. Other currently available vascular access grafts are commonly made out of ePTFE, which can lose integrity after repeated punctures and require a three to six week healing period between implantation and the initiation of dialysis treatment. We believe that the *Vectra* may provide significant advantages over existing synthetic vascular access grafts that may encourage its use by surgeons who are currently using natural vessels for vascular access. We currently sell *Vectra* through the Bard Peripheral Vascular division of C.R. Bard Corporation in the United States, Europe and selected countries in Scandinavia, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan.



## **Table of Contents**

### **Acquisition**

On September 30, 2003, we completed an asset purchase of the Immediate Response Mobile Analysis, or IRMA, point-of-care blood analysis system product line from Diagnostics Medical, Inc. ( Diagnostics ). We paid approximately \$5.2 million in cash and assumed trade payables. The purchase price was allocated based on the fair value of assets acquired as determined by an independent valuation firm.

There was no goodwill recorded with the transaction. As a result of the acquisition, \$220 relating to in-process research and development was expensed in the fourth quarter of 2003.

### **Restructuring Plan**

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

### **Recent Events**

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

On February 11, 2004 we announced that the board of directors authorized a stock repurchase program under which Thoratec common stock with a market value of up to \$25 million may be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of such activity is dependent on several conditions, including the price of Thoratec stock, general market conditions and other factors. As of the end of our fiscal first quarter, we had approximately 56 million shares outstanding. The purchases are funded from available cash and cash equivalents. Purchases may continue until the authorized limit is reached or the Company discontinues the program.

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

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

	<b>Three Months Ended</b>	
	<b>April 3, 2004</b>	<b>March 29, 2003</b>
Sales	100%	100%
Cost of sales	41	41
	<hr/>	<hr/>
Gross profit	59	59
	<hr/>	<hr/>
Operating expenses:		
Selling, general & administrative	31	28
Research & development	17	17
Amortization of purchased intangible assets	7	9
Legal settlement, merger, restructuring and other costs	—	—
	<hr/>	<hr/>
Total operating expenses	55	54
Income from operations	4	5
Interest and other income net	1	1
	<hr/>	<hr/>
Income before income taxes	5	6
Income tax expense	2	2
	<hr/>	<hr/>
Net income	3%	4%
	<hr/>	<hr/>

**Three months ended April 3, 2004 and March 29, 2003*****Product Sales***

Product sales in the first quarter of 2004 were \$42.8 million compared to \$36.1 million in the first quarter of 2003. The primary components of the \$6.7 million increase in revenues were as follows:

Higher VAD sales (\$2.2 million). This increase resulted from higher sales of the HeartMate VAD.

Higher revenue from sales of point-of-care diagnostic test systems at our ITC subsidiary (\$2.4 million).

Revenue from IRMA product line acquired by ITC in the fourth quarter of 2003 (\$1.7 million).

We are currently planning 2004 revenue in the range of \$190-200 million. This is highly dependent upon the success of our Destination Therapy activities in generating significant revenues. We anticipate the majority of these revenues in the second half of 2004.

***Gross Profit***

Gross profit as a percentage of sales in the first quarter of 2004 was 58.6% compared to 58.7% in 2003. Within these essentially flat margins were the following fluctuations:

A decrease in margins, driven by a shift in the mix of revenue from higher margin domestic pumps to lower margin product lines and geographies, including the lower margin IRMA product line, which we acquired in the fourth quarter of 2003, offset by

Lower manufacturing costs, and higher absorption of costs not variable with manufacturing activities.

As we recognize higher revenues for our current Destination Therapy initiatives, we anticipate that margins will trend upwards into the mid 60% range as the higher margin VAD products represent a larger portion of our overall revenues.

## **Table of Contents**

### ***Selling, General and Administrative***

Selling, general and administrative ( SG&A ) expenses in the first quarter of 2004 were \$13.0 million, or 31% of product sales, compared to \$10.1 million, or 28% of product sales, in the first quarter of 2003. Underlying the \$2.9 million increase in spending were the following drivers:

Increased SG&A headcount from 138 at the end of the first quarter of 2003 to 191 at the end of the first quarter of 2004, together with annual salary increases aggregating 4.5% effective January 2004.

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

Higher professional fees.

Higher facilities costs related to higher headcount.

We anticipate that selling, general and administrative costs will generally increase each year as our business grows, with some quarterly and annual spending around events such as product introductions. Spending as a percentage of revenue is expected to trend downward as revenues from current products increase, in particular as we realize revenue associated with Destination Therapy.

### ***Research and Development***

Research and development expenses in the first quarter of 2004 were \$7.3 million compared to \$6.3 million in the first quarter of 2003, both representing 17% of product sales. 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. Projects typically include efforts to develop new products such as the HeartMate II and HeartMate III, efforts to improve the operation and performance of current products such as efforts to improve the life of various components of the HeartMate and the Thoratec VAD products. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations. We anticipate that Research and Development costs will generally increase modestly each year as our business grows, with some quarterly and annual spikes in spending around events such as product introductions and regulatory approvals, and with spending as a percentage of revenue trending downward as revenues from current products increase, in particular as we realize revenue associated with Destination Therapy.

