

THORATEC CORP  
Form 10-K405  
March 15, 2002

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**

**Form 10-K**

(Mark one)

**ANNUAL REPORT UNDER SECTION 13 OR 15(d)**  
**OF THE SECURITIES EXCHANGE ACT OF 1934**  
**For the fiscal year ended December 29, 2001**

**TRANSITION REPORT UNDER 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)*

**6035 Stoneridge Drive, Pleasanton, California**

*(Address of Principal Executive Offices)*

**94-2340464**

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

**94588**

*(Zip Code)*

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

**Securities registered pursuant to Section 12(b) of the Exchange Act: None**

**Securities registered pursuant to Section 12(g) of the Exchange Act: Common Stock**

Indicate by a 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 a check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.   

The aggregate market value of the voting stock held by non-affiliates was \$572,000,000 computed by reference to the last sale reported of such stock on March 8, 2002 as listed on The Nasdaq National Stock Market.(1)

As of March 8, 2002, registrant had 57,229,146 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Designated portion of Thoratec's definitive proxy statement for its 2002 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

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- (1) Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to cause the direction of the management or policies of the issuer, or that such person is controlled by or under common control with the issuer.

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**FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K, including the documents incorporated by reference in this Annual Report, includes forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. Our actual results could differ materially from those discussed in, or implied by, these forward-looking statements. Forward-looking statements are identified by words such as believe, anticipate, expect, intend, plan, will, may and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Forward-looking statements include, but are not necessarily limited to, those relating to:

our ability to obtain and maintain regulatory approval of our products in the United States and internationally;

results and timing of our clinical trials, including the results of the REMATCH trial and publication of those results;

the other competing therapies that may, in the future, be available to heart failure patients;

our plans to develop and market new products;

our ability to improve our financial performance; and

effects of the merger and integration with Thermo Cardiosystems Inc., which we refer to as Thermo Cardiosystems or TCA.

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 Risk Factors section and in other documents we file with the Securities and Exchange Commission, including the prospectus, as amended and supplemented, contained in the Registration Statement on Form S-3 that we filed on February 12, 2002. We are not obligated to update or revise these forward-looking statements to reflect new events or circumstances.

You should assume that the information appearing in this Annual Report on Form 10-K is accurate only as of the date on the front cover. Our business, financial condition, results of operations and prospects may have changed since that date.

Thoratec, the Thoratec logo, Thoralon, TLC-II, HeartMate, HeartPak and *Vectra* are registered trademarks, and Aria is a trademark of Thoratec Corporation.

HEMOCHRON, ProTime, Surgicutt, Tenderlett and Tenderfoot are registered trademarks of International Technidyne Corporation, or ITC, our wholly-owned subsidiary.

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SIGNATURES

Addition to a Lease Dated the 16th of August, 1995

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Subsidiaries of Thoratec

Consent of Deloitte & Touche LLP

Consent of Arthur Andersen LLP

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**PART I**

**Item 1. Business**

**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, 4.7 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, or VAD, to treat patients with late-stage heart failure, which comprises approximately 5% 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.

We develop and market products that are used by physicians and hospitals for cardiac assist, vascular and diagnostic applications. Our three types of products are:

*Circulatory support products.* Our circulatory support products include ventricular assist devices for the short-term and long-term treatment of congestive heart failure. Our products address more indications than the products of any other cardiac assist device company.

*Vascular graft products.* We have developed small diameter grafts to address the vascular access and coronary bypass surgery markets. These grafts use our proprietary materials that are designed to improve performance. Our grafts are sold in the United States and internationally for use in hemodialysis patients and are currently in clinical trials for coronary artery bypass applications.

*Blood coagulation testing and skin incision devices.* We have a leading market position for devices that monitor blood coagulation and perform blood-screening analysis for patients undergoing various surgical procedures. We also offer a family of single-use skin incision devices used to create a blood sample.

Our ventricular assist devices are regarded as the most versatile and widely used circulatory support systems for patients with late-stage CHF. We currently market devices that may be implanted or worn outside the body and that are suitable for treatments of different durations for patients of varying sizes and ages. We estimate that our VADs have treated nearly 5,000 patients. Our devices are currently used primarily for patients awaiting a heart transplant or recovering from open heart surgery. However, we are pursuing approval to use our VADs in other indications, including as an alternative to maximum drug therapy, which we call destination therapy, for CHF patients who are not eligible for a heart transplant and for therapeutic recovery to partially reverse the complications of late-stage heart failure in certain patients. We estimate the combined market size for these indications could be over 200,000 patients annually in the United States alone. We have submitted Pre-Market Approval, or PMA, Supplements for both these indications and expect to receive FDA approvals for each by the end of 2002.

On February 14, 2001, we completed our merger with Thermo Cardiosystems, or TCA, a Massachusetts-based manufacturer of cardiac assist, blood coagulation testing and skin incision devices, which we refer to as the Merger. As a result of the Merger, we substantially increased the size of our company and became a leading provider of circulatory support products worldwide. We now sell VADs to virtually every leading heart transplant center worldwide and we market three out of the four VADs approved by the FDA as a bridge to heart transplant. At the time of the Merger, we changed our name from Thoratec Laboratories Corporation to Thoratec Corporation. Immediately after the Merger, the parent company of TCA, Thermo Electron Corporation, or Thermo Electron, owned approximately 35% of our outstanding stock. As of the date of this report, Thermo Electron owns approximately 14% of our total outstanding common stock.

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### **The REMATCH Trial**

On November 12, 2001, the results of a clinical trial called REMATCH, or Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure, were presented at the American Heart Association Scientific Sessions and the results were published in a website edition of The New England Journal of Medicine. The REMATCH trial, which cost approximately \$25 million according to one of the trial sponsors, was a collaboration among the National Institutes of Health, or NIH, as lead sponsor, Columbia University and our company. We were a partial sponsor of the REMATCH trial, providing approximately \$3.6 million of financial support and all necessary VADs and related equipment.

The REMATCH trial results, as published in the New England Journal of Medicine, involved 129 late-stage CHF patients who, because of their ages or other diseases, were not eligible to receive one of the very limited supply of donor organs for heart transplantation. The study was independently coordinated by Columbia University at 21 prestigious transplant centers in the United States. Patient enrollment for the initial study protocol began in 1998 and concluded in June 2001. The overall purpose of the study was to evaluate the efficacy, safety and cost effectiveness of our HeartMate ventricular assist device versus optimal medical management, which we call maximum drug therapy. The REMATCH publication provided a detailed evaluation of survivability, device safety and impact on patient quality of life.

Results from the REMATCH trial showed a significant survival benefit and improved quality of life for patients using the HeartMate compared to maximum drug therapy. The study showed the overall probability of one-year survival for those on the HeartMate was 52% versus 25% for patients treated with maximum drug therapy. The one year survival rates for patients younger than 60 years old was 74% for those patients on the HeartMate and 33% for those treated with maximum drug therapy. The one year survival rates for patients 60 to 69 years old was 47% for those patients on the HeartMate and 15% for those treated with maximum drug therapy. Two-year survival rates are estimated to be 23% for patients on the HeartMate and 8% for those treated with maximum drug therapy. The median length of survival was approximately 408 days for those on the HeartMate and 150 days for those treated with maximum drug therapy. The frequency of serious adverse events for patients in the HeartMate group was 2.35 times greater than for patients in the maximum drug therapy group, with a predominance of infection, bleeding and malfunction of the device. Some of these adverse events experienced by patients on the HeartMate included an ischemic stroke in approximately 10% of the patients, half of which were major.

The overall quality of life, as measured by the patient's emotional state, whether or not they were depressed, and their mobility, was significantly higher at one year for patients on the HeartMate than for those treated with maximum drug therapy. For example, as measured by the Medical Outcomes Study Short-Form General Health Survey, on a variable score from 0-100, the physical function mean score of patients on the HeartMate was approximately 45 compared to approximately 20 for patients on maximum drug therapy. This survey also showed that the emotional state mean score of patients on the HeartMate was approximately 65 compared to 18 for patients on maximum drug therapy. At the time the results of the REMATCH trial were published there were 27 HeartMate patients still alive, versus 7 patients receiving maximum drug therapy.

Based on a review of these data, the FDA approved an Investigational Device Exception, or IDE, Supplement allowing up to 30 additional non-randomized patients to be implanted with the HeartMate for destination therapy. This IDE Supplement also permits patients who were being treated with maximum drug therapy in the original study to be implanted with the HeartMate.

On October 16, 2001, we submitted a PMA Supplement for the HeartMate for destination therapy for patients suffering from late-stage CHF. On November 29, 2001 we received notification from the FDA that it expedited the review of our PMA Supplement. On March 4, 2002, the FDA Circulatory System Devices Advisory Panel, or the Panel, met to review our PMA Supplement. Based on results of the REMATCH trial, the Panel recommended that the FDA approve our PMA Supplement, with conditions, to provide long-term support for end-stage heart failure patients who are not eligible for heart transplantation. We and our REMATCH collaborators will be working to address the conditions outlined by the Panel. We have already



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initiated discussions with the Centers for Medicare and Medicaid Services, formerly HCFA, regarding reimbursement coverage for use of the HeartMate in this treatment.

We believe that this new application for our HeartMate device represents a market opportunity of up to 100,000 additional patients annually in the United States alone, which would represent a significant increase over our existing customer base. For these patients, maximum drug therapy is currently the only treatment available and, even with drug therapy, the 12-month mortality rate for these patients is 75%. We believe that the HeartMate will provide a significant survival benefit for this patient population.

### **Other Recent Developments**

On January 23, 2002, we announced a plan to redeem all of our outstanding 4.75% convertible subordinated debentures originally issued by Thermo Cardiosystems. We completed the redemption on March 11, 2002 using our restricted cash and cash equivalents of \$45.9 million and cash of \$9.8 million. We will record an extraordinary loss in the first quarter of 2002 related to the write-off of capitalized debt issuance costs associated with the initial issuance of the debentures, which were being amortized over the life of the debentures. As of December 29, 2001, the remaining balance of capitalized debt issuance costs was \$0.5 million.

Pursuant to the terms of a registration rights agreement between us and Thermo Electron dated October 3, 2000, we filed a Registration Statement on Form S-3 with the SEC to register 1,055,000 newly issued shares of our common stock and to register for resale 5,945,000 shares of our common stock held by selling shareholders, of which 5,825,000 shares were held by Thermo Electron. This Registration Statement became effective on February 12, 2002 and all of the shares were sold on February 15, 2002. We received \$16.1 million, net of underwriting fees and discounts, but before other expenses of the offering, from the sale of the 1,055,000 newly issued shares. In addition, the underwriters exercised a 30-day option to purchase from Thermo Electron 1,050,000 additional shares of our common stock to cover any over-allotments. We received no proceeds from the sale of shares by selling shareholders or from the sale of the over-allotment shares. As of the date of this report, Thermo Electron currently owns approximately 14% of our total outstanding shares.

### **Our Strategy**

We are a leading developer and manufacturer of medical devices for the CHF, cardiac surgery and vascular graft markets. Our key strategies to maintain and expand this leadership position are to:

*Obtain Approval for New Indications for our Products.* We believe that there are currently 4.7 million patients in the United States with CHF and that some of these patients who are currently not using ventricular assist devices can benefit from our products. We are in the process of obtaining FDA approvals to market our products for a number of new indications, including the following:

*Destination therapy.* We have filed a PMA Supplement with the FDA to obtain approval to market the HeartMate for destination therapy for treating late-stage CHF patients who are not candidates for heart transplants. We anticipate that we could receive FDA approval in 2002 and can be marketing for this indicated use shortly thereafter.

*Therapeutic recovery.* We believe that the use of our Thoratec VAD system may lead to recovery of the natural heart in certain patients. We have submitted a PMA Supplement for this indication and hope to receive approval in 2002. Although it is difficult to estimate the size of this market, we believe that the patient population that could benefit from this use could be substantial.

*Increase Penetration of Existing Markets.* We plan to treat a greater number and variety of patients within our current customer base. To accomplish this, we are leveraging our existing relationships with leading cardiac surgeons and hospitals and utilizing our existing sales channels to gain acceptance and adoption of our products.

*Leverage Benefits of our Merger with TCA.* We believe that our Merger resulted in substantial and significant strategic benefits including our ability to combine sales forces and share research and development and manufacturing resources. For example, we are in the process of consolidating our VAD manufacturing facilities into our Pleasanton facility, which we expect will result in significant cost savings. In addition,

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integrating our sales force with TCA's sales force has created cross-selling opportunities to further penetrate our markets. Prior to the Merger, each company had different sales forces selling our respective products to different hospitals and surgeons. By combining our distribution channels, we are now able to offer the combined Company's products to a greater number of hospitals, surgeons and patients.

*Offer a Broad Range of Product Solutions.* We believe that our broad and diverse product offering is an important competitive advantage because it allows us to address the various preferences of surgeons and the clinical needs of a wide variety of patients, as well as the economic needs and concerns of third party payors. An important part of our growth strategy is to further broaden our product line to meet customer needs by developing new products internally or acquiring or licensing new products. We intend to further develop a number of new or improved products including next generation versions of both our HeartMate and Thoratec VAD.

*Focus On and Partner with Leading Heart Centers.* We have developed extremely strong, long-standing relationships with leading cardiovascular surgeons and heart centers worldwide. We believe that no other cardiac assist company enjoys the same depth of relationship and access to these customers. Maintaining and expanding these relationships is an important part of our growth strategy, particularly for the development and introduction of new products and the pursuit of additional indications for our existing products.

*Grow Internationally.* In 2001, 20% of our revenue was derived from sources outside of the United States. We estimate that the international market opportunity for our products is at least as large as the market opportunity in the United States. Our recent Merger greatly expanded our international presence, particularly in Japan and Latin America. We plan to continue to grow internationally by leveraging our combined distribution channels and by developing marketing strategies on a country-by-country basis.

## **Our Markets**

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. In addition, other conditions, such as high blood pressure or diabetes, can also lead to CHF.

According to the American Heart Association, or the AHA, there are 4.7 million CHF patients in the United States and approximately 550,000 new cases are diagnosed each year. The AHA also estimates that approximately 50% of CHF patients die within five years of diagnosis. We believe that the number of patients suffering from CHF who could benefit from some form of cardiac assist could be over 200,000 annually. While the number of treatment options for CHF has increased in recent years, the use of medication remains the most widely used approach for treatment of the disease. These drug therapies include ACE inhibitors, anti-coagulants and beta-blockers, which facilitate blood flow, thin the blood or help the heart work in a more efficient manner. Other procedures used to treat CHF include angioplasty, biventricular pacing, valve replacement, bypass and left ventricular reduction surgery.

Despite attempts to manage CHF through drug therapy, there is currently only one curative treatment for the disease—a heart transplant. Unfortunately, the number of hearts available for transplant each year can meet the needs of only a small number of the patients who need a heart transplant. The United Network for Organ Sharing reported that there were only 2,340 hearts available for transplant in the United States in 1999. At any given time, there are approximately 4,000 to 5,000 patients on the U.S. national transplant waiting list and we believe a comparable number of patients are waiting in Europe. The median wait for a donor heart by patients on a heart transplant waiting list is approximately nine months, and many patients have to wait as long as one to two years before receiving one of the few donor hearts available. In 1999, approximately 17% of such patients died while waiting for a donor heart.

In the United States, there is currently one FDA-approved indication for ventricular assist devices for patients with CHF—as a bridge to heart transplant. We are pursuing two additional indications for our VAD products—for destination therapy and for therapeutic recovery of the heart. If approved, these additional

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indications will represent larger market opportunities than the current indication. Beyond the CHF markets, ventricular assist devices are also approved for use during recovery following coronary artery bypass graft, or CABG, surgery. All four indications are summarized below.

### ***Bridge to Transplant***

Ventricular assist devices provide additional cardiac support for patients who are in late-stage heart failure waiting for a donor heart. Of the approximately 4,000 to 5,000 patients on the waiting list for a heart transplant in the United States, we estimate that approximately 25% will receive a ventricular assist device.

We believe that the percentage of patients bridged to transplant continues to increase with surgeons' level of comfort with the technology, particularly for longer-term support cases. There are currently four devices approved in the United States as a bridge to transplant, three of which are manufactured by us. We estimate that the bridge to transplant indication represents a worldwide market opportunity of up to 8,000 patients annually.

### ***Destination Therapy***

We are pursuing approval to use our VAD for destination therapy for patients with late-stage CHF who are not candidates for heart transplantation due to other degenerative illnesses or advanced age. We believe that the success in transitioning this market from maximum drug therapy to ventricular assist devices is dependent on the development of VADs, like our HeartMate, with substantial longevities and proof of clinical efficacy.

The results of the REMATCH trial were presented at the American Heart Association Scientific Sessions on November 12, 2001 and were published in a website edition of The New England Journal of Medicine. We submitted a PMA Supplement for the HeartMate for destination therapy for patients suffering from late-stage CHF. These CHF patients are not candidates for heart transplants due to their age or medical condition. On November 29, 2001 we received notification from the FDA that it expedited the review of our PMA Supplement. On March 4, 2002, the FDA Circulatory System Devices Advisory Panel recommended that the FDA approve our PMA Supplement, with conditions, to provide long-term support for end-stage heart failure patients who are not eligible for transplantation. The FDA typically follows the Panel's recommendations, although it is not legally obligated to do so. If approved by the FDA, the HeartMate will become the first ventricular assist device approved for destination therapy for patients suffering from late-stage CHF. We estimate the size of this market opportunity at up to an additional 100,000 patients annually in the United States.

### ***Therapeutic Recovery***

We believe that, for most patients, recovery of their own heart is a better alternative than either heart transplantation or permanent implantation of a blood pumping device. Based on recently reported cases of recovery in heart failure patients, we believe that our Thoratec VAD system is a potential therapy that can reverse the complications of late-stage heart failure in certain patients.

While this therapeutic recovery indication is not yet approved for our devices, we are actively investigating the worldwide experience with our VAD systems as a means of therapeutic recovery and the requirements for pursuing regulatory approval for this indication. Although it is not certain how many patients with CHF could benefit from this indication, based upon the percentage of patients with late-stage CHF, we believe that the patient population could be substantial. We submitted a PMA Supplement to the FDA in December 2000 and hope to receive approval in the United States in 2002. We are also formulating a regulatory and clinical strategy for non-U.S. markets.

### ***Recovery Following Cardiac Surgery***

In addition to CHF, our devices are also used for patients who suffer from acute cardiac failure and undergo cardiac surgery. Following cardiac surgery, some patients have difficulty being weaned off heart/ lung

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machines a complication that arises in approximately one to three percent of the more than 900,000 open-heart procedures performed each year. Many of these patients ultimately die from heart failure when the heart, weakened by disease and the additional trauma of surgery, fails to maintain adequate blood circulation. We believe that only a small portion of this market is currently being treated with VADs and this patient population could benefit substantially from further awareness and use of our VADs in this market.

### ***Other Markets***

In addition to the circulatory support market, we sell other devices including those that address the vascular access graft market. Our vascular grafts program has developed the Aria graft for patients undergoing CABG surgery or who have too few and/or poor quality vessels of their own to use for the procedure. The Aria is currently in clinical trials. We have also developed and are marketing the *Vectra* Vascular Access Graft, or *Vectra*, for patients undergoing renal hemodialysis.

We believe that the market opportunity for the Aria could be up to 20% of those patients who undergo CABG surgery but do not have healthy native vessels. Industry sources estimate that this market could be approximately 180,000 patients each year. Our *Vectra* product targets the estimated 225,000 prosthetic access vascular grafts implanted in hemodialysis patients annually.

Finally, our diagnostic products for blood coagulation testing and our single-use skin incision devices, which we sell through ITC, address the market for those patients who must monitor their blood chemistry. We estimate this market is smaller than our other markets but that we hold a leading position for these devices. We currently estimate that the market for these products is over \$250 million per year.

## **Our Products**

We offer two complementary circulatory support product lines:

the Thoratec Ventricular Assist Device system, which we call the Thoratec VAD system, an external device for short to mid-term cardiac support; and

the HeartMate Left Ventricular Assist system, which we call the HeartMate, an internal device for longer term cardiac support.

In addition to our cardiac assist products, we offer vascular access grafts, used in hemodialysis for patients with end stage renal disease. We are also developing a small diameter access graft for use in CABG surgery. Additionally, we sell whole-blood coagulation testing equipment used in bedside anticoagulation management, coagulation screening and skin incision devices for the drawing of blood from adult, children and infant patients.

### ***Circulatory Support Products***

Ventricular assist devices perform some or most of the pumping function of the heart in patients with severe heart failure. A cannula connects the left ventricle of the heart to a blood pump that is driven by a power source, which can be either electric or pneumatic. Blood flows from the left ventricle to the pump chamber, via the cannula. An electric or air driven mechanism compresses the pump chamber and forces the blood through another cannula into the aorta. From the aorta, the blood then circulates throughout the body. Valves, which can be mechanical or tissue, enable unidirectional flow.

Certain VADs are implanted internally, while others are placed outside the body. Some external devices are placed immediately adjacent to the body (paracorporeal), while other external VADs are positioned at a distance from the body (extracorporeal). Between 15% and 20% of assist patients require biventricular support and therefore require a second pump for the right ventricle. Currently the power source remains outside the body for all FDA-approved VADs.

