

THORATEC CORP
Form 10-Q
May 13, 2004

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U.S. SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended 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.

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

	April 3, 2004	January 3, 2004
	<u> </u>	<u> </u>
Assets		
Current Assets:		
Cash and cash equivalents	\$ 48,022	\$ 62,020
Short-term available-for-sale investments	45,828	41,179
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	180,381
	<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 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
	<u> </u>	<u> </u>
Long-term deferred tax liability and other assets	65,600	67,123
	<u> </u>	<u> </u>
Total Liabilities	83,775	89,895

	_____	_____
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
	_____	_____
Total accumulated other comprehensive income	455	415
	_____	_____
Total Shareholders' Equity	381,912	386,236
	_____	_____
Total Liabilities and Shareholders' Equity	\$465,687	\$476,131
	_____	_____

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)

	Three Months Ended	
	April 3, 2004	March 29, 2003
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:

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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)

	Three Months Ended	
	April 3, 2004	March 29, 2003
Cash flows from operating activities:		
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/>
Cash flows from investing activities:		
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/>
Cash flows from financing activities:		
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

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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>
Supplemental Cash Flow Disclosure:		
Cash paid for taxes	\$ 48	\$ 260
Cash paid for interest	\$	\$
Supplemental Disclosure of Non-cash Investing and Financing Activities:		
Tax benefit related to stock option exercises	\$ 130	\$ 107

See notes to condensed consolidated financial statements.

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

	Three Months Ended	
	April 3, 2004	March 29, 2003
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.

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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 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, including a reclassification of \$41.2 million from long-term available-for-sale investments to short-term available-for-sale investments to reflect management's intent that these investments be considered available for current operations.

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):

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	Three Months Ended	
	April 3, 2004	March 29, 2003
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 2003. 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 because such marketable securities represent the investment of cash that is available for current operations. 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:

	As of	
	April 3, 2004	January 3, 2004
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:

	As of	
	April 3, 2004	January 3, 2004
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:

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

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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:

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As of April 3, 2004			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
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
Total Purchased Intangible Assets	\$198,172	\$(36,238)	\$ 161,934

As of January 3, 2004			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
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
Total Purchased Intangible Assets	\$198,172	\$(33,307)	\$ 164,865

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 Diametrics Medical, Inc. (Diametrics). We paid approximately \$5.2 million in cash and assumed trade payables. Approximately \$1.8 million of the total purchase price was allocated to purchased intangible assets.

Amortization expense related to identifiable intangible assets 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.

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:

	Three Months Ended March 29, 2003
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:

	Three Months Ended	
	April 3, 2004	March 29, 2003
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:

	Three Months Ended	
	April 3, 2004	March 29, 2003
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:

	Three Months Ended	
	April 3,	March 29,

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	<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>

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With the exception of historical facts, the statements contained in this Form 10-Q are forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements generally can be identified by use of statements that include phrases such as believe, expect, anticipate, intend, plan, foresee, may, hope, will, estimates, potential, continue, or phrases. Similarly, statements that describe our objectives, plans or goals also are forward-looking statements. All of these forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statement. 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 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, 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.

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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.

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