### ***Amortization of Purchased Intangible Assets***

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

### ***Income Taxes***

Our effective tax rate was 39% in both the first quarter of 2004 and the first quarter of 2003. The effective income tax expense rate for both quarters differed from the statutory federal income tax rate primarily due to the impact of state taxes.

### ***Liquidity and Capital Resources***

At April 3, 2004, we had working capital of \$154.5 million compared with \$116.4 million at January 3, 2004, Cash and cash equivalents and short-term available-for-sale investments at April 3, 2004 were \$93.9 million compared to \$62 million at January 3, 2004, an increase of \$31.9 million resulting primarily from our classification of investments as short-term at April 3, 2004, as compared to long-term at January 3, 2004 to reflect managements' intent that these investments be considered available for current operations.

**Table of Contents**

Cash used in operating activities was \$0.4 million which was after payments for legal settlement and annual bonuses, accrued at January 3, 2004, totaling \$5.2 million. In addition, we paid \$2.2 million to acquire property, plant and equipment, mainly equipment of \$1.7 million and leasehold improvements of \$0.5 million. Cash used in financing activities was \$6.0 million, as we paid \$6.7 million during the first quarter of 2004 to repurchase 510,000 shares of stock under our stock repurchase program. This was partially offset by \$0.7 million of proceeds received from stock option exercises during the quarter.

We believe that cash and cash equivalents and short-term available-for-sale investments on hand and expected cash flows from operations, will be sufficient to fund our operations, capital requirements and stock repurchase program for the foreseeable future.

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

**Critical Accounting Policies**

We have identified certain accounting policies as critical to our business operations and the understanding of our results of operations. The impact and associated risks related to those policies on our business operations is discussed in our fiscal 2003 consolidated financial statements filed with the SEC in our annual report on Form 10-K.

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

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



**Table of Contents**

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

**Interest Rate Risk**

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

**Foreign Currency Rate Fluctuations**

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

We use forward foreign currency contracts to hedge the gains and losses generated by the revaluation of these non-functional currency assets and liabilities. These derivatives are not designated as cash flow or fair value hedges under SFAS No. 133. As a result, changes in the fair value of the forward foreign currency contracts are included as incurred in Interest and Other Income Net. The change in the fair value of the forward foreign currency contracts typically offsets the change value from revaluation of the non-functional currency assets and liabilities. These contracts typically have maturities of three months or less. At April 3, 2004, the Company had forward foreign currency contracts in Pounds Sterling and Euros with a nominal value of \$10.3 million with a fair value of approximately \$0.1 million. There were no such contracts outstanding at March 29, 2003. The impact of the foreign currency revaluation, net of forward foreign currency contracts, was negligible for the periods ending April 3, 2004 and March 29, 2003.

**Table of Contents**

**ITEM 4. CONTROLS AND PROCEDURES**

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of April 3, 2004. Based on that evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, concluded that as of April 3, 2004 the Company's disclosure controls and procedures were effective in providing reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. There have been no changes in our internal controls during the fiscal quarter ended April 3, 2004 that have materially affected or are reasonably likely to materially affect the Company's internal control over financial reporting.

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

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

**Table of Contents****PART II. OTHER INFORMATION****ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES**

	<b>Total Number Of Shares Purchased</b>	<b>Average Price Paid Per Share</b>	<b>Total Number of Shares Purchased as Part Of Publicly Announced Program</b>	<b>Maximum Dollar Value Of Shares That May Yet Be Purchased Under The Program  (in millions)</b>
January 4, 2004 to January 31, 2004		\$		\$ 25.0
February 1, 2004 to February 28, 2004	185,000	\$13.59	185,000	\$ 25.0
February 29, 2004 to April 3, 2004	<u>325,000(2)</u>	\$12.97	<u>325,000</u>	\$ 18.3
Total	<u>510,000</u>	\$13.20	<u>510,000</u>	

(1) Our stock repurchase program, which authorizes the Company to repurchase up to \$25.0 million of shares, was announced on February 11, 2004. This program does not have an expiration date.

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

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

(a) Exhibits:

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

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

(b) Reports on Form 8-K:

On February 11, 2004, the Company filed a Current Report on Form 8-K, reporting under items 5 and 7, announcing a program to repurchase up to \$25 million in shares of its common stock.

On February 3, 2004, the Company filed a Current Report on Form 8-K, reporting under items 9 and 12, announcing the Company's results for the first fiscal quarter and fiscal year ended January 3, 2004.



**Table of Contents**

**SIGNATURES**

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

THORATEC CORPORATION

Date: August 16, 2004

/s/ D. Keith Grossman

---

D. Keith Grossman,  
Chief Executive Officer

Date: August 16, 2004

/s/ M. Wayne Boylston

---

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