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### *The Thoratec VAD*

The Thoratec VAD has been FDA-approved since 1995 and has treated 1,800 patients worldwide. The Thoratec VAD is a paracorporeal device that remains outside of the body. The product is less invasive than implantable VADs since only the cannulae must be implanted. The paracorporeal nature of the Thoratec VAD has several positive consequences including relatively shorter and less invasive implantation times (approximately two hours) and the ability to use the device in smaller patients.

A pneumatic power source drives our VAD. It is designed for intermediate duration use of a few weeks to several months, though this device has supported numerous patients for six to eighteen months. Offering left, right or biventricular support, the Thoratec VAD is the only biventricular support system approved for use as a bridge to transplant. This characteristic is significant since 15% to 20% of patients require right-sided ventricular assist. The Thoratec VAD is also the only device approved for both bridge to transplant and recovery following cardiac surgery. We submitted a PMA Supplement in December 2000 for a therapeutic recovery indication, which we expect to receive by the end of 2002. The Thoratec VAD is made with our proprietary biomaterial, Thoralon, which may reduce clotting.

Ambulation with most paracorporeal VADs is possible, but very limited because of the large size of the typical drive console. In order to improve patient mobility, we developed the TLC-II, a small portable driver, which increases portability and ambulation options. The portable driver was recently approved in the United States for use in off-site excursions and is in clinical trials for a home discharge indication. The TLC-II has been approved for use in Europe since 1998.

### *The HeartMate*

The HeartMate has been used to treat nearly 3,200 patients worldwide. There are currently two versions of the HeartMate available on the market with different sources of power. The pneumatic-powered version of the HeartMate, called the HeartMate IP, was approved in the United States in 1994 and was the first FDA-approved cardiac assist device. The electric HeartMate, called the HeartMate VE, received FDA approval in September 1998. Currently, the electric version accounts for over 90% of our total HeartMate sales and we recently introduced a number of enhancements to the HeartMate, which have been approved by the FDA. Compared with the Thoratec VAD, the HeartMate is designed for longer duration use of several months to up to two or three years. The HeartMate offers only left ventricular support. While the device is currently approved as a bridge to transplant indication and for home discharge, the REMATCH trial evaluated HeartMate for destination therapy for patients who are not eligible for a heart transplant.

Patients with a HeartMate do not require anti-coagulation, since the device utilizes proprietary textured surfaces and tissue valves rather than mechanical valves. As a result, we believe that this device has the lowest rate of stroke for patients using ventricular support. The implantable nature of this device enables patient ambulation and home discharge.

### *Implantable VAD*

We are developing and expect to commercialize the IVAD, which is an implantable version of the Thoratec VAD. The IVAD maintains the same blood flow path, valves and blood pump as the paracorporeal device and is better suited for longer-term support compared to the Thoratec VAD. The outer covering of the IVAD is made of a titanium alloy, which facilitates implantation. The device is approximately half the size of other implantable VADs and weighs less than one pound. The device can be implanted in patients ranging in weight from 40 kg to over 100 kg. The small blood pump is implanted in the body and is connected to a small, briefcase size, battery-powered, external control unit. The device can provide left, right, or biventricular support. The IVAD is being designed as a bridge to transplant and possibly for therapeutic recovery, but not as an alternative to transplant.

In February 2001, we received a conditional IDE approval to commence an IVAD clinical trial. The study will evaluate up to 30 patients in up to 10 centers, which are in the process of obtaining approval. We plan to submit a PMA Supplement in the first half of 2003, and expect approval in the second half of 2003.

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### *HeartMate II and HeartMate III*

HeartMate II, the next-generation HeartMate device, is being designed for use in many types of patients and indications, including for destination therapy. HeartMate II, is a small implantable electrically powered device that weighs only 12 ounces and is approximately 1.5 inches wide and 3 inches long. The small size of the device is made possible by a continuous axial flow mechanism, as compared with the pulsatile flow of other currently marketed products. The device is also designed to be quieter than currently marketed products. The pump speed can be controlled manually or by a proprietary automatic mode, which regulates pumping activity based on the demands of the body. We believe this will be a competitive advantage since most competitive axial pumps currently in development must be manually adjusted. The anticipated longevity of the device is expected to be five to seven years.

The first HeartMate II was implanted in Israel in 2000 and the first European implant occurred in April 2001. We filed for a U.S. IDE in August 2001. Our goal is to complete U.S. clinical trials in 2003, with HeartMate II launches anticipated in Europe by year-end 2002 and in the United States by the end of 2003.

In addition, we are developing our third generation HeartMate, the HeartMate III. The HeartMate III is a centrifugal flow pump that employs an electrically powered magnetic rotor that eliminates wear from touching parts. No bearings are present and the device is completely encased in titanium. HeartMate III maintains both continuous and pulsatile flow capabilities. The anticipated longevity of the device is 10-20 years. To date, preclinical studies have been performed, with the first six-month preclinical studies already completed.

### *Vascular Graft Products*

We are developing small diameter vascular graft products intended initially to address the vascular access and CABG markets. Both products utilize our proprietary Thoralon biomaterial, and are protected by several U.S. and foreign patents covering the material and the structure of the graft products, as well as several foreign patents covering aspects of the manufacturing processes used to make the products. We believe that our vascular grafts are highly compliant, have excellent handling and suturing properties and have the feel of a natural blood vessel. Our manufacturing process creates a structure in which the three different layers in the graft wall have different properties, which make the graft closely resemble natural blood vessels. The inner textured layer is designed for contact with blood and provides improved resistance to blood clots. The solid middle layer gives the graft its strength and self-sealing properties. The outer textured layer is designed to promote tissue ingrowth to enhance graft stability.

### *Aria Coronary Artery Bypass Graft*

We have developed a small diameter graft for use in coronary artery bypass surgery patients who have too few or no suitable vessels of their own. The most unique aspect of the Aria is its potential for improved long-term patency (up to eight years) in small diameter grafts. We believe that to date no other suitable small diameter graft has been developed which will remain patent over long periods of time when used in this critical application.

We received FDA approval for a Phase I IDE study of the Aria graft in May 2000. This study was designed to evaluate the Aria graft in patients with inadequate autologous vessels to complete revascularization. The Phase I results, based on 19 patients enrolled across the six centers, were submitted to the FDA in September 2001 and we requested approval to begin the pivotal Phase II. In November 2001, the FDA granted conditional approval for conducting the Phase II clinical trial at 20 centers for up to 162 patients.

### *Vectra Vascular Access Graft*

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

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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 Impra division of C.R. Bard Corporation (Impra) in the United States, Europe and selected countries in Scandinavia, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan.

### ***Blood Coagulation Testing and Skin Incision Devices***

Through ITC, we manufacture and supply whole blood coagulation testing equipment and related disposables, as well as premium-quality, single-use skin incision devices.

Our whole-blood coagulation testing equipment product lines offer systems for bedside anticoagulation management, coagulation screening and transfusion management. Each analyzes small blood samples, then processes and quickly displays comprehensive patient homeostasis information. Blood management of this type is essential for cardiopulmonary bypass surgery and angioplasty. HEMOCHRON models are designed for use in a clinical setting at the patient's bedside. They are lightweight, battery-operated, portable and some provide data-management features.

The Protime Microcoagulation System is designed to allow testing for patients who take the blood-thinning drug Warfarin (or Coumadin, the trade name for the generic drug, Warfarin). The system consists of a hand-held instrument, a five-channel cuvette and a finger incision device. These tests are performed in a doctor's office, clinic or by the patients at home.

We also manufacture a family of single-use skin incision devices for drawing blood from adults, children and infants. Each employs a patented skin incision technology to provide a standardized surgical incision.

## **Sales and Marketing**

We operate in the following business segments: Cardiovascular Products, formerly called VAD/graft, and Other Medical Equipment. Cardiovascular Products include our circulatory support products and vascular graft products. Other Medical Equipment includes our blood coagulation testing and skin incision devices.

### ***Circulatory Support Products***

The potential customers for our circulatory support products are hospitals that perform open heart surgery procedures and heart transplants. We estimate that 130 of the approximately 900 hospitals in the United States that perform open-heart surgery also perform heart transplants. We actively are marketing to these 130 heart transplant hospitals and large cardiac surgery centers in addition to 110 heart transplant hospitals in Europe.

We have recruited and trained a direct sales force that, as of December 29, 2001, was comprised of 18 experienced cardiovascular sales specialists to sell our circulatory support systems in the United States, Canada, France, Germany, Spain, United Kingdom, Austria, Switzerland, Netherlands, Portugal and South Africa.

The sales effort is complemented by 10 direct clinical specialists that conduct clinical educational seminars, assist with a new open-heart center's first VAD implant and resolve clinical questions or issues. We also partner with universities, experienced clinicians and opinion leaders to assist with expanding clinical educational needs. The sales team focuses on cardiac surgeons that perform heart transplantation and transplant surgeons, perfusionists and the transplant nursing staff. In addition to our direct selling effort, we have established a network of international distributors who cover those markets that represent the majority of ventricular assist device potential. We employ sales and marketing tactics commonly found within the cardiovascular device market such as direct mail, clinical education seminars, symposia, equipment purchase and lease programs and journal advertisement. We have also assembled a Medical Advisory Board consisting of opinion leaders who provide clinical input and direction on product development, marketing and market issues.

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Hospitals or other medical institutions that acquire a VAD system generally purchase VAD pumps, related disposables and training and purchase or rent two of the associated pump drivers (to ensure that a backup driver is available). The time from the initial contact with the cardiac surgeon until purchase is generally between nine and eighteen months, due to the expense of the product and common hospital capital equipment acquisition procedures. Upon receipt of a purchase order, we will usually ship the products within thirty days.

The introduction of a VAD system in a new hospital or other medical institution requires that the surgical and clinical support personnel possess certain expertise to use our products. For our customers that do not already have this expertise, we provide initial training for the surgical and clinical support teams generally after delivery of one of our VAD products. As many of our customers already possess sufficient experience and expertise to use our products, training is provided as a best practice to optimize the use and success of our products. In addition, a variety of training materials accompany the initial delivery of our VAD products including instructions for use, patient management manuals and assorted videos. As a follow-up to the initial training, we provide clinical support at the first implant whenever possible. We also provide 24-hour access to clinically trained personnel. Our sale force also assists customers with obtaining reimbursement from third-party payors.

### ***Vascular Graft Products***

We market the *Vectra* through *Impra* in the United States, Europe and selected countries in Scandinavia, the Middle East and Northern Africa and through *Goodman Co. Ltd.* in Japan. We intend to market the *Aria CABG* device through our direct sales force in the United States and Europe and potentially through distributors in other international markets.

The *Aria* is being developed as a preferable clinical option for patients who lack suitable native vessels. We believe that more clinician education will be required for the *Aria* graft in terms of patient indications, product use, and product capabilities. We may accomplish this education by sponsoring educational programs, video educational tools and scientific lecture programs. We also anticipate that we may need a larger domestic sales force structure to effectively market the *Aria* graft.

### ***Blood Coagulation Testing and Skin Incision Devices***

ITC maintains a direct sales staff of 31 in the United States who sell to hospitals as well as to third party dealers and distributors including *Alliance Healthcare*. Outside of the United States, ITC has two salespeople selling principally to third-party dealers.

## **Manufacturing**

We manufacture our products at the following facilities:

The Thoratec VAD systems are manufactured at our facility in Pleasanton, California. This facility has been inspected, approved and licensed by the FDA and the State of California Department of Health Services, Food and Drug Section for the manufacture of medical devices and has received the International Standards Organization (ISO) 9001 certification. Our manufacturing processes for the Thoratec VAD system consist of the assembly of standard and custom component parts, including blood-contacting components fabricated from our proprietary biomaterials and the testing of completed products. We rely on single sources of supply for several components of the Thoratec VAD system. We are aware of alternative suppliers for all single-sourced items other than the Thoratec VAD mechanical valves, which have been supplied by *Arrow International Inc.*

*HeartMate* devices are manufactured in Woburn, Massachusetts. We are in the process of moving portions of this facility (including all manufacturing) to Pleasanton, California and expect the move to be completed by the end of 2002. We will continue operating marketing, research and development and administrative functions at the Woburn facility.

Blood coagulation testing and skin incision devices are manufactured in Edison, New Jersey.



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### **Patents and Proprietary Rights**

We seek to patent certain aspects of our technology. We hold, or have exclusive rights to, several U.S. and foreign patents. Except for the patents mentioned below, the Thoratec VAD system is not protected by any patents other than one patent pertaining to the TLC-II. We do not believe that this lack of patent protection will have a material adverse effect on our ability to sell the Thoratec VAD system because of the lengthy regulatory period required to obtain approval of a ventricular assist device. We are not aware of any ventricular assist devices that are based on our product design currently approved by the FDA or undergoing clinical trials. Several patents cover aspects of our HeartMate products.

Our patents relating to blood coagulation and skin incision devices are assigned to ITC. We own or hold rights in the remainder of the U.S. patents by virtue of the Merger between Thoratec and Thermo Cardiosystems. However, documents transferring ownership of some of these patents have not yet been submitted to the United States Patents and Trademarks Office, or PTO, and, while documents have been submitted to the PTO for others, those documents have not yet been recorded by the PTO. Until documents transferring rights to us as a result of the Merger are recorded, our rights in the respective patents could be subject to rights of others who purchased those rights from Thoratec or Thermo Cardiosystems without knowledge of the Merger.

Several patents cover aspects of our proprietary biomaterials technology, some of which were sold to TH Goldschmidt AG, a German chemical manufacturer, in 1989, but we have retained worldwide, royalty-free, exclusive rights to these patents for most medical applications. The patent license from Goldschmidt will remain in effect for the duration of the patents sold to Goldschmidt and includes medical uses that we expect are necessary for our business as now conducted or as proposed to be conducted in the future. For example, the medical applications include blood pumps, artificial hearts and cardiac assist devices of all kinds, cardiovascular products, including heart valves and prosthetic blood vessels and cannulae and blood tubing of all kinds. Aspects of our vascular graft products are covered by patents covering materials, graft structure, and, in some foreign countries, manufacturing processes used to make the graft products. Aspects of our blood coagulation and skin incision device products are covered by patents directed to blood coagulation testing equipment and methods, and to skin incision devices and methods of manufacturing such devices. The duration of some of our patents on our HeartMate products range from 14 to 15 years, on our biomaterials, 2 1/2 years, on our grafts, from 3 months to 3 1/2 years and on our blood coagulation and skin incision device products, from 3 to 15 years. During the term of our patents, we have the right to prevent third parties from manufacturing, marketing or distributing products that infringe upon our patents.

We hold, or have exclusive rights to, several international patents, including several biomaterial patents licensed from Goldschmidt referred to above. In August 1998, we obtained a license to incorporate technology developed by Sulzer Electronics Ltd. into the HeartMate III. HeartMate III is a miniature centrifugal pump featuring a magnetically controlled system that has been developed by Levitronix GmbH. The license from Sulzer gives us the exclusive right to use in our HeartMate products technology protected by several U.S. and foreign patents covering implantable magnetically controlled pumps for the duration of those patents, subject to our payment of royalties. In December 2000, we were informed by Sulzer Electronics that Sulzer had sold all of their business in the bearingless motor and magnetic bearing fields to Levitronix and had assigned the agreements between Sulzer and us to Levitronix. The license remains in full force and effect.

The validity of any of our patents may be challenged by others, and we could encounter legal and financial difficulties in enforcing our patent rights against alleged infringements. In addition, others could develop technologies that avoid infringement of our patents or obtain patents which would render our patents obsolete. Although we do not believe patents are the sole determinant in the commercial success of our products, the loss of a significant percentage of our patents or the patents relating to our products could seriously harm our business.

We have developed technical knowledge, which although non-patentable, we consider to be significant in enabling us to compete. However, the proprietary nature of such knowledge may be difficult to protect. It is our policy to enter into confidentiality agreements with each of our employees prohibiting such employee from disclosing any confidential information or trade secrets. In addition, these agreements provide that any

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inventions or discoveries relating to our business by these individuals will be assigned to us and become our sole property. However, we cannot guarantee that every person who gets access to our confidential information or trade secrets will have signed such an agreement, or that every person who has signed such an agreement will abide by it. If they do not, or if our confidential information or trade secrets are otherwise disclosed, there is no guarantee that any legal remedies will prevent the harmful disclosure or use of our confidential information or trade secrets.

Claims by competitors and other third parties that our products allegedly infringe the patent rights of others could seriously harm our business. The medical device industry is characterized by frequent and substantial intellectual property litigation. The cardiovascular device market is characterized by extensive patent and other intellectual property claims. Intellectual property litigation is complex and expensive and the outcome of this litigation is difficult to predict. Any future litigation, regardless of outcome, could result in substantial expense and significant diversion of the efforts of our technical and management personnel. An adverse determination in any such proceeding could subject us to significant liabilities or require us to seek licenses from third parties or pay royalties that may be substantial. Furthermore, we cannot assure you that necessary licenses would be available on satisfactory terms, or at all. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing or selling certain of our products, any of which could seriously harm our business.

We have received correspondence from a third party alleging that the textured surface of our HeartMate housing infringes certain patent rights of such third party. In general, an owner of intellectual property can prevent others from using such property without a license and is entitled to damages for unauthorized usage. We have investigated the basis of the allegation and, based upon an evaluation of all of the facts and circumstances, we believe that we have meritorious defenses. However, we cannot be sure that our defenses would prevail, and given the inherent uncertainties in dispute resolution, if we were sued and the outcome was unfavorable, our results of operations or financial condition could be seriously harmed.

## **Competition**

Principal competitors of our VAD systems include:

World Heart Corporation, which manufactures and markets an implantable left ventricular assist device approved only for bridge to heart transplant in the United States; and

ABIOMED, Inc., which manufactures and markets a biventricular assist device approved only for temporary circulatory support of patients in post-heart surgery shock and other recovery indications in the United States.

We believe that the principal competitive factors in the circulatory support market are patient outcomes, product performance, size and portability, quality, cost-effectiveness and customer service. We believe that our principal competitive advantages are:

our ability to provide left, right or biventricular support;

our ability to provide short-term or long-term circulatory support;

the lowest known rate of stroke for patients using ventricular support;

our ability to provide implantable or paracorporeal VAD placement;

our ability to provide support in the hospital or in the home;

our ability to provide support to a greater range of patients as a result of the smaller size and placement of the paracorporeal system outside the body;

the greater range of cannulation options available;

the quality of our biomaterials;

the availability and quality of service and field support; and



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our ability to offer numerous products from one company.

Although we believe that these attributes of our VAD systems offer certain advantages over existing ventricular assist devices, we expect our current competitors to defend their market positions vigorously.

Our principal competitors in the vascular access graft market are W.L. Gore, Inc., C.R. Bard and Boston Scientific Corporation, who manufacture and market ePTFE grafts worldwide. Smaller competitors include CardioTech International, Inc., which manufactures and markets a polyurethane graft that is available for sale outside of the United States. Finally, Possis Medical, Inc. manufactures a self-sealing silicone rubber graft marketed with limited indications in the United States through Horizon Medical Products, Inc.

ITC's principal competitor for the HEMOCHRON coagulation monitoring instruments, used in the operating room and in cardiac catheterization, is the HemoTec division of Medtronic, Inc. Roche Holding AG competes with the ProTime product with a blood coagulation monitor that is marketed to clinics and also is used for patient self-testing. There are also several new competitors that have recently entered the blood coagulation monitoring market. ITC's products compete primarily on the basis of reputation, utility, and price.

ITC's skin incision devices compete with products offered by a number of companies, including Organon Teknika B.V.; Becton, Dickinson and Company; and Owen-Mumford Ltd. The skin incision devices compete primarily on the basis of safety, quality and reputation.

## **Government Regulations**

Regulation by governmental authorities in the United States and foreign countries is a significant factor in the manufacture and marketing of our current and future products and in our ongoing product research and development activities. All of our proposed products will require regulatory approval prior to commercialization. In particular, medical devices are subject to rigorous preclinical testing as a condition of approval by the FDA and by similar authorities in foreign countries.

### ***U.S. Regulations***

In the United States, the FDA regulates the design, manufacture, distribution and promotion of medical devices pursuant to the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder, or the FDA Act and Regulations. Our VAD systems, blood coagulation testing devices, skin incision devices, and Aria and *Vectra* graft products are regulated as medical devices. To obtain FDA approval to market ventricular assist devices similar to those under development, the FDA requires proof of safety and efficacy in human clinical trials performed under an IDE. An IDE application must contain preclinical test data supporting the safety of the product for human investigational use, information on manufacturing processes and procedures, proposed clinical protocols and other information. If the IDE application is accepted, human clinical trials may begin. The trials must be conducted in compliance with FDA regulations and with the approval of one or more institutional review boards. The results obtained from these trials, if satisfactory, are accumulated and submitted to the FDA in support of either a PMA application or a 510(k) premarket notification. Premarket approval from the FDA is required before commercial distribution of devices similar to those under development by us is permitted in the United States.

The PMA Supplement must be supported by extensive data, including preclinical and human clinical data, to prove the safety and efficacy of the device with respect to the modifications disclosed in the supplement. By regulation, the FDA has 180 days to review a PMA application and during that time an advisory committee may evaluate the application and provide recommendations to the FDA. While the FDA has approved PMA applications within the allotted time period, reviews more often occur over a significantly protracted period, usually 18 to 36 months, and a number of devices have never been cleared for marketing. This is a lengthy and expensive process and there can be no assurance that such FDA approval will be obtained.

Under the FDA's requirements, if a manufacturer can establish that a newly developed device is substantially equivalent to a legally marketed predicate device, the manufacturer may seek marketing clearance from the FDA to market the device by filing a 510(k) premarket notification with the FDA. This is

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the process that is used to gain FDA market clearance for most of the ITC products including HEMOCHRON and ProTime. The 510(k) premarket notification must be supported by data establishing the claim of substantial equivalence to the satisfaction of the FDA. The process of obtaining a 510(k) clearance typically can take several months to a year or longer. If substantial equivalence cannot be established, or if the FDA determines that the device requires a more rigorous review, the FDA will require that the manufacturer submit a PMA application that must be approved by the FDA prior to marketing the device in the United States.

Both a 510(k) and a PMA, if approved, may include significant limitations on the indicated uses for which a product may be marketed. FDA enforcement policy prohibits the promotion of approved medical devices for unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial marketing.

The approval process for each of our products is expensive and time consuming and we cannot assure you that any regulatory agency will grant its approval. Our inability to obtain, or delays in obtaining, such approval would adversely affect our ability to commence marketing our products. We cannot assure you that we will have sufficient resources to complete the required testing and regulatory review processes. Furthermore, we are unable to predict the extent of adverse governmental regulation which might arise from future U.S. or foreign legislative or administrative action.

In addition, any products distributed pursuant to the above authorizations are subject to pervasive and continuing regulation by the FDA. Products must be manufactured in registered establishments and must be manufactured in accordance with cGMP regulations and adverse events must be reported to the FDA. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The failure to comply with the FDA's regulations can result in enforcement action, including seizure, injunction, prosecution, civil penalties, recall and suspension of FDA approval. The export of devices is also subject to regulation in certain instances.

We are also subject to regulation by the California Department of Health Services, Food and Drug Section and the New Jersey Department of Health, which may inspect us and enforce regulations. Failure to comply with applicable state regulations may result in seizures, injunctions or other types of enforcement actions.

***International Regulations***

We are also subject to regulation in each of the foreign countries in which we sell products with regard to product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. Many of the regulations applicable to our products in such countries are similar to those of the FDA. The national health or social security organizations of certain countries require our products to be qualified before they can be marketed in those countries.

In order to be positioned for access to European and other international markets, we sought and obtained certification under the ISO 9000 Series of Standards. ISO 9000 is a set of integrated requirements, which when implemented, form the foundation and framework for an effective quality management system. These standards were developed and published by the ISO, a worldwide federation of national bodies, founded in Geneva, Switzerland in 1947. ISO has over 90 member countries. ISO certification is widely regarded as essential to enter Western European markets. We obtained certification and were registered as an ISO 9002 compliant company in January 1995. Commencing in mid-1998, all companies are required to obtain CE Marks for medical devices sold or distributed in the European Union. The CE Mark is an international symbol of quality. With it, medical devices can be distributed within the European Union, which is comprised of 15 European countries representing a population of over 379 million people. A prerequisite for obtaining authority to CE Mark products is to achieve full quality system certification in accordance with ISO 9001 and EN 46001. These are quality standards that cover design, production, installation and servicing of medical devices. We have our ISO 9001 and EN 46001 certification and authority to CE Mark all VAD systems, including the HeartMate, blood coagulation testing and skin incision devices and the *Vectra* graft. We are also

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certified to be in compliance with the requirements of the European Medical Device Directive, another prerequisite for applying the CE Mark.

### ***Other Regulations***

We are also subject to various federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially hazardous substances used in connection with our research and development work. Specifically, the manufacture of our biomaterials is subject to compliance with federal environmental regulations and by various state and local agencies. Although we believe we are in compliance with these laws and regulations in all material respects, we cannot assure you that we will not be required to incur significant costs to comply with environmental laws or regulations in the future.

### **Third Party Reimbursement and Cost Containment**

Our products are purchased primarily by hospitals and other users, which then bill various third party payors for the services provided to the patients. These payors, which include Medicare, Medicaid, private health insurance companies and managed care organizations, reimburse part or all of the costs and fees associated with these devices and the procedures performed with these devices.

Third party payors are increasingly challenging the prices charged for medical products and services and may deny reimbursement if they determine that a device was not used in accordance with cost-effective treatment methods as determined by the payor, was experimental or was used for an unapproved application. To date, some private insurers and Medicare and Medicaid have determined to reimburse the costs of our VAD systems. Changes in reimbursement, policies and practices of third party payors could seriously harm sales of our products.

### **Employees**

As of December 29, 2001, we had 672 full-time employees, 302 of whom worked in manufacturing, 96 in engineering, 90 in quality control and regulatory affairs, 106 in marketing and sales support, 36 in administration and finance and 42 in other support functions, including human resources, management information systems, purchasing and facilities. Out of our total full-time employees, 657 are employed in the United States and 15 are employed in the United Kingdom and other European countries. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

### **Research and Development**

Thoratec's research and development expenses in 2001, 2000 and 1999 were \$22.1 million, \$16.2 million and \$16.0 million, respectively.

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**RISK FACTORS**

*We make statements in this Annual Report on Form 10-K and other statements from time to time that relate to future plans, events or performance that are forward-looking statements which involve risks and uncertainties. Actual results, events or performance may differ materially from those anticipated in any forward-looking statements as a result of a variety of factors, including those set forth below and elsewhere in this Annual Report on Form 10-K. You should consider each of the risks and uncertainties described in this section and all of the other information in this Annual Report on Form 10-K in evaluating our company and our business before deciding to invest in our common stock.*

**We have a history of net losses, and we may not achieve or maintain profitability.**

We were founded in 1976 and have a history of incurring losses from operations. As of December 29, 2001, our accumulated deficit was approximately \$31.2 million. We anticipate that our expenses will increase as a result of increased preclinical and clinical testing, research and development and selling, general and administrative expenses. We could also incur significant additional costs in connection with the Merger and the development and marketing of new products and indicated uses for our existing products. Such costs could prevent us from achieving or maintaining profitability in future periods.

**We could face significant challenges in integrating TCA and, as a result, may not realize the expected benefits of the Merger.**

Thoratec and TCA have different technologies, products and business operations that have operated independently. The ongoing combination of these businesses has been complex and costly. If we fail to integrate the employees and products of both companies, or if we fail to complete the relocation of our Woburn manufacturing operations to Pleasanton, the operating results of the combined company could be adversely affected and we may not achieve the benefits or operating efficiencies that we hoped to obtain from the Merger.

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

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

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

As a result of the Merger in February 2001, the number of our employees has increased significantly, from 183 on December 30, 2000 to 672 on December 29, 2001. We expect to continue to grow and we may suffer if we do not integrate and train our new employees quickly and effectively. Our revenues 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. If we do not introduce

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these new products, product improvements and new indications on a timely basis, or if they are not well-accepted by the market, our future growth may suffer.

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

As of December 29, 2001, we had \$293.8 million of net intangible assets, representing 55% of our total assets and 79% of our shareholders equity. These intangible assets consist primarily of goodwill and other intangible assets arising from our Merger and our trademarks and patented technology. Amortization expense relating to these intangible assets for 2001 was \$15.7 million. Of this amount, \$4.4 million represented amortization of goodwill, which is no longer amortized after we adopted Statement of Financial Accounting Standards No. 142 at the beginning of 2002 (see *Recent Accounting Pronouncements* in Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations* ). Ongoing amortization of purchased intangibles will reduce our future earnings or increase our future losses.

We may not receive the recorded value for our intangible assets if we sell or liquidate our business or assets. The material concentration of intangible assets increases the risk of a large charge to earnings in the event that the recoverability of these intangible assets is impaired, and in the event of such a charge to earnings, the market price of our common stock could be adversely affected.

**We rely on specialized suppliers and alternative suppliers may not be available.**

We depend on a number of custom-designed components and materials supplied by other companies including, in some cases, single source suppliers for components and materials used in our VAD systems. We do not have long-term written agreements with most of our vendors and receive components on a purchase order basis. For example, Arrow International Inc., with whom we have no long-term written contract, is the only supplier of the mechanical valves for the Thoratec VADs and an alternative supplier may not be available. Sales of our VAD system accounted for approximately 29% of our revenues for 2001. 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 such components or materials ourselves. Cessation or interruption of sales of circulatory support products would seriously harm our business, financial condition and results of operations.

Alternative suppliers, if available, may not agree to supply us. In addition, we may need to obtain FDA approval before using new suppliers or manufacturing our own components or materials. Existing suppliers could also be subject to an FDA enforcement action, which could also disrupt our supplies. If alternative suppliers are not available, we may not have the expertise or resources necessary to produce such materials or component parts internally. Any interruption in supply of materials or component parts could seriously harm our ability to manufacture products until we locate a new supply source.

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

Competition from medical device companies and medical device subsidiaries of health care and pharmaceutical companies is intense and is expected to increase. Competitors for the VAD system include, for example, World Heart Corporation and ABIOMED, Inc. Principal competitors in the vascular graft market include W.L. Gore, Inc., C.R. Bard and Boston Scientific Corporation. The principal competitors in the coagulation monitoring equipment market are the Hemotec division of Medtronic, Inc. and Roche Holding AG. The primary competitors in the skin incision device market are Organon Teknika B.V.; Becton, Dickson and Company; and Owen-Mumford Ltd.

Many of our competitors have substantially greater financial, technical, distribution, marketing and manufacturing resources than we do. Accordingly, our competitors may be able to develop, manufacture and



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market products more efficiently and at a lower cost than we can. We expect that the key competitive factors will include the relative speeds with which we can:

develop products;

complete clinical testing;

receive regulatory approvals; and

manufacture and sell commercial quantities of products.

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

**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.**

Before we can market new products in the United States, we must obtain clearance from the FDA. This process is lengthy and uncertain. In the United States, one must obtain clearance from the FDA of a 510(k) premarket notification or approval of a more extensive submission known as a 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 preclinical and clinical trial data. Preclinical data may need to be obtained in accordance with FDA good laboratory practices.

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

The FDA also requires us to adhere to cGMP 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 cGMP 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 in a device is required to be made in compliance with cGMP regulations, which 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.

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.

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

We may encounter difficulties manufacturing our products. We do not have experience in manufacturing 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. If we have difficulties manufacturing our products, our business will be harmed.

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

With the exception of Canada and most countries in Europe, we sell our VAD and HeartMate systems in foreign markets through distributors. In addition, we sell our vascular access graft products through the IMPRA division of C.R. Bard Corporation, which we refer to as Impra, in the United States, Europe and selected countries in Scandinavia, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan. ITC had sales through a distributor, Allegiance Healthcare, of approximately \$13.5 million for 2001. Our agreement with Allegiance Healthcare expires in June 2002, unless terminated earlier by either party if there is a material breach of the agreement which remains uncured.

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

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

Significant uncertainty exists as to the reimbursement status of newly-approved health care products such as ventricular assist devices and vascular grafts. 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 of 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 that we have dealt with, and Medicare and Medicaid, have determined to reimburse some portion of the costs of our ventricular assist devices and our diagnostic and vascular graft products. We cannot, however, estimate what portion of such costs have been 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 we fail to obtain such reimbursement or if the reimbursement levels are partially or completely reduced, our revenues would be reduced.

### **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 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.

Aside from the biomaterials patents, which are utilized in the Thoratec VAD blood pump and cannulae, and one patent covering aspects of our TLC-II, our VAD systems are not protected by any patents. We rely principally on trade secret protection and, to a lesser extent patents, to protect our rights to the HeartMate. We rely principally on patents to protect our coagulation testing equipment and skin incision devices.

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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 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.

We own or hold rights in some U.S. patents by virtue of the Merger between Thoratec and Thermo Cardiosystems. However, documents transferring ownership of some of these patents have not yet been submitted to the PTO and, while documents have been submitted to the PTO for others, those documents have not yet been recorded by the PTO. Until documents transferring rights to us as a result of the Merger are recorded, our rights in the respective patents could be subject to rights of others who purchased those rights from Thoratec or Thermo Cardiosystems without knowledge of the Merger.

In addition, we have received correspondence from another company alleging that our HeartMate infringes certain patent rights of that company. We cannot assure you that we will be successful if the matter is litigated.

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

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

### **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. 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.

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

Our VAD systems have lengthy sales cycles and we may incur substantial sales and marketing expenses and expend significant effort without making a sale. Even after making the decision to purchase our VAD systems, our customers often deploy our products slowly. For example, the length of time between initial contact with cardiac surgeons and the purchase of our VAD systems is generally between nine and eighteen months. As a result, it is difficult for us to predict the quarter in which our customers may purchase our VAD systems and our revenue and operating results may vary significantly from quarter to quarter, which increases the risk of an operating loss for us for any given quarter.

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

During 2000, sales originating outside the United States and U.S. export sales accounted for approximately 16% of our total revenues. For 2001, sales originating outside the United States and U.S. export sales accounted for approximately 20% of our total revenues. We anticipate that sales outside the United States and U.S. export sales will continue to account for a significant percentage of our revenues 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;

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 may be more difficult to enforce in foreign countries; 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.

### **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 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 may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

### **Our stock price has been volatile, is likely to continue to be volatile, and could decline substantially.**

The price of our common stock has been, and is likely to continue to be, highly volatile. The price of our common stock could fluctuate significantly for the following reasons:

future announcements concerning us or our competitors;

timing and reaction to the publication of clinical trial results;

quarterly variations in operating results;

charges, amortization and other financial effects relating to our Merger;

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

acquisition or loss of significant customers, distributors or suppliers;

business acquisitions or divestitures;

changes in earnings estimates by analysts;

changes in third party reimbursement practices;

regulatory developments and disclosure regarding completed ongoing or future clinical trials; or

fluctuations in the economy or general market conditions.

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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 have frequently been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our stock may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

In the past, shareholders have often instituted securities class action litigation after periods of volatility in the market price of a company's securities. If a shareholder files a securities class action suit against us, we would incur substantial legal fees and our management's attention and resources would be diverted from operating our business in order to respond to the litigation.

### **Future issuances and sales of our stock could dilute shareholder ownership and cause our stock price to decline.**

Future sales of substantial amounts of our stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our stock. Sale of our shares and the potential for such sales, could cause our stock price to decline.

### **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, 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 facility is located. If any disaster were to occur, we may not be able to operate our business at our facilities, which could seriously harm our business and operations. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions.

### **Management may invest or spend the proceeds of our recent offering in ways you may not agree with and in ways that may not yield a return.**

Our management will have broad discretion as to how the net proceeds of our recent offering will be used. Investors will be relying on the judgment of management regarding the application of the proceeds of the offering. The results and effectiveness of the application of the proceeds are uncertain.

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

Since our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign exchange rates. At present, we do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar.

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

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

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### **Item 2. *Properties***

We are headquartered in Pleasanton, California, where we lease approximately 62,000 square feet of commercial space. Our lease for these facilities expires in 2012. Additionally, we lease the following facilities:

Approximately 11,000 square feet of office and research facilities in Rancho Cordova, California expiring in 2002,

Approximately 24,000 square feet of office, manufacturing and research facilities in Edison, New Jersey expiring in 2017,

Approximately 3,800 square feet of office facilities in the United Kingdom expiring 2008, and

Approximately 34,000 square feet of space in Woburn, Massachusetts under a sublease expiring in 2004.

We also own approximately 66,000 square feet of office, manufacturing and research facilities in Edison, New Jersey.

Each of our manufacturing areas have been inspected, approved and licensed for the manufacture of medical devices by the FDA. Additionally, the Pleasanton facility is subject to inspections, approvals and licensing by the State of California Department of Health Services (Food and Drug Section). The Edison facility is subject to inspections, approvals and licensing by State of New Jersey Department of Health.

We believe our facilities will be sufficient for the next two years and that additional space will be available at a reasonable price to satisfy space needs thereafter.

### **Item 3. *Litigation***

We are not a party to any material legal proceedings.

### **Item 4. *Submission of Matters to a Vote of Security Holders***

No matters were submitted to a vote of security holders during the quarter ended December 29, 2001.

## **Our Officers**

*D. Keith Grossman*,\* *President, Chief Executive Officer and Director*, joined our company as President and Chief Executive Officer in January 1996. He was elected to the Board of Directors in February 1996. Prior to joining us, Mr. Grossman was a Division President of Major Pharmaceuticals, Inc., from June 1992 to September 1995, at which time it was sold. From July 1988 to June 1992, Mr. Grossman served as the Vice President of Sales and Marketing for Calcitek, Inc., a manufacturer of implantable medical devices, and division of SulzerMedica formerly Intermedics, Inc. Prior to 1988, Mr. Grossman held various other sales and marketing management positions within the McGaw Laboratories Division of American Hospital Supply Corporation.

*M. Wayne Boylston*,\* *Senior Vice President, Chief Financial Officer and Secretary*, became our Senior Vice President, Chief Financial Officer and Secretary in August 2001. Prior to joining us, Mr. Boylston was Chief Financial Officer at Flashcom, Inc., a provider of broadband communications services. Flashcom filed for bankruptcy protection in December 2000. From July 1998 until March 2000, Mr. Boylston served as Executive Vice President, Chief Financial Officer, Treasurer and Assistant Secretary of iXL Enterprises, Inc., an Internet consulting service provider. From 1995 until 1998, Mr. Boylston served as Vice President Finance, Chief Financial Officer and Treasurer of Healthdyne Technologies, Inc., a medical device manufacturer. Prior to 1995, Mr. Boylston held a variety of financial management positions with Healthdyne, Inc., a diversified healthcare products and services company. Mr. Boylston is a Certified Public Accountant.

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\* Denotes executive officer as of the date of this report.

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*Lawrence Cohen, President of ITC*, joined our Company in May 2001 as President of ITC. Prior to joining ITC, Mr. Cohen served as CEO of HemoSense, Inc., a developer of medical diagnostic products, from August 1998 to April 2000. From October 1989 to March 1998, Mr. Cohen held the positions of Vice President Marketing and Sales, Vice President International and Worldwide Executive Vice President at Ortho-Clinical Diagnostics, a Johnson & Johnson company. From 1980 to 1989, Mr. Cohen has also held executive management positions at Instrumentation Laboratory and Beckman Coulter Corporation. He is a past president of the Biomedical Marketing Association and is currently on the Board of Trustees of the National Blood Foundation.

*David J. Farrar, Ph.D., Vice President Research and Development* joined our company as Program Manager of our circulatory support products in January 1980 and became Vice President Circulatory Support Products in 1988, and Vice President Research & Development in 1996. In addition, Dr. Farrar has a research appointment in the Department of Cardiac Surgery at the California Pacific Medical Center of San Francisco. Dr. Farrar has over 20 years of research experience in the cardiovascular and medical device industry.

*Bradley D. Goskowicz, Vice President Sales and Marketing* joined our company as Vice President, Sales and Marketing in January 2001. Prior to joining our company, Mr. Goskowicz was Director of Marketing in the Cardiac Surgery Division of Medtronic, Inc. where he was responsible for directing, developing and implementing marketing strategies for a broad line of cardiovascular surgery products worldwide. He joined Medtronic in March 1999, as part of Medtronic's acquisition of Avecor Cardiovascular, and was one of the original Directors when Avecor Cardiovascular was formed in 1991. Before assuming the role of Director of Marketing, he held the position of Director of Sales. Prior to 1991 Mr. Goskowicz held various sales and marketing positions with Bio-Medicus, Inc., Medtronic, Inc. and Johnson & Johnson.

*Jeffrey C. Mack, Vice President Finance* joined our company as Controller in 1996. He became Director of Finance and Corporate Controller in September 1999 and Vice President of Finance in September 2000. Prior to joining our company, he served as Director of Finance and Corporate Controller for The North Face, a designer and manufacturer of outdoor apparel and equipment. He also held various other financial and operational positions with Kenetech Corporation, a manufacturer and operator of utility grade wind turbines, and Deloitte & Touche, LLP. Mr. Mack is a Certified Public Accountant.

*Donald A. Middlebrook, Vice President Regulatory Affairs/Quality Assurance* joined our company as Vice President Regulatory Affairs/Quality Assurance in September 1996. Before joining our company, he held the position of Senior Director, Global Regulatory Affairs and Assurance for Chiron Vision Corporation, a manufacturer of implantable ophthalmic devices and surgical equipment. Prior to that, Mr. Middlebrook spent fifteen years with Baxter International in a number of positions, including Vice President of Regulatory Affairs and Quality Assurance for the CardioVascular Group, a producer of a wide range of cardiopulmonary, critical care, vascular and cardiovascular products.

*Victor Poirier, Chief Technology Advisor*, joined our company in February 2001. Prior to joining us, Mr. Poirier was President and Director of Thermo Cardiosystems from 1998 to 2001, and Chief Executive Officer, President and Director of Thermo Cardiosystems from 1990 to 1998. Prior to that, Mr. Poirier was Executive Vice President of Thermo Cardiosystems and Sr. Vice President of Thermedics from 1984 to 2000. Mr. Poirier has more than 40 years of research experience in the cardiovascular industry.

*Joseph G. Sharpe, Vice President Operations* joined our company as Vice President Operations in September 1997. Prior to joining us, Mr. Sharpe was Director of Operations for the IV Systems Division of Baxter International, Inc. from 1992 to September 1997. Prior to that, Mr. Sharpe held a number of other positions at Baxter International, Inc. including Director of Engineering of the Pharmaseal Division, and Honeywell Information Systems.

*Beth A. Taylor, Vice President Human Resources* joined our company as Director of Human Resources in November 1999 and became Vice President of Human Resources in February 2001. Prior to joining our company, Ms. Taylor served as Director of Human Resources for CCI/Triad. She has also held various other human resource positions such as Corporate Employee Development Manager with Valent U.S.A. Corporation, and as Director of Human Resources with Automatic Data Processing, Inc.



**Table of Contents****PART II****Item 5. *Market for Common Equity and Related Stockholder Matters***

Our common stock is traded on the NASDAQ National Market under the symbol THOR . The following table sets forth, for the periods indicated, the high and low closing sales price per share of our common stock, as reported by the NASDAQ National Market. As of March 8, 2002 there were 57,229,146 shares of our common stock outstanding with approximately 931 holders of record, including multiple beneficial holders at depositories, banks, and brokerages listed as a single holder in the street name of each respective depository, bank, or broker.

	<u>High</u>	<u>Low</u>
Fiscal Year 2000		
First Quarter	\$ 19.88	\$ 8.50
Second Quarter	18.63	8.50
Third Quarter	24.75	15.13
Fourth Quarter	\$ 20.56	\$ 7.75
Fiscal Year 2001		
First Quarter	\$ 12.88	\$ 7.09
Second Quarter	15.55	6.56
Third Quarter	20.02	13.77
Fourth Quarter	\$ 20.85	\$ 15.67

We have not declared or paid any dividends on our common stock and we anticipate that for the foreseeable future we will continue to retain our earnings for use in our business.

**Table of Contents****Item 6. Selected Consolidated Financial Data**

The selected consolidated financial data presented below for the five fiscal years ended December 29, 2001 is derived from audited financial statements. The data set forth below should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and related notes thereto appearing elsewhere in this Annual Report, the consolidated financial statements of TCA filed with the SEC on Form 8-K/A on March 30, 2001 and on Form 10-K on March 17, 2000, March 12, 1999 and March 18, 1998 (as amended on February 16, 1999). Certain reclassifications have been made to the financial statements previously filed with the SEC to conform to current practice.

The Merger of Thoratec with TCA was completed on February 14, 2001. We issued new shares of our common stock to the shareholders of TCA in exchange for all the outstanding common stock of TCA at an exchange ratio of 0.835 shares of Thoratec stock for each share of TCA. The Merger was accounted for as a reverse acquisition because former shareholders of TCA owned a majority of our outstanding stock subsequent to the Merger. For accounting purposes, TCA is deemed to have acquired Thoratec and therefore for fiscal years 1997, 1998, 1999 and 2000 all financial information presented herein represents the results of operations of TCA. Our 2001 consolidated financial information presented herein includes the financial results of TCA for the full fiscal year and Thoratec's financial results for the post-merger period from February 14, 2001 through December 29, 2001. The weighted average number of common shares previously reported by TCA has been adjusted for all periods presented to reflect the exchange ratio of 0.835 to 1.

Our fiscal year ends on the Saturday closest to December 31. Accordingly, our fiscal year will periodically contain more or less than 365 days. For example, 1997 ended on January 3, 1998, 1998 ended on January 1, 1999, 1999 ended on December 31, 1999, 2000 ended on December 30, 2000, and 2001 ended on December 29, 2001.

	Fiscal Year				
	2001	2000	1999	1998	1997
(In thousands, except per share data)					
<b>Statement of Operations:</b>					
Product sales	\$ 113,384	\$ 83,396	\$ 78,611	\$ 65,301	\$ 60,842
Gross profit	60,544	48,566	45,285	38,244	25,462
Amortization of goodwill and purchased intangible assets	15,674				
In-process research and development	76,858				
Merger, restructuring and other costs	7,134	1,831			
Net income (loss)	(87,866)	7,524	9,584	7,820	9,019
Basic and diluted earnings (loss) per share	\$ (1.68)	\$ 0.23	\$ 0.30	\$ 0.24	\$ 0.28
<b>Balance Sheet Data:</b>					
Cash and cash equivalents	\$ 91,726	\$ 30,236	\$ 418	\$ 42,026	\$ 71,158
Working capital	135,924	149,207	115,471	98,904	136,702
Total assets	530,241	176,685	169,928	172,363	173,208
Subordinated convertible debentures	54,838	54,838	58,011	70,000	70,000
Long-term deferred tax liability and other	81,020				
Total shareholders' equity	\$ 373,343	\$ 105,869	\$ 96,940	\$ 88,714	\$ 92,963

**Table of Contents****Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*The statements in Management's Discussion and Analysis of Financial Condition and Results of Operations that relate to future plans, events or performance are forward-looking statements which involve risks and uncertainties. These factors, and others, are discussed more fully below and in the prospectus, as amended and supplemented, contained in our Registration Statement on Form S-3 filed with the SEC on February 12, 2002, and our other filings with the SEC. Actual results, events or performance may differ materially from those anticipated in these forward-looking statements as a result of a variety of factors, including those set forth in Risk Factors presented elsewhere in this Annual Report on Form 10-K. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We undertake no obligation to publicly release the result of any revisions to these forward-looking statements that may be needed to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.*

**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, 4.7 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 FDA approval to commercially market a ventricular assist device, or VAD, to treat patients with late-stage heart failure, which comprises approximately 5% 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. We also develop and sell products that are used by physicians and hospitals for vascular and diagnostic applications that include vascular grafts, blood coagulation testing and skin incision devices. We conduct business both domestically and internationally.

**The Merger with Thermo Cardiosystems**

On February 14, 2001, we completed our Merger with TCA. Pursuant to the Merger agreement between Thoratec and TCA dated October 3, 2000, we issued 32,226,074 shares of our common stock to the shareholders of TCA in exchange for all the outstanding common stock of TCA (38,594,281 shares outstanding as of February 14, 2001) at an exchange ratio of 0.835 to 1. Immediately following the transaction, TCA's shareholders owned 59% of our then outstanding common stock and our former shareholders owned the remaining shares of our common stock. Thermo Electron, the majority shareholder of TCA prior to the Merger, received 19,312,959 shares of the 32,226,074 newly issued shares. Immediately following the Merger, Thermo Electron owned approximately 35% of our then outstanding shares of common stock. As of the date of this report, Thermo Electron owns approximately 14% of our total outstanding shares.

The Merger was accounted for under the purchase method of accounting and was treated as a reverse acquisition because the shareholders of TCA owned the majority of our common stock after the Merger. TCA was deemed the acquirer for accounting and financial reporting purposes. Accordingly, all financial information prior to 2001 included in this report reflects TCA's results.

Due to the nature of the reverse acquisition, Thoratec's assets and liabilities were recorded based upon estimated fair values at the date of acquisition. As of December 29, 2001, \$309.1 million of the purchase price of \$346.2 million has been allocated to goodwill and other purchased intangible assets. As a result of the Merger, \$76.9 million relating to in-process research and development was expensed upon completion of the Merger. Through the end of 2001, goodwill and other intangibles were amortized over their estimated useful lives of six to twenty years. Beginning in 2002, we adopted Statement of Financial Accounting Standards, or SFAS, No. 142, Goodwill and Other Intangible Assets. SFAS No. 142 requires companies to cease amortizing goodwill that existed at June 30, 2001 and also establishes a new method of testing goodwill for impairment on an annual basis or on an interim basis if an event occurs or circumstances change that would

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reduce the fair value of a reporting unit below its carrying value. As such, at the beginning of 2002, we stopped amortizing goodwill and began testing goodwill for impairment under the new standard. If impairment occurs, such impairment could harm our future results of operations. We expect that the adoption of SFAS No. 142 will result in a decrease in goodwill amortization of approximately \$5.0 million in 2002.

Pursuant to the terms of a Registration Rights Agreement between us and Thermo Electron dated October 3, 2000, we filed a Registration Statement on Form S-3 with the SEC, which became effective on June 15, 2001, to register for resale 4,828,240 shares of our common stock held by Thermo Electron. Subsequent to that filing, Thermo Electron sold substantially all of the 4,828,240 registered shares from which we received no proceeds. We filed another Registration Statement on Form S-3 with the SEC to register 1,055,000 newly issued shares of our common stock and to register for resale 5,945,000 shares of our common stock held by selling shareholders, of which 5,825,000 shares were held by Thermo Electron. This registration statement became effective on February 12, 2002 and all shares registered were sold on February 15, 2002. We received \$16.1 million, net of underwriting fees and discounts, but before other expenses of the offering, from the sale of the 1,055,000 newly issued shares. In addition the underwriters exercised a 30-day option to purchase from Thermo Electron 1,050,000 shares of our common stock to cover any over-allotments. We received no proceeds from the sale of shares by selling shareholders or from the sale of the over-allotment shares. As of the date of this report, Thermo Electron owns approximately 14% of our total outstanding common stock.

## **Restructuring Plan**

In June 2001, we approved a plan to consolidate all of our ventricular assist device manufacturing operations to our manufacturing facilities and headquarters in Pleasanton, California, which we call the Restructuring Plan. The restructuring initiatives, which have already commenced, are related to our desire to provide maximum value to customers through achievement of operating efficiencies. We estimate that annual savings of approximately \$2.0 million will result upon completion of this plan. This plan specifically provides for the reduction of approximately 90 of our manufacturing and related workforce at our Woburn and Chelmsford, Massachusetts facilities, both of which were acquired in the Merger in February 2001. We notified the affected employees during the second quarter of 2001 both through direct personal contact and written notification. The Chelmsford facility was closed in February 2002. Our HeartMate family of products, which are currently manufactured at the Woburn facility, will be transitioned to the Pleasanton facility. The restructuring activities are estimated to take 18 months because of FDA certification requirements for the relocated manufacturing operations in Pleasanton. Through December 29, 2001, we have accrued \$1.1 million of restructuring charges, in accordance with Emerging Issues Task Force (EITF) 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity, and Staff Accounting Bulletin (SAB) 100, Restructuring and Impairment Charges. These charges represent estimated severance costs and stock option acceleration charges. As of December 29, 2001, we have paid approximately \$0.1 million in severance payments to 2 employees related to the restructuring. We expect to pay out the remaining accrued restructuring charges by the end of 2002.

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

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

	Fiscal Year		
	2001	2000	1999
Product sales	100%	100%	100%
Cost of product sales	47	42	42
Gross profit	53	58	58
Operating expenses:			
Selling, general & administrative	29	28	28
Research & development	19	20	21
Amortization of goodwill and purchased intangible assets	14		
In-process research and development	68		
Merger, restructuring and other costs	6	2	
Total operating expenses	136	50	49
Income (loss) from operations	(83)	8	9
Interest and other income net	2	6	5
Income (loss) before income taxes and extraordinary item	(81)	14	14
Income tax expense (benefit)	(3)	5	4
Income (loss) before extraordinary item	(78)	9	10
Extraordinary item net of tax			2
Net income (loss)	(78)%	9%	12%

**Fiscal Years 2001 and 2000****Product Sales**

Product sales in 2001 were \$113.4 million compared to \$83.4 million in 2000, an increase of \$30.0 million or 36%. This increase was primarily attributable to the addition of Thoratec product sales of \$34.7 million as a result of our Merger and an increase in other medical equipment sales of \$1.2 million, partially offset by a \$5.9 million reduction in sales of HeartMate products due primarily to significant distractions and uncertainties among TCA's sales force during the first and second quarters of 2001 while the Merger was being closed and the companies were being integrated.

The impact of the reduction in HeartMate sales was principally in the VAD domestic market because we use employees to sell these products domestically compared to the international markets where distributors are primarily used. Domestic sales of the HeartMate in 2001 were \$7.4 million lower than the previous year, partially offset by a \$1.5 million increase in sales of the HeartMate internationally. The decrease in domestic HeartMate sales in 2001 was also attributable, in part, to fluctuations in the ventricular assist device market as customers used existing inventories to address their implantation needs.

The increase in sales of other medical equipment of \$1.2 million was primarily due to increases in sales of our ProTime products of \$1.4 million and coagulation products of \$0.5 million, partially offset by a decrease in sales of our skin incision products of \$0.7 million.

***Gross Profit***

Gross profit in 2001 was \$60.5 million, or 53% of product sales, compared to \$48.6 million, or 58% of product sales in 2000. This decrease in gross profit as a percentage of sales was primarily due to a lower proportion of domestic sales to total product sales as our products that are sold in the United States generally

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have a higher gross profit than those sold in the rest of the world. In addition, production costs for the HeartMate product line were higher in 2001 due to \$1.4 million of employee retention and plant relocation costs and \$0.4 million of write-offs of product inventory related to the HeartMate pneumatic driver, which was discontinued in the second half of 2001.

In addition, approximately 1% of our decrease in gross profit as a percentage of sales was attributable to a lower gross profit on our other medical equipment product line. This decrease was primarily due to lower average selling prices of our skin incision products because of increased market competition.

***Selling, General and Administrative***

Selling, general, and administrative expenses in 2001 were \$32.3 million, or 29% of product sales, compared to \$23.6 million, or 28% of revenues, in 2000, an increase of \$8.7 million, or 37%. This increase resulted from the addition of Thoratec's selling, general and administrative expenses of \$12.0 million as a result of our Merger, offset by lower employee related expenses due to personnel reductions primarily in the sales and marketing areas since the Merger.

***Research and Development***

Research and development expenses in 2001 were \$22.1 million, or 20% of product sales, compared to \$16.2 million, or 19% of product sales, in 2000, an increase of \$5.9 million, or 36%. This increase resulted from the addition of Thoratec's research and development expenses of \$8.0 million as a result of our Merger, offset by a decrease in clinical trial and other costs related to the TLC-II, Aria graft and REMATCH trials and various other research and development projects.

***Amortization of Goodwill and Purchased Intangible Assets***

Amortization of goodwill and purchased intangible assets in 2001 was \$15.7 million, or 14% of product sales. As of December 29, 2001, goodwill of \$99.5 million and intangible assets of \$209.6 million have been recorded as a result of our Merger and are being amortized over their estimated useful lives of six to twenty years. Beginning in 2002, we have stopped amortizing goodwill in accordance with SFAS No. 142, which requires companies to cease amortizing goodwill that existed as of June 30, 2001 and begin evaluating goodwill for impairment. We expect that the adoption of SFAS No. 142 will result in a decrease in goodwill amortization of approximately \$5.0 million in 2002.

***In-process Research and Development Costs***

In-process research and development expense in 2001 was \$76.9 million, or 68% of product sales, and represents the one-time write-off of nonrecurring charges associated with our Merger in February 2001 for technology that had not reached technological feasibility, had no alternative future use and for which successful development was uncertain.

The valuation of intangibles related to the Merger was based upon our management's estimates of after tax net cash flow using discount rates ranging from 42% to 48%. The valuation gave consideration to the following: (i) comprehensive due diligence concerning all potential intangibles; (ii) the value of developed and core technology, ensuring that the relative allocation to core technology and in-process research and development was consistent with the contribution of each to the final products; and (iii) the allocation to in-process research and development based upon a calculation that only considered the efforts completed as of the date of the Merger, and only the cash flows associated with the completion or acceleration of existing products. The valuations were performed by an independent valuation group and were deemed reasonable in light of all the quantitative and qualitative information available.

There have been no significant developments subsequent to the Merger related to the current status of any of the in-process research and development, or IPR&D, projects that would result in material changes to the assumptions or resulting valuation performed at the time of the Merger. Development of IPR&D products continues and while the timing of completion of these projects may vary due to the highly regulatory and

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technical nature of our products, current estimates remain materially consistent with our initial estimates. The current status of each IPR&D project follows:

### ***Thoratec VAD (Discharge and Therapeutic Recovery)***

We continue to participate in various studies designed to demonstrate the Thoratec VAD's role to provide ventricular assistance in patients after they have been discharged from the hospital and as a support to recovery of the heart from open-heart surgery, acute cardiac failure and various infections of the heart muscle. Cost projections for this project are consistent with initial estimates. At the time of the Merger, the estimated cost to complete the studies was approximately \$2.3 million. We hope to complete these studies and obtain approval from the FDA in 2002.

### ***TLC-II Driver***

The TLC-II Driver received FDA approval in 2001.

### ***IVAD***

Conditional approval to start IVAD clinical trials in the U.S. has been received from the FDA and cost projections are consistent with initial estimates. At the time of the Merger, the estimated cost to complete this project was approximately \$2.5 million. We hope that the IVAD will be approved by the FDA in 2003.

### ***Aria Graft***

Clinical trials for the Aria graft are ongoing and cost projections are consistent with initial estimates. At the time of the Merger, the estimated cost to complete the Aria graft was approximately \$4.7 million. We hope that the Aria graft will be completed and approved by the FDA in 2004.

There can be no assurances that we will be able to complete the development of these products on a timely basis. Failure to complete these projects could have an adverse impact on our financial condition or results of operations.

### ***Merger, Restructuring and Other Costs***

Merger, restructuring and other charges in 2001 were \$7.1 million, or 6% of product sales, compared to \$1.8 million, or 2% of product sales, in 2000, an increase of \$5.3 million, or 290%. The \$7.1 million of merger, restructuring and other charges included merger related costs consisting mainly of employee severance of \$2.8 million, executive waiver agreement costs of \$0.7 million, consulting, accounting and legal expenses of \$1.8 million, restructuring costs of \$1.1 million, representing estimated severance costs related to the consolidation of ventricular assist device manufacturing operations, and costs of \$0.7 million related to the events of September 11, 2001. Merger, restructuring and other costs for 2000 consisted of pre-merger retention costs for TCA employees of \$1.8 million.

### ***Interest and Other Income Net***

Interest and other income net in 2001 was \$2.4 million, or 2% of product sales, compared to \$5.0 million, or 6% of product sales, in 2000, a decrease of \$2.6 million, or 52%. This decrease was due to a \$2.5 million reduction in interest income caused by both lower cash balances and a reduction in interest rates.

### ***Income Taxes***

Our effective tax benefit rate was 4% in 2001 compared to an effective tax provision rate of 39% in 2000. Our effective tax benefit rate for 2001 differed from the statutory federal income tax rate primarily due to the impact on the reported net loss of nondeductible expenses related to our Merger with TCA, including the write-off of IPR&D costs, the amortization of goodwill and other nondeductible merger transaction costs. For





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2000, the effective tax provision rate exceeded the federal statutory income tax rate primarily due to the impact of state income taxes.

***Extraordinary Item***

We recorded an extraordinary gain of \$0.2 million as a result of our purchase of a portion of our 4.75% subordinated convertible debentures. There was no extraordinary item in 2001.

**Fiscal Years 2000 and 1999**

***Product Sales***

Product sales in 2000 were \$83.4 million compared to \$78.6 million in 1999, an increase of \$4.8 million or 6%. Ventricular assist device revenues increased to \$43.1 million in 2000 from \$39.8 million in 1999, due to an increase in revenues from our HeartMate products, principally due to higher demand. Product sales from blood coagulation testing and skin incision devices increased to \$40.3 million in 2000 from \$38.8 million in 1999 due to a \$2.0 million increase in revenues from blood coagulation testing systems due to increased demand and the introduction of new products, offset in part by a decrease in revenues from skin incision devices due to lower demand caused by competitive pricing pressures.

***Gross Profit***

Gross profit in 2000 was \$48.6 million, or 58% of product sales, compared to \$45.3 million, or 58% of product sales in 1999. An increase in the average sales price for the HeartMate and improved overhead absorption were offset by a decrease in gross profit margin for blood coagulation testing and skin incision devices during 2000.

***Selling, General and Administrative***

Selling, general, and administrative expenses in 2000 were \$23.6 million, or 28% of product sales, compared to \$22.0 million, or 28% of revenues, in 1999, an increase of \$1.6 million or 7%. This increase was due to an increase in selling and marketing expenses in support of increased product sales.

***Research and Development***

Research and development expenses in 2000 were \$16.2 million, or 20% of product sales, compared to \$16.0 million, or 21% of product sales, in 1999, an increase of \$0.2 million or 1%. This increase was due to increased expenses relating to ventricular assist products for the development of the HeartMate II and continuing expenses related to the REMATCH trial.

***Merger, Restructuring and Other Costs***

Merger, restructuring and other charges in 2000 were \$1.8 million, or 2% of product sales. All merger, restructuring and other charges were due to employee retention costs in connection with the Merger. There were no such charges in 1999.

***Interest and Other Income Net***

Interest and other income net in 2000 was \$5.0 million, or 6% of product sales, compared to \$4.0 million, or 5% of product sales, in 1999, an increase of \$1.0 million or 25%. Interest income increased to \$7.6 million in 2000 from \$7.1 million in 1999, due to an increase in interest rates. Interest expense decreased to \$2.9 million in 2000 from \$3.6 million in 1999, due to the purchase of \$15.2 million principal amount of our 4.75% subordinated convertible debentures due 2004.

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### ***Income Taxes***

The effective tax rate in 2000 was 39% compared to 26% in 1999. Our effective tax rate exceeded the statutory federal income tax rate in 2000 due to the impact of state income taxes. Our effective tax rate was lower than the statutory federal income tax rate in 1999 as a result of a favorable resolution of our claim for prior-year research and development tax credits. The effect of the credit decreased the tax provision recorded in 1999 by \$1.5 million.

### ***Extraordinary Item***

We recorded extraordinary gains of \$0.2 million and \$1.2 million in 2000 and 1999, respectively, resulting from the purchase of a portion of our 4.75% subordinated convertible debentures.

## **Liquidity and Capital Resources**

At the end of 2001, we had working capital of \$135.9 million compared with \$149.2 million at the end of 2000, a decrease of \$13.3 million. Cash and cash equivalents at the end of 2001 were \$91.7 million compared to \$128.9 million at the end of 2000, a decrease of \$37.2 million. The 2001 statement of cash flows was prepared by combining TCA's balance sheet as of December 2000 with Thoratec's balance sheet as of the Merger date of February 14, 2001, and comparing it to the consolidated balance sheet as of December 29, 2001, which included both entities.

Cash used by operating activities was \$3.1 million in 2001, compared with cash provided of \$8.7 million in 2000 and \$6.7 million in 1999. The decrease in operating cash flows was due to higher accounts receivable and lower accounts payable and other liabilities balances as a result of the addition of Thoratec's operations as of the merger date.

Cash provided by investing activities was \$55.3 million in 2001, compared with cash provided of \$23.4 million in 2000 and cash used of \$37.3 million in 1999. The increase in cash flows was due to the sale and maturity of \$52.8 million in short-term investments, and cash acquired in the Merger of \$16.2 million, offset by transaction costs of \$5.8 million capitalized in conjunction with the Merger and capital expenditures of \$7.9 million. Cash used for capital expenditures in 2001 increased to \$7.9 million from \$2.4 million in 2000 and \$2.5 million in 1999. The higher level of capital expenditures in 2001 was due primarily to the acquisition of a new enterprise resource planning system and research and development equipment.

Cash provided by financing activities was \$9.4 million in 2001, compared to cash used of \$2.3 million in 2000 and \$11.0 million in 1999. The increase in cash flows in 2001 was due to cash received from the exercise of stock options of \$11.1 million, offset by stock repurchases of \$1.7 million. In 2000 and 1999, we repurchased \$2.8 million and \$10.0 million in principle of our subordinated convertible debentures. No subordinated convertible debentures were repurchased in 2001.

During 2001, we made cash payments of \$11.8 million for merger, restructuring and other costs. These payments consisted mainly of employee retention and severance costs, legal, banking and accounting costs related to the Merger. During 2001, prior to the Merger, TCA incurred \$5.8 million of merger costs, consisting principally of banking, legal and accounting costs, which were paid and capitalized in the purchase consideration (now a component of goodwill).

On April 12, 2001, we announced a stock repurchase program under which up to \$20 million in market value of our common stock may be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of purchases is based on several conditions, including the price of our stock, general market conditions and other factors. Through December 29, 2001, \$1.7 million in common stock was repurchased, representing 192,700 shares. These repurchased shares were subsequently retired.

Pursuant to the terms of a Registration Rights Agreement between us and Thermo Electron dated October 3, 2000, we filed a Registration Statement on Form S-3 with the SEC, which became effective on June 15, 2001, to register for resale 4,828,240 shares of our common stock held by Thermo Electron.

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Subsequent to that filing, Thermo Electron sold substantially all of the 4,828,240 registered shares from which we received no proceeds. We filed another Registration Statement on Form S-3 with the SEC to register 1,055,000 newly issued shares of our common stock and to register for resale 5,945,000 shares of our common stock held by selling shareholders, of which 5,825,000 shares were held by Thermo Electron. This registration statement became effective on February 12, 2002 and all shares registered were sold on February 15, 2002. We received \$16.1 million, net of underwriting fees and discounts, but before other expenses of the offering, from the sale of the 1,055,000 newly issued shares. In addition the underwriters exercised a 30-day option to purchase from Thermo Electron 1,050,000 shares of our common stock to cover any over-allotments. We received no proceeds from the sale of shares by selling shareholders or from the sale of these over-allotment shares. As of the date of this report, Thermo Electron owns approximately 14% of our total outstanding common stock.

On January 23, 2002, we announced a plan to redeem at par value all outstanding 4.75% convertible subordinated debentures due 2004, which were originally issued by TCA. We completed the redemption on March 11, 2002 using our restricted cash and cash equivalents of \$45.9 million and cash of \$9.8 million. We will record an extraordinary loss in the first quarter of 2002 related to the write-off of capitalized debt issuance costs associated with the initial issuance of the debentures, which were being amortized over the life of the debentures. As of December 29, 2001, the remaining balance of capitalized debt issuance costs was \$0.5 million.

We believe that cash on-hand, proceeds from our stock offering and expected cash flows from operations will be sufficient to fund our operations and capital requirements for the foreseeable future. We expect that our operating expenses will increase in future periods as we spend more on product manufacturing, marketing, and research and development of new product lines as well as incur substantial costs associated with the consolidation of our VAD manufacturing operations.

The impact of inflation on our financial position and the results of operations was not significant during either 2001 or 2000.

## **Critical Accounting Policies**

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 is discussed below. For a more detailed discussion on the application of these and other accounting policies, see the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K. The 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.

### ***Merger Accounting***

On February 14, 2001, Thoratec completed its Merger with TCA. Pursuant to the Merger agreement between Thoratec and TCA, Thoratec issued new shares of its common stock to the shareholders of TCA in exchange for all the outstanding common stock of TCA. Immediately following the transaction, TCA's shareholders owned 59% of the then outstanding common stock of Thoratec and the former Thoratec shareholders owned the remaining shares of Thoratec common stock. The merger was treated as a reverse acquisition because the shareholders of TCA owned the majority of Thoratec common stock after the Merger. TCA was considered the acquiror for accounting and financial reporting purposes. The Merger was accounted for under the purchase method of accounting. Under that method, the fair market value of the outstanding Thoratec common stock, determined using volume-weighted average stock trading prices beginning two days before and ending two days after the announcement of the merger, was used to establish the purchase price for accounting purposes. Due to the reverse acquisition, Thoratec's assets and liabilities were recorded based upon their estimated fair values at the date of acquisition. The fair value of Thoratec's net assets have been estimated for purposes of allocating the purchase price. The purchase price is also allocated to intangible

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assets, including goodwill. As of December 29, 2001, approximately \$309.1 million of the total purchase price of \$346.2 million has been allocated to goodwill and other purchased intangibles. The determination of the value of such intangible assets requires management to make estimates and assumptions that affect our consolidated financial statements. The amounts allocated to goodwill and other intangible assets will affect the amount of amortization expense we recognize in future periods and could result in a possible impairment expense if at some future date such assets were determined to be impaired.

As a result of the Merger, \$76.9 million relating to in-process research and development, or IPR&D, has been expensed in the first quarter of 2001. The write-off of IPR&D related to projects that were in development, had not reached technological feasibility, had no alternative future use and for which successful development was uncertain. There have been no significant developments subsequent to the Merger related to the current status of any of the IPR&D projects that would result in material changes to the assumptions or resulting valuation performed at the time of the Merger. Development of IPR&D projects continues and while the timing of completion of these projects may vary due to the highly regulatory and technical nature of the Company's products, current estimates remain materially consistent with the Company's initial estimates.

### ***Revenue Recognition***

The Company recognizes revenue from product sales provided persuasive 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. Estimated contractual warranty obligations are recorded when related sales are recognized. Sales to distributors are recorded when title transfers upon shipment. One distributor has certain limited product return rights. A limited number of other distributors have certain rights of return upon termination of their distribution agreement. A reserve for sales returns is recorded for these customers applying reasonable estimates of product returns based upon significant historical experience in accordance with SFAS No. 48, *Revenue Recognition When Right of Return Exists*. No other direct sales customers or distributors have return rights or price protection.

Sales of certain Cardiovascular segment products to first-time customers are recognized when it has been determined that the customer has the ability to use such products. These sales frequently include the sale of products and training services under multiple element arrangements. For most customers, training is not essential to the functionality of the products as the customers already possess sufficient expertise and experience to use the products. In these situations, training is provided as a best practice to optimize the use and success of the products. The amount of sales under these arrangements allocated to training is based upon fair market value of the training, performed principally by third party providers. The amount of sales allocated to the Cardiovascular segment products is done on a residual method basis. Under this method, the total value of the arrangement is allocated first to the undelivered training element based on the fair market value, with the remainder being allocated to the Cardiovascular segment products. The amount of sales allocated to training is recorded as deferred revenue and is recognized when the training is completed.

Certain judgments affect the application of our revenue recognition policies. Revenue results and product returns are difficult to predict, and any shortfall in revenue or delay in recognizing revenue could cause our operating results to vary significantly from quarter to quarter and could result in future operating results.

### ***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.

We write down our inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by our management, additional inventory write-downs may be required.

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Accrued merger costs recorded during 2001 and 2000 principally consisted of employee severance, pre-merger employee retention costs, and outside consulting, accounting and legal expenses associated with our Merger. Early in 2000, Thermo Electron announced its intent to sell TCA. In conjunction with this announcement, TCA put in place an employee retention plan, which offered a bonus to certain key employees to continue employment with TCA through the completion of the sale of the company. Management estimated the accrual for employee severance and employee retention costs based upon amounts to be paid as specified in agreements with the employees and anticipated turnover rates. Management estimated the accrual for outside consulting, accounting and legal expenses based on estimated fees from the third parties. The ultimate amount of merger costs to be paid is dependent upon the completion of all merger-related activities and could differ from the amounts originally estimated.

In June 2001, we approved a Restructuring Plan to consolidate all of our ventricular assist device manufacturing operations to our manufacturing facilities and headquarters in Pleasanton, California. Through December 29, 2001, we have accrued \$1.0 million of restructuring charges in accordance with Emerging Issues Task Force 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity and Staff Accounting Bulletin 100, Restructuring and Impairment Charges. These charges represent estimated severance costs. The Restructuring Plan is estimated to take 18 months because of FDA certification requirements for the new manufacturing activities in Pleasanton. Substantially all of the milestones related to the relocation that are controllable by us will be completed within 12 months of the date of announcement. Because our products are regulated by the FDA, it is estimated it will take an additional six months to complete the FDA review and certification process before the HeartMate products can be manufactured in Pleasanton. We believe we can make reasonable estimates of the involuntary employee termination benefits since we have specifically identified the employees that will be involuntarily terminated as well as the benefits that each affected employee will receive. We do not believe there are likely to be any developments during the intervening 18 months required to relocate the manufacturing operations, which would have a significant impact on our original restructuring cost estimates. Although the relocation plan has been documented, in detail, small changes in the timing of specific activities are expected. The impact on the estimate for these changes is not expected to be material.

***Commitments***

As of December 29, 2001, we have the following outstanding commitments:

*Subordinated Convertible Debt* In May 1997, we issued \$70 million worth of 4.75% subordinated convertible debentures due May 2004. Interest is payable semi-annually in November and May of each year. The outstanding debentures are convertible into our common stock at a price of \$37.62 per share. To date, no debentures have been exchanged for shares. On January 23, 2002, we announced a plan to redeem all of the outstanding subordinated debentures at par plus accrued interest. We completed the redemption on March 11, 2002 using our restricted cash and cash equivalents of \$45.9 million and cash of \$9.8 million. We will record an extraordinary loss in the first quarter of 2002 related to the write-off of capitalized debt issuance costs associated with the initial issuance of the debentures, which were being amortized over the life of the debentures. As of December 29, 2001, the remaining balance of capitalized debt issuance costs was \$0.5 million.

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*Leases* The Company leases manufacturing, office, research facilities, and equipment under various operating lease agreements. Future minimum lease payments as of the end of 2001 are noted below:

<b>Fiscal year:</b>		
2002	\$ 1.7	million
2003	1.6	million
2004	1.3	million
2005	1.2	million
2006	1.2	million
Thereafter	9.7	million
<hr/>		
Total	\$ 16.7	million

Rent expense for all operating leases was \$1.8 million in 2001, \$0.6 million in 2000 and \$0.5 million in 1999.

Included in these leases is a sublease of office and research facilities from Thermo Electron. We are charged for actual square footage occupied at approximately the same rent paid per square foot by Thermo Electron under its prime lease. The sublease expires in February 2004. Our statements of income include expenses from the sublease of \$0.2 million for each of 2001, 2000 and 1999, respectively.

Future minimum annual payments due under these noncancellable sublease arrangements at December 29, 2001, are \$0.2 million in 2002 and 2003 and \$32,000 in 2004.

*Purchase Commitments* We had various firm purchase commitments totaling approximately \$13.0 million at December 29, 2001.

We purchase metal fabrication products and services from Tecomet, Inc. in connection with the manufacture of the ventricular-assist products we sell. Tecomet was a division of Thermo Electron until November 15, 2001 when it was sold by Thermo Electron to an unrelated third party. We paid \$2.9 million \$3.3 million and \$3.7 million to Tecomet in 2001, 2000 and 1999, respectively.

*Other Commitments* Upon closing the Merger with TCA in February 2001, \$45 million in cash and cash equivalents was pledged as collateral for a letter of credit guarantee to Thermo Electron Corporation related to Thermo Electron's guarantee of our subordinated debentures. This letter of credit is fully collateralized with cash and cash equivalents, which are recorded in restricted cash and cash equivalents on our 2001 balance sheet. The balance of the restricted cash and cash equivalents as of December 29, 2001 was \$45.9 million, which includes interest earnings. In March 2002, all of the subordinated debentures were redeemed using the restricted cash and cash equivalents and \$9,793,000 of additional cash (see Note 7 to our 2001 consolidated financial statements). As a result of the redemption, the letter of credit guarantee to Thermo Electron was extinguished.

In July 1998, we established an Executive Officer Severance Benefits Plan and an Employee Severance Benefits Plan as part of the employee benefits package. The plans provide severance benefits to certain employees whose employment is terminated, other than for cause. An Executive Officer's standard severance pay benefit is equal to one times annualized base salary. An employee's severance benefit is equal to an amount based on job level and length of service.

**Recent Accounting Pronouncements**

In June 2001, the Financial Accounting Standards Board, or FASB, approved SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 prohibits the pooling of interests method of accounting for business combinations initiated after June 30, 2001. SFAS No. 142, which is effective for fiscal years beginning after December 15, 2001, requires companies to cease amortizing goodwill that existed at June 30, 2001 and establishes a new method of testing goodwill and intangibles for impairment. Allocations made to certain intangible assets and goodwill, as well as the useful

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lives assigned to intangible assets in the TCA merger will be re-assessed. We have adopted SFAS No. 141 and 142 effective the beginning of 2002. We expect that the adoption of SFAS No. 142 will result in a decrease in goodwill amortization of \$5.0 million in 2002. Amortization of goodwill was \$4.4 million for the year ended December 29, 2001. Amortization of purchased intangibles was \$11.3 million for the year ended December 29, 2001.

To test goodwill for impairment under the new standard, we will establish reporting units to which assets, liabilities and goodwill will be allocated. Goodwill will be tested for impairment on an annual basis or on an interim basis if an event occurs or circumstances change that could reduce the fair value of the reporting unit below its carrying amount. Impairment tests will be performed using the lower of cost or market, purchase price allocation two-step approach. The first step requires comparison of the fair value of the reporting unit to its carrying amount. If the fair value of a reporting unit is less than its carrying amount, the second step is performed which requires allocation of the fair value of the reporting unit to the assets, liabilities and goodwill of that unit as if the unit had been acquired in a business combination and the fair value of the reporting unit determined in step 1 was the price paid to acquire the reporting unit. Goodwill is considered to be impaired to the extent that the amount allocated to goodwill in the hypothetical purchase price allocation is below the carrying amount of the goodwill. If an impairment occurs it will be included in income from operations and could have a negative impact on our future results of operations.

In June 2001, the FASB issued SFAS No. 143, *Accounting for Asset Retirement Obligations*. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs, including legal obligations. We are required to adopt SFAS No. 143 at the beginning of fiscal year 2003. The impact of the adoption of SFAS No. 143 is currently being evaluated by the Company.

In October 2000, the FASB approved SFAS No. 144, *Accounting for the Impairment of Long-Lived Assets*. This Statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This Statement supersedes FASB Statement No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of*, and the accounting and reporting provisions of APB Opinion No. 30, *Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*, for the disposal of a segment of a business (as previously defined in that Opinion). This Statement also amends ARB No. 51, *Consolidated Financial Statements*, to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary. The Company will adopt this Standard at the beginning of fiscal year 2002. We do not expect the adoption of SFAS No. 144 to have a material impact on our financial position, results of operations or cash flows.

### **Item 7A. *Quantitative and Qualitative Disclosures About Market Risk***

#### **Subordinated Debentures**

Our subordinated debentures carry a fixed rate of interest of 4.75% and are currently callable at par value. At December 29, 2001, the fair value of our subordinated debentures was \$52.9 million and is estimated based on broker information available to us for debentures with similar terms and remaining maturities. We believe the fair value of our subordinated debentures is below our carrying value due primarily to a lack of liquidity in the market for these types of subordinated debentures and the current price of our common stock being below the stated conversion price of the debentures.

On January 23, 2002, we announced a plan to redeem at par value all outstanding 4.75% convertible subordinated debentures due 2004, which were originally issued by TCA. We completed the redemption on March 11, 2002 using our restricted cash and cash equivalents of \$45.9 million and cash of \$9.8 million. We will record an extraordinary loss in the first quarter of 2002 related to the write-off of capitalized debt issuance costs associated with the initial issuance of the debentures, which were being amortized over the life of the debentures. As of December 29, 2001, the remaining balance of capitalized debt issuance costs was \$0.5 million.



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**Short-Term Investments**

We do not use derivative financial instruments for speculative or trading purposes. However, we are exposed to market risk related to changes in interest rates. Our investment portfolio at the end of 2001 consisted of short-term state and municipal government bonds and money market funds that are classified as cash and cash equivalents and have maturities of three months or less. The fair market value of these investments will fall if market interest rates increase. If market interest rates were to increase by 10% from levels at December 29, 2001, the fair market value of our investment portfolio would decline by an immaterial amount.

**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. The employees 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. The resulting translation adjustments are included in comprehensive income. The period-end translation of the non-functional currency balances (the result of foreign sales, foreign expenses, and intercompany transactions) in our wholly-owned subsidiary in the United Kingdom at the period-end exchange rate into the functional currency of our subsidiary results in foreign currency exchange gains and losses. These foreign currency exchange gains and losses are included in interest and other income-net. Net foreign currency exchange loss was approximately \$0.1 million for 2001. There were no such gains or losses in 2000 as Thoratec's United Kingdom subsidiary did not become part of our operations until completion of our Merger on February 14, 2001. Currently, we do not expect to be subject to material foreign currency risk with respect to future costs or cash flows from our foreign operations. To date, we have not entered into any significant foreign currency hedging contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange, however, we are currently evaluating possible future use of such contracts and instruments.

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**Item 8. *Financial Statements and Supplementary Data***

**THORATEC CORPORATION AND SUBSIDIARIES**

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**INDEPENDENT AUDITORS REPORT**

To the Shareholders and Board of Directors of

Thoratec Corporation:

We have audited the accompanying consolidated balance sheet of Thoratec Corporation and subsidiaries (the Company) as of December 29, 2001 and the related consolidated statements of operations, comprehensive income (loss), shareholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Thoratec Corporation and subsidiaries as of December 29, 2001 and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California

February 21, 2002,  
(March 11, 2002 as to Note 7)

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**REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

To the Shareholders and Board of Directors of Thoratec Corporation:

We have audited the accompanying consolidated balance sheet of Thoratec Corporation (formerly Thermo Cardiosystems Inc., a Massachusetts corporation and 60%-owned subsidiary of Thermo Electron Corporation) and subsidiaries as of December 30, 2000, and the related consolidated statements of income, cash flows, and comprehensive income and shareholders' investment for each of the two years in the period ended December 30, 2000. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Thoratec Corporation (formerly Thermo Cardiosystems Inc.) and subsidiaries as of December 30, 2000, and the results of their operations and their cash flows for each of the two years in the period ended December 30, 2000, in conformity with accounting principles generally accepted in the United States.

/s/ ARTHUR ANDERSEN LLP

Boston, Massachusetts  
February 5, 2001

Table of Contents**THORATEC CORPORATION AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

	As of Fiscal Years	
	2001	2000
(In thousands)		
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 91,726	\$ 30,236
Short-term available-for-sale investments at quoted market value, amortized cost of \$98,743 in 2000		98,682
Receivables, net of allowances of \$551 in 2001 and \$939 in 2000	26,988	15,358
Inventories	25,673	17,381
Deferred tax asset	11,789	3,454
Prepaid expenses and other	788	74
	<u>          </u>	<u>          </u>
Total current assets	156,964	165,185
Property, plant and equipment, net	22,645	7,084
Restricted cash and cash equivalents	45,884	
Goodwill	95,209	
Purchased intangible assets	198,608	
Long-term deferred tax asset	9,313	2,619
Other assets	1,618	1,797
	<u>          </u>	<u>          </u>
Total Assets	\$530,241	\$ 176,685
	<u>          </u>	<u>          </u>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 8,271	\$ 3,972
Accrued compensation	6,481	3,999
Accrued merger and restructuring	1,335	1,708
Estimated liabilities for warranty, legal and other	1,781	1,316
Other accrued liabilities	3,172	4,983
	<u>          </u>	<u>          </u>
Total current liabilities	21,040	15,978
Subordinated convertible debentures	54,838	54,838
Long-term deferred tax liability and other	81,020	
	<u>          </u>	<u>          </u>
Total Liabilities	156,898	70,816
Commitments		
Shareholders' equity:		
Common shares; 100,000 authorized, issued and outstanding 56,114 in 2001 and 32,215 in 2000	409,081	49,125
Deferred compensation	(4,555)	(251)
Retained earnings (accumulated deficit)	(31,166)	57,025
Accumulated other comprehensive income (loss):		
Unrealized loss on investments		(39)
Cumulative translation adjustments	(17)	9
	<u>          </u>	<u>          </u>
Total accumulated other comprehensive loss	(17)	(30)
	<u>          </u>	<u>          </u>

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Total Shareholders	Equity	373,343	105,869
		<u>          </u>	<u>          </u>
Total Liabilities and Shareholders	Equity	\$530,241	\$176,685
		<u>          </u>	<u>          </u>

See notes to consolidated financial statements.

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

	For the Fiscal Years Ended		
	2001	2000	1999
	(In thousands, except per share data)		
Product sales	\$ 113,384	\$ 83,396	\$ 78,611
Cost of product sales	52,840	34,830	33,326
Gross profit	60,544	48,566	45,285
Operating expenses:			
Selling general and administrative	32,346	23,587	22,018
Research and development	22,082	16,190	16,044
Amortization of goodwill and purchased intangible assets	15,674		
In-process research and development	76,858		
Merger, restructuring and other costs	7,134	1,831	
Total operating expenses	154,094	41,608	38,062
Income (loss) from operations	(93,550)	6,958	7,223
Interest and other income net	2,359	5,005	4,014
Income (loss) before taxes and extraordinary item	(91,191)	11,963	11,237
Income tax expense (benefit)	(3,325)	4,630	2,865
Income (loss) before extraordinary item	(87,866)	7,333	8,372
Extraordinary item net of tax		191	1,212
Net income (loss)	\$ (87,866)	\$ 7,524	\$ 9,584
Basic and diluted earnings (loss) per share	\$ (1.68)	\$ 0.23	\$ 0.30
Shares used to compute earnings (loss) per share:			
Basic	52,336	32,193	32,100
Diluted	52,336	32,209	32,132

See notes to consolidated financial statements.

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**THORATEC CORPORATION AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

	<b>For the Fiscal Years Ended</b>		
	<b>2001</b>	<b>2000</b>	<b>1999</b>
	<b>(In thousands)</b>		
Net income (loss)	\$(87,866)	\$7,524	\$9,584
Other net comprehensive income (loss):			
Unrealized gain (loss) on securities	39	299	(458)
Foreign currency translation adjustments	(26)	(38)	18
Comprehensive income (loss)	\$(87,853)	\$7,785	\$9,144

See notes to consolidated financial statements.



**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY**

	Common Stock		Retained Earnings	Deferred	Accumulated Other	Total
	Shares	\$	(Accumulated Deficit)	Compensation	Comprehensive Inc (Loss)	Shareholders Equity
(In thousands)						
BALANCE, FISCAL YEAR ENDED 1998	32,139	\$ 48,649	\$ 39,917	\$	\$ 149	\$ 88,715
Exercise of common stock options for cash	7	49				49
Common stock issued under restricted common stock award	56	625		(625)		
Activity under employees and directors stock plans	14	(145)				(145)
Repurchase of common stock	(88)	(925)				(925)
Deferred compensation amortization				104		104
Other comprehensive income:						
Unrealized loss on available-for-sale investments, net of reclassification adjustment					(458)	(458)
Foreign currency translation adjustment					18	18
Net income			9,584			9,584
BALANCE, FISCAL YEAR ENDED 1999	32,128	\$ 48,253	\$ 49,501	\$ (521)	\$ (291)	\$ 96,942
Exercise of common stock options for cash	44	266				266
Exercise of common stock warrant for cash	50	350				350
Tax benefit related to employees and directors stock plans		319				319
Activity under employees and directors stock plans	(5)	19				19
Termination of restricted common stock award	(2)	(82)		82		
Amortization of deferred compensation				188		188
Other comprehensive income:						
Unrealized gain on available-for-sale investments, net of reclassification adjustment					299	299
Foreign currency translation adjustment					(38)	(38)
Net income			7,524			7,524
BALANCE, FISCAL YEAR ENDED 2000	32,215	\$ 49,125	\$ 57,025	\$ (251)	\$ (30)	\$ 105,869
Common stock issued in connection with merger of Thoratec and Thermo Cardiosystems	22,452	306,889		(841)		306,048

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Common Stock options granted for Thermo Cardiosystems merger		33,524				33,524
Common stock issued for services	12	136				136
Non-cash compensation for services		166				166
Exercise of common stock options for cash	1,378	11,077				11,077
Tax benefit related to employees and directors stock plans		5,402				5,402
Common stock issued under restricted common stock award	250	4,140		(4,140)		
Repurchase of common stock	(193)	(1,378)	(325)			(1,703)
Amortization of deferred compensation				677		677
Other comprehensive income:						
Unrealized gain on available-for-sale investments, net of reclassification adjustment					39	39
Foreign currency translation adjustment					(26)	(26)
Net Income (Loss)			(87,866)			(87,866)
BALANCE, FISCAL YEAR ENDED 2001	56,114	\$409,081	\$(31,166)	\$(4,555)	\$ (17)	\$373,343

See notes to consolidated financial statements.

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For the Fiscal Years Ended		
	2001	2000	1999
	(In thousands)		
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$(87,866)	\$ 7,524	\$ 9,584
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	19,845	2,840	2,880
Write-off of in-process research and development costs	76,858		
Non-cash compensation expense	303		
Amortization of deferred compensation	677	270	104
Change in net deferred tax liability	(2,993)		(780)
Gain on sale of investments		(3)	
Extraordinary item, net of taxes		(191)	(1,212)
Changes in assets and liabilities:			
Receivables	(5,892)	(1,000)	(2,132)
Inventories	(560)	(2,444)	(3,012)
Prepaid expenses and other assets	814	(7)	640
Accounts payable and other liabilities	(4,326)	1,745	589
	<u>(3,140)</u>	<u>8,734</u>	<u>6,661</u>
<b>Cash flows from investing activities:</b>			
Repayments from affiliate, net		13,961	(13,961)
Purchases of short-term available-for-sale investments		(120,002)	(160,722)
Sales and maturities of short-term available-for-sale investments	52,838	131,802	139,943
Capitalized transaction costs	(5,838)		
Purchases of equipment and improvements	(7,947)	(2,360)	(2,540)
Cash and equivalents acquired in business acquisition	16,199		
	<u>55,252</u>	<u>23,401</u>	<u>(37,280)</u>
<b>Cash flows from financing activities:</b>			
Common stock issued upon exercise of options	11,077	601	193
Payment of withholding taxes related to stock option exercises		(47)	(290)
Repurchase of common stock	(1,703)		(925)
Repurchase of convertible debentures		(2,825)	(9,985)
	<u>9,374</u>	<u>(2,271)</u>	<u>(11,007)</u>
Effect of exchange rate changes on cash and cash equivalents	4	(46)	18
	<u>61,490</u>	<u>29,818</u>	<u>(41,608)</u>
Cash and cash equivalents at beginning of period	30,236	418	42,026
	<u>\$ 91,726</u>	<u>\$ 30,236</u>	<u>\$ 418</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for taxes	\$ 470	\$ 4,691	\$ 4,670

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Cash paid for interest	\$ 2,604	\$ 2,918	\$ 3,382
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Supplemental disclosure of noncash investing and financing activities:</b>			
Issuance of restricted stock for services	\$ 4,140	\$	\$ 625
	<u>          </u>	<u>          </u>	<u>          </u>
Cash reclassified to restricted cash and cash equivalents	\$ 45,884	\$	\$
	<u>          </u>	<u>          </u>	<u>          </u>
Tax benefit related to stock option exercises	\$ 5,402	\$ 319	\$
	<u>          </u>	<u>          </u>	<u>          </u>

See notes to consolidated financial statements

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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Operations and Significant Accounting Policies**

*Operations* Thoratec Corporation (the Company) is headquartered in Pleasanton, California and is a leading manufacturer of circulatory support products for use by patients with congestive heart failure. The Company develops, manufactures and markets products that are used by physicians and hospitals for cardiac assist, vascular and diagnostic applications. The Company organizes and manages its business by functional operating entities, which operate in two business segments: ventricular-assist products and grafts ( Cardiovascular, formerly known as VAD/graft ) and Other Medical Equipment. The Company's Cardiovascular segment develops, manufactures and markets proprietary medical devices used for circulatory support and vascular graft applications. The Company's Other Medical Equipment segment develops, manufactures and markets near-patient, whole-blood coagulation testing equipment and related disposables, as well as premium quality, single-use skin incision devices. The Company conducts business both domestically and internationally. In February 2001, the Company merged with Thermo Cardiosystems, Inc. ( TCA ) (Note 2). Prior to the merger (the Merger ), TCA was a subsidiary of Thermo Electron Corporation ( Thermo Electron ).

*Fiscal Year* The Company reports on a 52-53 week fiscal year, which ends on the Saturday closest to December 31. The fiscal years ended January 1, 2000, ( 1999 ), December 30, 2000, ( 2000 ), and December 29, 2001, ( 2001 ), all included 52 weeks.

*Principles of Consolidation* The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

*Use of Estimates* The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

*Major Customers and Concentration of Credit Risk* The Company primarily sells its products to large hospitals and distributors in the United States and Europe. For fiscal years 2001, 2000 and 1999, one distributor customer accounted for 12%, 17% and 21% of total product sales, respectively. Accounts receivable for this same distributor customer accounted for 8% and 13% of total accounts receivable as of the end of 2001 and 2000, respectively. No other customer accounted for more than 10% of total product sales in 2001, 2000 or 1999 or had an accounts receivable balance greater than 10% of total accounts receivable at the end of 2001 or 2000.

Credit is extended based on an evaluation of a customer's financial condition and generally collateral is not required. To date, credit losses have not been significant, however, the Company maintains allowances for potential credit losses.

Additionally, the Company is potentially subject to concentrations of credit risk in its investments. To mitigate this credit risk, the Company invests in high-grade instruments, which it places with high quality financial institutions.

*Certain Risks and Uncertainties* The Company is subject to certain risks and uncertainties and believes that changes in any of the following areas could have a material adverse effect on the Company's future financial position or results of operations: the ability to achieve or maintain profitability; the integration of TCA, including the ability to complete the relocation of its ventricular assist device ( VAD ) manufacturing operations from Woburn, Massachusetts to Pleasanton, California, or any other future acquisitions; the ability to manage current and future growth; stock price volatility due to general economic conditions or future issuances and sales of Company stock; foreign currency fluctuations; new product development and introduction, including Food and Drug Administration ( FDA ) approval and market receptiveness; the long and

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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

variable sales and deployment cycle of the Company's VAD systems; the ability to protect the Company's proprietary technologies or an infringement of others' patents; competition from other products; worldwide demand for circulatory support and graft products and blood coagulation testing and skin incision devices; product liability or other claims; the ability to obtain timely deliveries of parts from suppliers; the reliance on specialized suppliers; the ability to manufacture products on an efficient and timely basis and at a reasonable cost and in sufficient volume; the dependence upon distributors; the ability of third party payors to provide appropriate levels of reimbursement for the Company's products; the ability to attract and retain talented employees; the occurrence of natural catastrophic disasters; the ability to realize the full value of our intangible assets; and other risks as detailed from time to time in the Company's filings with the Securities and Exchange Commission (SEC).

*Cash and Cash Equivalents* Cash and cash equivalents include cash on deposit of \$5,758,000 and money market securities and municipal government auction bonds of \$85,968,000 in 2001 and commercial paper in 2000 of \$29,117,000 with original maturities of three months or less. Cash equivalents are carried at cost, which approximates market value.

*Short-Term Available-For-Sale Investments* The Company's short-term investments are classified as available-for-sale and reported at fair market value. Net unrealized gains and losses are excluded from earnings and reported as a separate component of shareholders' equity. As of the end of 2000, short-term investments were comprised primarily of government agency securities and corporate bonds having maturity of one year or less from the date of investment.

*Inventories* Inventories are stated at the lower of first-in, first-out cost or market.

*Property, Plant and Equipment* Property, plant and equipment are stated at cost. Depreciation is computed using the straight-line method based on estimated useful lives of 2 to 30 years. Leasehold improvements are amortized over the lesser of the useful life or the remaining term of the lease. Property, plant and equipment includes certain medical devices rented to customers on a short-term or long-term basis. Amortization expense of all rental equipment included in the Company's rental program is recognized ratably over 2 to 4 years and is recorded in cost of product sales.

The Company reviews for the impairment of long-lived assets whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. An impairment loss would be recognized when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposal is less than carrying amount.

*Capitalized Software Costs* The Company capitalizes the costs of computer software developed or obtained for internal use in accordance with Statement of Position 98-1, Accounting for the Costs of Computer Software Developed or Obtained for Internal Use. Capitalized computer software costs consist of purchased software licenses, implementation costs and consulting for certain projects that qualify for capitalization. The Company expenses costs related to preliminary project assessment, research and development, re-engineering, training and application maintenance as incurred. Costs capitalized as of 2001 and 2000 were \$2,416,000 and nil, respectively. For each of 2001, 2000 and 1999, no depreciation has been charged, as the related computer software systems have not yet been placed into service. The capitalized software costs will be depreciated on a straight-line method over a period of eight years upon being placed in service.

*Restricted Cash and Cash Equivalents* Upon closing the Merger with TCA in February 2001, \$45,000,000 in cash and cash equivalents was pledged as collateral for a letter of credit guarantee to Thermo Electron related to Thermo Electron's guarantee of the Company's subordinated debentures (Note 7). Accordingly, these cash and cash equivalents have been reclassified to restricted cash and cash equivalents on the Company's 2001 balance sheet. The balance of these restricted cash and cash equivalents as of December 29, 2001 was \$45,884,000, which includes interest earnings.

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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Purchased Intangible Assets and Goodwill* Purchased intangible assets are recorded at their fair market value as of the date of acquisition and amortized on a straight-line basis over their estimated useful lives of up to 20 years. Through 2001, goodwill was amortized on a straight-line basis over its useful life of 20 years. Beginning in 2002, amortization of goodwill was ceased in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 142, Goodwill and Other Intangible Assets. Accumulated amortization on purchased intangible assets and goodwill totaled \$15,674,000 and nil at the end of 2001 and 2000, respectively.

*Other Assets* Other assets principally include deposits on the Company s building leases and interest earned on those deposits, long-term prepaid software maintenance contracts and patents and trademarks associated with the Company s Other Medical Equipment segment. The patents and trademarks are amortized on a straight-line basis over their estimated useful life of twenty years. At the end of 2001 and 2000, accumulated amortization of the patents and trademarks was \$324,000 and \$287,000, respectively.

*Income Taxes* In accordance SFAS No. 109, Accounting for Income Taxes, the Company recognizes deferred income taxes based on the expected future tax consequences of differences between the financial statement basis and the tax basis of assets and liabilities, calculated using enacted tax rates in effect for the year in which the differences are expected to be reflected in the tax return.

*Fair Value of Financial Instruments* Financial instruments include cash and cash equivalents, customer receivables, accounts payable, certain other accrued liabilities and subordinated convertible debentures. The fair value of the subordinated convertible debentures was \$52,900,000 at December 29, 2001 and is estimated based on broker information available to the Company for debentures with similar terms and maturities. We believe the fair value of the Company s subordinated debentures is below the carrying value due primarily to a lack of liquidity in the market for these types of subordinated debentures and the current price of the Company s common stock being below the stated conversation price of the debentures. The carrying amounts of all other items are a reasonable estimate of their fair values.

*Foreign Currency Translation* All assets and liabilities of the Company s non-United States operations are translated into United States dollars at period-end exchange rates, and the resulting translation adjustments are included in comprehensive income. Income items are translated at actual or average monthly rates of exchange. Exchange rate fluctuations resulting from the period-end translation of the current portion of the intercompany obligation of the Company s wholly-owned subsidiary into United States dollars are recorded in the statements of operations as foreign currency translation gains or losses and are included in interest and other income-net.

*Repurchases of Common Stock* On April 12, 2001 the Company s board of directors authorized a stock repurchase program under which up to \$20,000,000 of the Company s common stock may be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of purchases is based on several conditions, including the price of Thoratec stock, general market conditions and other factors. For each share repurchased, the Company reduces the common stock account by the average value per share reflected in the account prior to the repurchase with the excess allocated to retained earnings. The Company retires all shares repurchased.

*Revenue Recognition and Product Warranty* The Company recognizes revenue from product sales provided persuasive 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. Estimated contractual warranty obligations are recorded when related sales are recognized. Sales to distributors are recorded when title transfers upon shipment. One distributor has certain limited product return rights. A limited number of other distributors have certain rights of return upon termination of their distribution agreement. A reserve for sales returns is recorded for these customers applying reasonable estimates of product returns based upon significant historical experience in accordance with SFAS

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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

No. 48, Revenue Recognition when Right of Return Exists. No other direct sales customers or distributors have return rights or price protection.

Sales of certain Cardiovascular segment products to first-time customers are recognized when it has been determined that the customer has the ability to use such products. These sales frequently include the sale of products and training services under multiple element arrangements. For most customers, training is not essential to the functionality of the products as the customers already possess sufficient expertise and experience to use the products. In these situations, training is provided as a best practice to optimize the use and success of the products. The amount of revenues under these arrangements allocated to training is based upon fair market value of the training, performed principally by third party providers. The amount of revenues allocated to the Cardiovascular segment products is done on a residual method basis. Under this method, the total value of the arrangement is allocated first to the undelivered training element based on the fair market value, with the remainder being allocated to the Cardiovascular segment products. The amount of revenues allocated to training is recorded as deferred revenue and is recognized when the training is completed. As of the end of 2001, \$1,093,000 of products have been delivered and recorded as product sales for customers that were determined to be able to use those products, but for which training had not yet been completed. The amount of revenue deferred related to this training not yet completed was \$38,000 at the end of 2001. As of the end of 2000 and 1999, all training related to product sales had been completed.

The Company also rents certain medical devices to customers on a month-to-month or as-used basis. Rental income is based on utilization and is included in product sales as earned. Included in product sales for 2001, 2000 and 1999 are \$3,456,000, \$2,724,000 and \$1,958,000, respectively, of income earned from the rental of these medical devices.

Revenues and profits on long-term research and development contracts are recognized using the percentage-of-completion method and recorded as interest and other income net. Revenues recorded under the percentage-of-completion method were nil, \$306,000 and \$479,000 in 2001, 2000 and 1999, respectively. The percentage-of-completion is determined by relating the actual costs incurred to date to management's estimate of total costs to be incurred on each contract. If a loss is indicated on any contract in process, a provision is made currently for the entire loss. Contracts generally provide for the billing of customers on a cost-plus-fixed-fee basis as costs are incurred.

*Accounting for Stock-Based Compensation* The Company accounts for stock-based awards to employees using the intrinsic value method in accordance with Accounting Principals Board Opinion No. 25, Accounting for Stock Issued to Employees. Proforma disclosures of net earnings and earnings per share consistent with the method of SFAS No. 123, Accounting for Stock-Based Compensation are included in Note 9.

*Earnings (Loss) Per Share* Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted earnings (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock. Diluted loss per share for 2001 excludes any effect from such securities as their inclusion would be antidilutive (see Note 16). Therefore, diluted loss per share is the same as basic loss per share for 2001.

*Comprehensive Income (Loss)* Comprehensive income (loss) includes net income (loss) and is defined as the change in net assets during the period from non-owner sources, including unrealized gains and losses on investments and foreign currency translation adjustments.

*Recently Issued Accounting Standards* The Company adopted SFAS No. 133, Accounting for Derivative Instruments and for Hedging Activities, in the first quarter of fiscal 2001. SFAS No. 133, as amended, requires the Company to recognize all derivative instruments on the balance sheet at fair value. The gains or losses resulting from changes in the fair value of derivative instruments are recognized in current



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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

earnings. The Company's adoption of SFAS No. 133, as amended, did not have any impact on its consolidated financial position, results of operations or cash flows.

In June 2001, the Financial Accounting Standards Board ( FASB ) approved SFAS No. 141, Business Combinations, and SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 141 prohibits the pooling of interests method of accounting for business combinations initiated after June 30, 2001. SFAS No. 142, which is effective for fiscal years beginning after December 15, 2001, requires companies to cease amortizing goodwill that existed at June 30, 2001 and establishes a new method of testing goodwill and intangibles for impairment. The Company has adopted SFAS No. 141 and 142 effective the beginning of 2002 and expects that the adoption of SFAS No. 142 will result in a decrease in goodwill amortization of \$5,000,000 in 2002. Amortization of goodwill was \$4,353,000 for the year ended December 29, 2001. Amortization of purchased intangibles was \$11,321,000 for the year ended December 29, 2001.

To test goodwill for impairment under the new standard, the Company will establish reporting units to which assets, liabilities and goodwill will be allocated. Goodwill will be tested for impairment on an annual basis or on an interim basis if an event occurs or circumstances change that could reduce the fair value of the reporting unit below its carrying amount. Impairment tests will be performed using the lower of cost or market, purchase price allocation two-step approach. The first step requires comparison of the fair value of the reporting unit to its carrying amount. If the fair value of a reporting unit is less than its carrying amount, the second step is performed which requires allocation of the fair value of the reporting unit to the assets, liabilities and goodwill of that unit as if the unit had been acquired in a business combination and the fair value of the reporting unit determined in step 1 was the price paid to acquire the reporting unit. Goodwill is considered to be impaired to the extent that the amount allocated to goodwill in the hypothetical purchase price allocation is below the carrying amount of the goodwill. If an impairment occurs it will be included in income from operations.

In June 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. SFAS No. 143 addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs, including legal obligations. The Company is required to adopt SFAS No. 143 at the beginning of fiscal year 2003. The impact of the adoption of SFAS No. 143 is currently being evaluated by the Company.

In October 2000, the FASB approved SFAS No. 144, Accounting for the Impairment of Long-Lived Assets. This Statement addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This Statement supersedes FASB Statement No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and the accounting and reporting provisions of Accounting Principles Board ( APB ) Opinion No. 30, Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business (as previously defined in that Opinion). This Statement also amends Accounting Research Board No. 51, Consolidated Financial Statements, to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary. The Company will adopt this Standard at the beginning of fiscal year 2002. The Company does not expect the adoption of SFAS No. 144 to have a material impact on its financial position, results of operations or cash flows.

*Presentation* Certain 2000 and 1999 amounts have been reclassified to conform to the presentation in the 2001 financial statements.

**2. Merger of Thoratec and TCA**

On February 14, 2001, Thoratec completed its Merger with TCA. Pursuant to the Merger agreement between Thoratec and TCA dated October 3, 2000, Thoratec issued 32,226,074 new shares of its common

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

stock to the shareholders of TCA in exchange for all the outstanding common stock of TCA (38,594,281 shares outstanding as of February 14, 2001) at an exchange ratio of 0.835 shares of Thoratec stock for each share of TCA stock. Immediately following the transaction, TCA's shareholders owned 59% of the then outstanding common stock of Thoratec and the former Thoratec shareholders owned the remaining shares of Thoratec common stock. Thermo Electron, the majority shareholder of TCA prior to the Merger, received 19,312,959 shares of the 32,226,074 newly issued shares. Immediately following the Merger, Thermo Electron owned 35% of the then outstanding common stock of Thoratec. Pursuant to the terms of a Registration Rights Agreement between the Company and Thermo Electron dated October 3, 2000 (Registration Rights Agreement), the Company filed a Registration Statement on Form S-3 with the SEC, which became effective on June 15, 2001, to register for resale 4,828,240 shares of the Company's common stock held by Thermo Electron. Subsequent to that filing, Thermo Electron sold substantially all of the 4,828,240 registered shares. The Company filed another Registration Statement on Form S-3 with the SEC to register 1,055,000 newly issued shares of its common stock and to register for resale 5,945,000 shares of the Company's common stock held by selling shareholders, of which 5,825,000 shares were held by Thermo Electron. This registration statement became effective on February 12, 2002 and all shares registered were subsequently sold. The Company received \$16,120,000, net of underwriting fees and discounts, but before other expenses of the offering, from the sale of the 1,055,000 newly issued shares. In addition, the underwriters exercised a 30-day option to purchase from Thermo Electron 1,050,000 additional shares of the Company's common stock to cover any over-allotments. The Company received no proceeds from the sale of shares by selling shareholders or from the sale of the over-allotment shares. Subsequent to the sale of these shares, Thermo Electron owned approximately 14% of the Company's total outstanding common stock.

The Merger was accounted for under the purchase method of accounting and was treated as a reverse acquisition because the shareholders of TCA owned the majority of Thoratec common stock after the Merger. TCA was considered the acquiror for accounting and financial reporting purposes. Due to the reverse acquisition, Thoratec's assets and liabilities were recorded based upon their estimated fair values at the date of acquisition. The consolidated financial information for 2000 and 1999 includes the results of operations of TCA. The operating results of Thoratec have been included in the accompanying consolidated financial statements from the date of acquisition forward. All reported amounts of outstanding common shares and common share equivalents (stock options and convertible debentures) prior to the Merger have been adjusted to reflect the exchange ratio of 0.835 to 1. As of December 29, 2001, approximately \$309,076,000 of the total purchase price of \$346,193,000 has been allocated to goodwill and other purchased intangible assets.

As a result of the Merger, \$76,858,000 relating to in-process research and development (IPR&D) was expensed in the first quarter of 2001. The write-off of IPR&D related to projects that were in development, had not reached technological feasibility, had no alternative future use and for which successful development was uncertain. There have been no significant developments subsequent to the Merger related to the current status of any of the IPR&D projects that would result in material changes to the assumptions or resulting valuation performed at the time of the Merger. Development of IPR&D projects continues and while the timing of completion of these projects may vary due to the highly regulatory and technical nature of the Company's products, current estimates remain materially consistent with the Company's initial estimates.

The current status of each IPR&D project follows:

***Thoratec VAD (Discharge and Therapeutic Recovery)***

The Company continues to participate in various studies designed to demonstrate the Thoratec VAD's role to provide ventricular assistance in patients after they have been discharged from the hospital and as a support to recovery of the heart from open-heart surgery, acute cardiac failure and various infections of the heart muscle. Cost projections for this project are consistent with initial estimates. At the time of the Merger, the estimated cost to complete the studies was approximately \$2.3 million. The Company hopes to complete these studies and obtain approval from the FDA in 2002.

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****TLC-II Driver***

The TLC-II Driver received FDA approval in 2001.

***IVAD***

Conditional approval to start IVAD clinical trials in the U.S. has been received from the FDA and cost projections are consistent with initial estimates. At the time of the Merger, the estimated cost to complete this project was approximately \$2.5 million. The Company hopes that the IVAD will be approved by the FDA in 2003.

***Aria Graft***

Clinical trials for the Aria graft are ongoing and cost projections are consistent with initial estimates. At the time of the Merger, the estimated cost to complete the Aria graft was approximately \$4.7 million. The Company hopes that the Aria graft will be completed and approved by the FDA in 2004.

There can be no assurances that the Company will be able to complete the development of these products on a timely basis. Failure to complete these projects could have an adverse impact on the Company's financial condition or results of operations.

In connection with the Merger, five-year warrants to purchase 164,400 shares of Thoratec stock issued in 1996 were canceled pursuant to the original terms of the warrants.

The fair value of Thoratec's net assets have been estimated for purposes of allocating the purchase price. The purchase price and allocation of purchase price as of December 29, 2001 are summarized as follows (in thousands):

Purchase price:	
Common stock	\$ 306,889
Stock options	33,524
Transaction costs	5,780
	<hr/>
Total purchase price	\$ 346,193
	<hr/>
Allocation of purchase price:	
Tangible assets acquired (primarily cash and cash equivalents, receivables, inventory, and equipment and improvements)	\$ 41,018
Fair market valuation of property lease	2,285
Deferred tax asset	4,332
Deferred compensation	841
Intangible net assets acquired:	
Patents, trademarks and tradenames, purchased technology and assembled workforce	209,572
Goodwill	99,504
In-process research and development	76,858
Liabilities assumed	(10,824)
Deferred tax liability	(77,393)
	<hr/>
Total	\$ 346,193
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**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The unaudited consolidated results of operations on a pro forma basis as if the Merger had occurred as of the beginning of the periods presented are as follows (in thousands):

	Fiscal Year		
	2001	2000	1999
Revenue	\$ 116,908	\$ 113,825	\$ 101,119
Net loss(a)	\$ (90,902)	\$ (8,341)	\$ (4,438)
Net loss per share basic and diluted	\$ (1.65)	\$ (0.15)	\$ (0.08)

- (a) Included in 2001 and 2000 are \$7,753,000 and \$6,000,000 of merger and restructuring costs, respectively (Note 15). Included in each of 2001, 2000 and 1999 is \$17,877,000 of amortization of goodwill and purchased intangibles. Included in 2001 only is \$76,858,000 of write-off of in-process research and development.

The pro forma financial information is presented for informational purposes only and is not indicative of the operating results that would have occurred had the merger been consummated as of the above dates, nor are they necessarily indicative of future operating results.

At the time of the Merger, the Company recorded a liability for the estimated costs associated with evaluating and restructuring its product distribution networks. Negotiations with the distributors were ongoing throughout 2001 and adjustments to the estimated distributor contract restructuring costs have been reflected as adjustments to the purchase price allocation.

**3. Investments*****Short-Term Available-For-Sale Investments***

The Company's short-term investments are considered available-for-sale investments in the accompanying balance sheet and are carried at fair value with the difference between cost and fair value, net of related tax effects, recorded in the accumulated other comprehensive items component of the consolidated statements of shareholders' equity. The Company classifies investments that mature in less than one year of purchase date as short-term investments. The accompanying 2000 balance sheet includes \$98,237,000 with contractual maturities of one year or less and \$445,000 with contractual maturities of more than five years through ten years. Actual maturities may differ from contractual maturities as a result of the Company's intent to sell these securities prior to maturity.

The aggregate market value, cost basis and gross unrealized gains and losses of short-term available-for-sale investments for 2000 by major security type are as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Fiscal 2000				
Government-agency securities	\$92,724	\$ 18	\$ (98)	\$92,644
Corporate bonds	4,989	2		4,991
Other	1,030	62	(45)	1,047
	<u>\$98,743</u>	<u>\$ 82</u>	<u>\$(143)</u>	<u>\$98,682</u>

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The cost of available-for-sale investments that were sold was based on specific identification in determining realized gains and losses recorded in the accompany statement of income. Gains and losses on sale of investments resulted in a realized gain of \$3,000 in 2000 relating to the sale of available-for-sale investments.

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. Inventories**

Inventories consist of the following (in thousands):

	Fiscal Year	
	2001	2000
Finished goods	\$ 15,276	\$ 3,177
Work-in-process	4,322	10,261
Raw materials	6,075	3,943
	<u>          </u>	<u>          </u>
Total	\$ 25,673	\$ 17,381
	<u>          </u>	<u>          </u>

**5. Property, Plant and Equipment**

Property, plant, and equipment consist of the following (in thousands):

	Fiscal Year	
	2001	2000
Land	\$ 341	\$ 341
Building	2,445	2,445
Building lease	2,285	
Equipment	20,409	17,518
Rental drivers	4,653	1,762
Leasehold improvements	7,360	1,162
Construction in progress	4,057	539
	<u>          </u>	<u>          </u>
Total	41,550	23,767
Accumulated depreciation and amortization	(18,905)	(16,683)
	<u>          </u>	<u>          </u>
	\$ 22,645	\$ 7,084
	<u>          </u>	<u>          </u>

Included in construction in progress for 2001 was \$2,416,000 related to the purchase of a new Enterprise Resource Planning System.

**6. Leases**

The Company leases manufacturing, office, research facilities, and equipment under various operating lease agreements. Future minimum lease payments as of the end of 2001 are noted below (in thousands):

<b>Fiscal year:</b>	
2002	\$ 1,677
2003	1,550

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2004	1,326
2005	1,229
2006	1,227
Thereafter	9,655
	<hr/>
Total	\$ 16,664
	<hr/>

Rent expense for all operating leases was \$1,778,000 in 2001, \$623,000 in 2000 and \$481,000 in 1999.



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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. Subordinated Convertible Debentures**

In May 1997, the Company issued \$70,000,000 worth of 4.75% subordinated convertible debentures due May 2004. Interest is payable semi-annually in November and May of each year. The outstanding debentures are convertible into Company stock at a price of \$37.62 per share. To date, no debentures have been exchanged for shares. At the issuance date, \$1,972,000 in costs related to the issuance of the debentures was capitalized and is being amortized to interest expense over the life of the debentures.

As of December 29, 2001, the outstanding principal balance of the debentures is \$54,838,000 reflecting repurchases in the open market from time to time. During 2001 there were no such repurchases. During 2000, the Company purchased \$3,173,000 principal amount of the debentures for \$2,825,000 in cash, resulting in an extraordinary gain of \$191,000, net of taxes of \$117,000.

Upon closing the Merger with TCA in February 2001, \$45,000,000 in cash and cash equivalents was pledged as collateral for a letter of credit guarantee to Thermo Electron Corporation related to Thermo Electron's guarantee of the Company's subordinated debentures. This letter of credit is fully collateralized with restricted cash and cash equivalents of \$45,884,000 as of December 29, 2001.

On January 23, 2002, the Company announced a plan to redeem all of the outstanding subordinated debentures at par plus accrued interest. The redemption was completed on March 11, 2002 using restricted cash and cash equivalents of \$45,884,000 and cash of \$9,793,000. An extraordinary loss will be recorded in the first quarter of 2002 related to the write-off of capitalized debt issuance costs associated with the initial issuance of the debentures, which were being amortized over the life of the debentures. As of December 29, 2001, the remaining balance of capitalized debt issuance costs was \$530,000. As a result of the redemption, the letter of credit guarantee to Thermo Electron was extinguished.

**8. Common and Preferred Stock and Warrants**

The Company has authorized 100,000,000 no par common shares, and 2,500,000 shares of preferred stock, of which 540,541 shares have been designated Series A and 500,000 shares designated Series B.

The Series A preferred stock is entitled to cumulative annual dividends of \$1.30 per share and has a liquidation preference of \$9.25 per share plus cumulative unpaid dividends. The Company may redeem the Series A preferred stock at any time for its liquidation preference. Each share of preferred stock is convertible into one-third of a share of common stock, after adjusting for earned but unpaid dividends. At December 29, 2001, no shares of Series A preferred stock were outstanding.

The Series B preferred stock is senior to the Series A in all preferences. Series B is entitled to cumulative annual dividends of \$0.96 per share and has a liquidation preference of \$8.00 per share plus cumulative unpaid dividends. The Series B preferred stock is redeemable by the company five years after its issuance for \$8.00 per share plus cumulative unpaid dividends. Each share of Series B preferred stock is convertible at any time into three and one-third shares of common stock and has certain anti-dilution provisions. Series B preferred vote on an as-converted basis. At December 29, 2001, no shares of Series B preferred stock were outstanding.

The Company filed a Registration Statement on Form S-3 with the SEC to register for sale 1,055,000 newly issued shares of the Company's common stock and 5,945,000 shares held by selling shareholders, of which 5,825,000 shares were held by Thermo Electron. This Registration Statement became effective February 12, 2002, and all of the registered shares were subsequently sold. The Company received \$16.1 million, net of underwriting discounts and fees, but before other expenses of the offering, from the sale of the 1,055,000 newly issued shares. In addition, the underwriters exercised a 30-day option to purchase from Thermo Electron 1,050,000 shares of common stock to cover any over-allotments. The Company received no proceeds from the sale of these over-allotment shares.

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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In 2001, an award of 250,000 shares of restricted common stock was made to a Company executive under the Company's 1997 Stock Option Plan. The stock award was valued at \$4,140,000 and recorded as deferred compensation to be amortized to expense over the restriction lapse period. As of December 29, 2001, none of the restrictions have lapsed for shares issued under this award.

**9. Stock-Based Compensation**

Historically, TCA had a variety of stock-based compensation plans for employees and directors that allowed the granting of options, stock, and stock-based awards. There were no grants under any of TCA's plans during 2001. Pursuant to the terms of the Thoratec and TCA Merger agreement, all TCA stock-based compensation plans were assumed by Thoratec effective February 14, 2001. Moreover, all outstanding options and restrictions on past TCA grants were accelerated and became fully vested as of the Merger date of February 14, 2001 and were converted to 971,222 Thoratec common stock options at the Merger conversion ratio of 0.835 to 1. Although assumed by Thoratec, the TCA stock options remain exercisable upon the same terms and conditions as under the TCA stock option plan pursuant to which it was granted and the applicable option agreement.

TCA's prior stock option plans are summarized below:

Prior to the Merger, TCA maintained stock-based compensation plans for its key employees, directors and others. Two of these plans permitted the granting of non-qualified and incentive stock options. Two other plans permitted the granting of a variety of stock and stock-based awards as determined by the human resources committee of TCA's Board of Directors (the Board Committee). Generally, options granted under these plans were exercisable immediately, but were subject to certain transfer restrictions and the right of TCA to repurchase shares issued upon exercise of the options at the exercise price, upon certain events. The restrictions and repurchase rights generally lapsed ratably over a one- to ten-year period, depending on the term of the option, which ranged from five to twelve years. Nonqualified options were granted at any price determined by the Board Committee, although incentive stock options were granted at not less than the fair market value of the TCA's stock on the date of grant. TCA also had a directors' stock option plan that provided for the grant of stock options to outside directors pursuant to a formula approved by TCA's shareholders. Options awarded under this plan were exercisable six months after the date of the grant and expired three or seven years after the date of the grant. In addition to TCA's stock-based compensation plans, certain officers and key employees also participated in the stock-based compensation plans of Thermo Electron and Thermedics, a subsidiary of Thermo Electron at the time.

In June 1999, TCA awarded 67,000 shares of its restricted common stock to certain key employees. The shares had an aggregate value of \$625,000 and vest three years from the date of award, assuming continued employment, with certain exceptions. TCA recorded the fair value of the restricted stock as deferred compensation in 1999 and was amortizing such amount over the vesting period. At the time of the Merger in February 2001, all options became fully vested, all restrictions on the restricted stock awards lapsed and all unamortized deferred compensation was expensed.

Substantially all of TCA's full-time employees were eligible to participate in an employee stock purchase plan program sponsored by TCA and Thermo Electron. Under this program, shares of TCA's and Thermo Electron's common stock were able to be purchased at 85% of the lower of the fair market value at the beginning or end of the period, and shares purchased were subject to a one-year resale restriction. Shares were purchased through payroll deductions of up to 10% of each participating employee's gross wages. During 2000 and 1999, TCA issued 17,800 and 9,100 shares, respectively, of its common stock under this program. The employee stock purchase plan was canceled effective November 2000.

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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The stock-based compensation plans placed in effect after the Merger and post-merger activity under these plans are summarized as follows:

In 1993, the Directors approved the 1993 Stock Option Plan ( 1993 SOP ), which permits the Company to grant options to purchase up to 666,667 shares of common stock. No options were granted under this plan in 2001.

In 1996, the Directors adopted the 1996 Stock Option Plan ( 1996 SOP ) and the 1996 Non-employee Directors Stock Option Plan ( Directors Option Plan ). The 1996 SOP consists of two parts. Part One permits the Company to grant options to purchase up to 500,000 shares of common stock. During 2001 no options were granted at fair market value under Part One of the 1996 SOP. Part Two related to the Chief Executive Officer ( CEO ) and permitted the Company to grant non-qualified options to the CEO to purchase up to 333,333 shares of common stock. During 1996, 333,333 options were granted at fair market value under Part Two of the 1996 SOP. The Directors Option Plan was amended by approval by a vote of the Company s shareholders in May 1999 for all option grants going forward. The amendments include increasing the number of shares granted to the Board of Directors in the initial grants from 10,000 to 15,000 shares (granted in four equal installments, once when elected to the Board then quarterly thereafter), and the annual grants from 5,000 to 7,500 shares (granted in four equal installments after re-election). Provisions were also made for immediate vesting of both initial and annual grants, and for changing the term of the options from ten to five years. In addition, the number of shares reserved for issuance under the Directors Option Plan was increased from 150,000 to 350,000 and the plan administrator has been provided with the discretion to impose any repurchase rights in favor of the Company on any optionee. The Company currently has seven non-employee directors, six of whom are eligible to participate in the Directors Option Plan. During 2001 45,000 options were granted at fair market value under the Directors Option Plan.

In 1997, the Directors adopted the 1997 Stock Option Plan ( 1997 SOP ). The 1997 SOP was amended by approval of a vote of the Company s shareholders in February 2001 and amended again by the Board of Directors in December 2001. During 2001, 3,863,112 options were granted at fair market value under this plan. As of December 30, 2000, prior to the February amendment, 365,091 options remained available for grant under this plan. The amendment increased the number of shares of the Company s common stock reserved for issuance of options and share awards granted under this plan by 6,400,000. This increase was to enable the Company to assume the options to purchase shares of TCA common stock that were outstanding upon the closure of the Merger and exchange them for options to purchase Thoratec common stock, as well as to grant additional shares over time after the Merger to an expanded employee base.

Including the 1993 SOP, the 1996 SOP, the Directors Option Plan, the 1997 SOP, and several older plans, the Company had seven common stock option plans with options still outstanding at December 29, 2001. Options may be granted by the Board of Directors at the fair market value on the date of grant. Options generally become exercisable within five years of grant and expire between five and ten years from the date of grant. At December 29, 2001, options to purchase 3,349,916 common shares remain available for grant under all the plans.

Agreements have been entered into with selected consultants whereby options to purchase the Company s common stock were accepted by these consultants as full or partial payment for the services rendered to the Company. The fair market value of the consulting services is the basis for recording the transaction in the Company s financial records and is recognized as the related services are performed. No options were issued under these agreements in 2001.

The Company applies APB Opinion 25 and related Interpretations in accounting for its employee stock-based compensation plans. 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 credited to equity. If compensation cost for the Company s stock-based plans had been determined based on the fair

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

value at the grant dates for awards under those plans, consistent with the method of FASB Statement 123, the Company's reported net income (loss) would have been adversely affected, as shown by the pro forma amounts indicated in the following table (in thousands, except per share data):

	Fiscal Year		
	2001	2000	1999
Net income (loss):			
As reported	\$(87,866)	\$ 7,524	\$9,584
Pro forma	\$(96,475)	\$ 16,187	\$7,209
Basic and diluted earnings (loss) per share:			
As reported	\$ (1.68)	\$ 0.23	\$ 0.30
Pro forma	\$ (1.84)	\$ 0.19	\$ 0.22

The fair value of each option granted is estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions used for grants made:

	Fiscal Year		
	2001	2000	1999
Risk-free interest rate	5.08%	4.90%	5.60%
Expected volatility	71%	61%	54%
Expected option life	2.85 years	4.8 years	3.1 years
Dividends	None	None	None

Stock option activity is summarized as follows (in thousands, except per share data):

	Number of Options	Weighted Average Exercise Price
Outstanding at fiscal year end 1998		
(1,222 exercisable at \$16.72 weighted average price per share)	1,226	\$ 16.75
Granted (\$4.56 weighted average fair value per share)	100	11.39
Cancelled & Expired	(96)	20.25
Exercised	(57)	5.40
Outstanding at fiscal year end 1999		
(1,173 exercisable at \$16.55 weighted average price per share)	1,173	16.55
Granted (\$6.40 weighted average fair value per share)	45	11.65
Cancelled & Expired	(208)	20.67
Exercised	(33)	8.30
Outstanding at fiscal year end 2000		
(977 exercisable at \$15.72 weighted average price per share)	977	15.72
Granted (\$5.22 weighted average fair value per share)	2,817	11.02
Cancelled & Expired	(527)	12.35

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Exercised	(1,378)	8.04
Options assumed during Merger	3,696	8.09
	<u>          </u>	<u>          </u>
Outstanding at fiscal year end 2001		
(2,615 exercisable at \$9.99 weighted average price per share)	5,585	\$10.51
	<u>          </u>	<u>          </u>

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In conjunction with the Merger, 887,621 options of the 3,696,000 Thoratec options assumed as a result of the Merger became fully vested pursuant to existing change of control agreements at the close of the Merger on February 14, 2001. This acceleration of vesting was provided in the terms of the original Thoratec grants. Of the 887,621 options that accelerated, waiver agreements involving options to purchase 868,750 shares were entered into whereby certain executive option holders agreed not to sell or transfer any of their shares for a period of up to 18 months and to remain employed at the Company for a period of 12 months after the effective date of the Merger. In exchange, the options holders received a cash payment on the one-year anniversary of the Merger.

In addition, all options to purchase TCA shares that were outstanding at the date of the Merger were exchanged for options to purchase 971,222 Thoratec shares and became fully vested as of the Merger date. This acceleration of vesting was provided for in the terms of the underlying TCA grants.

The status of options outstanding as of the end of 2001 is summarized as follows:

Price Category	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Exercise Price
\$ 1.14	3,041	0.02	\$ 1.14	3,041	\$ 1.14
1.41 - 5.00	290,399	4.34	3.99	290,199	3.99
5.25 - 8.25	1,223,471	6.53	7.01	941,894	6.96
8.44 - 11.56	2,587,844	8.54	9.67	695,415	10.17
11.62 - 14.65	743,719	5.95	13.53	436,036	13.49
14.73 - 20.85	662,761	8.06	17.36	174,772	17.48
29.40 - 33.05	73,458	4.28	32.43	73,458	32.43
\$ 1.14 - \$33.05	5,584,693	7.42	\$ 10.51	2,614,815	\$ 9.99

**10. Related Parties*****Corporate Service Agreement***

The Company had a corporate services agreement with Thermo Electron, which terminated upon completion of the Merger. Thermo Electron's corporate staff provided to the Company certain administrative and financial services. The Company paid Thermo Electron an annual amount equal to 0.8% of the Company's revenues for these services. In addition, the Company incurred direct charges that Thermo Electron paid directly on its behalf. In 2001, 2000 and 1999, the Company paid \$124,000, \$980,000 and \$837,000, respectively, for these administrative and financial services and direct charges.

***Operating Leases***

The Company subleases office and research facilities from Thermo Electron, and is charged for actual square footage occupied at approximately the same rent paid per square foot by Thermo Electron under its prime lease. The sublease expires in February 2004. The accompanying statement of income includes expenses from the sublease of \$193,600, \$177,000 and \$171,000 in 2001, 2000 and 1999, respectively.

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The Company subleased a portion of an office and research facility from Thermo Electron and was charged for actual square footage occupied at approximately the same rent paid per square foot by Thermo Electron under its prime lease. The sublease agreement between the Company and Thermo Electron was terminated in May 2000. The Company rented the same space from a third party up until the lease terminated

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and the Company moved out of this facility in February 2002. The accompanying statement of income includes expenses from the sublease with Thermo Electron of nil, \$36,000 and \$65,000 in 2001, 2000 and 1999, respectively.

Future minimum annual payments due under these noncancellable lease arrangements at December 29, 2001, are \$193,600 in 2002 and 2003 and \$32,267 in 2004.

**Purchases**

The Company purchases metal fabrication products and services from Tecomet, Inc. in connection with the manufacture of the ventricular-assist products sold by the Company. Tecomet was a division of Thermo Electron until November 15, 2001 when it was sold by Thermo Electron to an unrelated third party. The Company paid \$2,931,000, \$3,283,000 and \$3,651,000 to Tecomet in 2001, 2000 and 1999, respectively.

**Subordinated Convertible Debentures**

The outstanding principal balance of the subordinated convertible debentures as of the end of 2001 and 2002 of \$54,838,000 includes \$1,500,000 of debentures held by Thermo Electron (Note 7).

**11. Taxes on Income**

The provisions for income taxes (benefits) and extraordinary items, are as follows (in thousands):

	Fiscal Year		
	2001	2000	1999
Current:			
Federal	\$	\$3,747	\$2,702
State	420	352	943
	420	4,099	3,645
Deferred:			
Federal	(2,915)	465	(643)
State	662	66	(137)
	(2,253)	531	(780)
	(1,833)	4,630	2,865
Reduction of valuation allowance	(1,492)		
	\$ (3,325)	\$4,630	\$2,865



**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The provision for income taxes in the accompanying statements of operations differs from the provision calculated by applying the U.S. federal statutory income tax rate of 35% to income before provision for income taxes and extraordinary item due to the following (in thousands):

	2001		2000		1999	
			Fiscal Year			
U.S. federal statutory income tax expense (benefit)	\$ (31,916)	(35.0)%	\$ 4,187	35.0%	\$ 3,933	35.0%
State income tax expense (benefit), net of federal tax expense (benefit)	(794)	(0.9)	272	2.3	524	4.7
Non-deductible amortization of goodwill	1,524	1.7				
Non-deductible acquired IPR&D	26,900	29.5				
Non-deductible merger expenses	175	0.2				
Export benefits	(50)	(0.1)	(134)	(1.1)	(116)	(1.0)
Federal research and development credits	(100)	(0.1)			(1,508)	(13.4)
Other	936	1.1	305	2.5	32	0.2
	<u>\$ (3,325)</u>	<u>(3.6)%</u>	<u>\$ 4,630</u>	<u>38.7%</u>	<u>\$ 2,865</u>	<u>25.5%</u>

During 1999, the Company received a favorable resolution of a claim for prior-year research and development tax credits, which reduced the tax provision by \$1,508,000.

Deferred income taxes reflect the net tax effects of: (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating loss and tax credits carryforwards.

Significant components of the Company's net deferred taxes are as follows (in thousands):

	Fiscal Year	
	2001	2000
Deferred tax assets:		
Write-off of acquired technology	\$ 1,304	\$ 1,427
Reserves and accruals	2,186	2,576
Depreciation and amortization	2,709	1,179
Inventory basis difference	2,361	958
Research and development credit carryforwards	1,609	
Net operating loss carryovers	10,586	
State tax loss and credit carryforwards		1,492
Other, net	347	(67)
	<u>21,102</u>	<u>7,565</u>

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Valuation allowance		(1,492)
	<u>          </u>	<u>          </u>
Net deferred tax assets	21,102	6,073
	<u>          </u>	<u>          </u>
Deferred tax liabilities:		
Purchased intangibles	(79,697)	
	<u>          </u>	<u>          </u>
Net deferred tax assets (liabilities)	<u>\$ (58,595)</u>	<u>\$ 6,073</u>

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**THORATEC CORPORATION AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The valuation allowance relates to the realizability of state net operating loss ( NOL ) carryovers of \$2,100,000, which would have expired in 2001 through 2005 and state tax credit carryforwards of \$1,290,000, which would have expired in 2001 through 2012. These NOL and tax credit carryforwards were extinguished upon the closing of the Merger.

At the end of 2001, the Company had federal and state NOL carryforwards of approximately \$29,000,000, which expire from 2003 through 2021. Use of \$7,400,000 of the NOL carryforwards, which arose prior to a greater than 50% change in ownership in 1992, is limited to approximately \$440,000 per year.

**12. Enterprise and Related Geographic Information**

The Company organizes and manages its business by functional operating entities. The Company's functional entities operate in two segments: (1) Cardiovascular and (2) Other Medical Equipment. The Cardiovascular segment develops, manufactures and markets proprietary medical devices used for circulatory support and vascular graft applications. The Other Medical Equipment segment develops, manufactures and markets near-patient, whole-blood coagulation testing equipment and related disposables, as well as premium quality, single-use skin incision devices. All 2000 and 1999 financial information presented herein represents the results of operations of TCA's Cardiovascular segment and Other Medical Equipment segment. The 2001 financial information presented herein includes the financial results of TCA's segments for the entire fiscal year and the financial results of Thoratec's Cardiovascular segment only for the post-merger period from February 14, 2001 through December 29, 2001.

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Business segments (in thousands):**

	Fiscal Year		
	2001	2000	1999
<b>Product sales:</b>			
Cardiovascular	\$ 71,809	\$ 43,049	\$ 39,810
Other medical equipment	41,575	40,347	38,801
	<u>          </u>	<u>          </u>	<u>          </u>
Total product sales	\$ 113,384	\$ 83,396	\$ 78,611
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Income (loss) before income taxes and extraordinary item:</b>			
Cardiovascular	\$ (177)	\$ 1,499	\$ (729)
Other medical equipment	8,953	8,270	8,789
Corporate(a)	(2,660)	(980)	(837)
Amortization of goodwill and purchased intangibles	(15,674)		
In-process research and development	(76,858)		
Merger, restructuring and other costs	(7,134)	(1,831)	
	<u>          </u>	<u>          </u>	<u>          </u>
Total operating income (loss)	\$ (93,550)	\$ 6,958	\$ 7,223
Interest and other income, net	2,359	5,005	4,014
	<u>          </u>	<u>          </u>	<u>          </u>
Total income (loss) before taxes and extraordinary item	\$ (91,191)	\$ 11,963	\$ 11,237
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Total assets:</b>			
Cardiovascular	\$ 57,299	\$ 25,136	\$ 36,893
Other medical equipment	19,883	15,808	14,801
Corporate(b)	159,242	135,741	118,234
Goodwill and purchased intangible assets	293,817		
	<u>          </u>	<u>          </u>	<u>          </u>
Total assets	\$ 530,241	\$ 176,685	\$ 169,928
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Depreciation and amortization:</b>			
Cardiovascular	\$ 3,634	\$ 1,664	\$ 1,536
Other medical equipment	1,214	1,446	1,448
Amortization of goodwill and purchased intangible assets	15,674		
	<u>          </u>	<u>          </u>	<u>          </u>
Total depreciation and amortization	\$ 20,522	\$ 3,110	\$ 2,984
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Capital expenditures:</b>			
Cardiovascular	\$ 6,789	\$ 1,243	\$ 1,103
Other medical equipment	1,158	1,117	1,437
	<u>          </u>	<u>          </u>	<u>          </u>
Total capital expenditures	\$ 7,947	\$ 2,360	\$ 2,540
	<u>          </u>	<u>          </u>	<u>          </u>

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

(b) Represents items not specifically identified to any particular business segment.

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**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Geographic Areas (in thousands):**

	Fiscal Year		
	2001	2000	1999
Product Sales:			
Domestic	\$ 90,678	\$69,786	\$65,980
Europe	13,000	8,140	7,259
All other international	9,706	5,470	5,372
Total international	22,706	13,610	12,631
Total	\$113,384	\$83,396	\$78,611

**13. Commitments**

The Company had various firm purchase commitments totaling approximately \$13,000,000 at December 29, 2001.

In July 1998, the Company established an Executive Officer Severance Benefits Plan and an Employee Severance Benefits Plan as part of the employee benefits package. The plans provide severance benefits to certain employees whose employment is terminated, other than for cause. An Executive Officer's standard severance pay benefit is equal to one times annualized base salary. An employee's severance benefit is equal to an amount based on job level and length of service.

**14. Retirement Savings Plan**

Substantially all of the Company's full-time employees are eligible to participate in a 401(k) retirement savings plan. As of the date of the Merger and continuing through June 30, 2001, two retirement savings plans were in effect, representing the pre-merger plan of Thoratec and a new plan set in place as of the Merger date. Prior to February 14, 2001, TCA participated in Thermo Electron's retirement savings plan. Effective July 1, 2001, the two plans were combined into a new savings plan (the Retirement Plan). Under the Retirement Plan, employees may elect to contribute up to 15% of their eligible compensation to the Retirement Plan, subject to certain limitations. In 2001 the Company match was 50%, up to the first 6% of eligible employee plan compensation. Employees vest under the Retirement Plan at the rate of 25% per year, with full vesting after four years of service with the Company. For 2001, 2000 and 1999, the Company made contributions to the Retirement Plan of approximately \$674,000, \$804,000 and \$726,000, respectively.

**15. Merger, Restructuring and Other Costs**

During 2001 and 2000, the following merger, restructuring and other costs were recorded in expense (in thousands):

	Fiscal Year	
	2001	2000
Merger	\$5,326	\$1,831
Restructuring	1,093	
Other	715	

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Total	\$7,134	\$1,831
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No merger, restructuring and other costs were recorded in 1999.

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Merger Costs***

Merger costs recorded during 2001 and 2000 principally consisted of employee severance, pre-merger employee retention costs, and outside consulting, accounting and legal expenses associated with the Merger. Early in 2000, Thermo Electron announced its intent to sell TCA. In conjunction with this announcement, TCA put in place an employee retention plan, which offered a bonus to certain key employees to continue employment with TCA through the completion of the sale of the company. Upon closure of the Merger between TCA and Thoratec, certain Thoratec executives' stock options accelerated per the original terms of the stock option agreements. In exchange for a waiver of their rights to immediately exercise these options and to sell the related stock, the Company put in place a bonus plan to serve as compensation to these executives for that waiver.

The following table reflects the activity in accrued merger costs for 2001 and 2000 (in thousands):

	Fiscal Year	
	2001	2000
Accrued Merger Costs:		
Beginning balance	\$ 1,708	\$
Add:		
Pre-merger retention accrual		1,831
Executive waiver agreement accrual	684	
Employee severance accrual	2,825	
Less:		
Payments of pre-merger retention	(1,708)	(123)
Payments of employee severance	(2,825)	
Payments of waiver agreement	(212)	
Ending balance	\$ 472	\$ 1,708

Certain 2001 merger costs were recorded directly to expense and did not pass through accrued merger costs. These expenses consisted primarily of legal, audit, consulting and other professional fees related to the Merger and totaled \$1,817,000 for 2001.

***Restructuring Costs***

In June 2001, the Company approved a restructuring plan (the Restructuring Plan) to consolidate all of its VAD manufacturing operations to its manufacturing facilities and headquarters in Pleasanton, California. The restructuring initiatives, which have already commenced, are related to the Company's desire to provide maximum value to shareholders through achievement of operating efficiencies. The Company estimates that substantial savings will result upon completion of the Restructuring Plan. The Restructuring Plan specifically provides for the reduction of approximately 90 of the Company's manufacturing and related workforce at its Woburn and Chelmsford, Massachusetts facilities. The Company notified the affected employees during the second quarter of 2001, both through direct personal contact and written notification. The Chelmsford facility was closed in February 2002. The Company's HeartMate® family of products, which are currently manufactured at the Woburn facility, will be transitioned to the Pleasanton facility. The Restructuring Plan is estimated to take 18 months because of FDA certification requirements for the new manufacturing activities in Pleasanton. Substantially all of the milestones related to the relocation that are controllable by the Company will be completed within 12 months of the date of announcement. Because the Company's products are regulated by the FDA, it is estimated it will take an additional six months to complete the FDA review and certification process before the HeartMate products can be manufactured in Pleasanton.



**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company believes it can make reasonable estimates of the involuntary employee termination benefits since it has specifically identified the employees that will be involuntarily terminated as well as the benefits that each affected employee will receive. Management does not believe there are likely to be any developments during the intervening 18 months required to relocate the manufacturing operations, which would have a significant impact on Thoratec's original restructuring cost estimates. Although the relocation plan has been documented, in detail, small changes in the timing of specific activities are expected. The impact on the estimate for these changes is not expected to be material. Through December 29, 2001, the Company has accrued \$995,000 of restructuring charges in accordance with Emerging Issues Task Force 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity and Staff Accounting Bulletin 100, Restructuring and Impairment Charges. These charges represent estimated severance costs. As of December 29, 2001, the Company has paid approximately \$132,000 in severance payments to 2 employees related to the restructuring. The following is a summary of the Company's accrued restructuring costs activity in 2001 and 2000 (in thousands):

	Fiscal Year	
	2001	2000
Accrued Restructuring Costs:		
Beginning balance	\$	\$
Employee severance accrual	995	
Payments of employee severance	(132)	
Ending balance	\$ 863	\$

In addition to the employee severance, estimated restructuring costs includes \$98,000 of expense related to the estimated fair value of options granted to the employees to be severed in the Restructuring Plan, which were accelerated upon the Merger.

**Other Costs**

Other costs of \$715,000 were incurred in the third quarter of 2001 related to the events of September 11, 2001. As of December 29, 2001, the total amount of these other costs were paid.

**16. Earnings (Loss) Per Share**

Although Thoratec is the surviving legal entity after the Merger, the Merger is treated as an acquisition of Thoratec by TCA for accounting and financial reporting purposes. The weighted average number of common shares previously reported by TCA has been adjusted for all periods to reflect the exchange ratio of 0.835 to 1.

Basic earnings (loss) per share are computed by dividing net income (loss) 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 5,584,693 shares of common stock were not included in the computations of diluted loss per share for 2001 as their inclusion would be antidilutive. Options to purchase 774,000 and 1,191,000 shares of common stock were not included in the computations of diluted earnings per share for 2000 and 1999 because their effect would have been antidilutive due to the options' exercise prices exceeding the average market price for the common stock. In addition, the computation of diluted earnings per share for each period presented excluded the effect of assuming the conversion of the Company's 4.75% subordinated convertible debentures, convertible at \$37.62 per share, because their effect would have been antidilutive.

**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Basic and diluted earnings (loss) per share were calculated as follows (in thousands, except per share data):

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Net income (loss) before extraordinary item	\$(87,866)	\$ 7,333	\$ 8,372
Extraordinary item net of taxes		191	1,212
Net income (loss)	<u>\$(87,866)</u>	<u>\$ 7,524</u>	<u>\$ 9,584</u>
Weighted average number of common shares-Basic	52,336	32,193	32,100
Dilutive effect of employee stock options		16	32
Weighted average number of common shares-Diluted	<u>52,336</u>	<u>32,209</u>	<u>32,132</u>
Basic and diluted earnings (loss) per common share before extraordinary item	<u>\$ (1.68)</u>	<u>\$ 0.23</u>	<u>\$ 0.26</u>
Basic and diluted earnings (loss) per common share	<u>\$ (1.68)</u>	<u>\$ 0.23</u>	<u>\$ 0.30</u>

**17. Extraordinary Item**

During 2000, the Company repurchased \$3,173,000 principal amount of its 4.75% subordinated convertible debentures, convertible at \$37.62 per share, for \$2,825,000 in cash, resulting in an extraordinary gain of \$191,000, net of taxes of \$117,000.

During 1999, the Company repurchased \$11,989,000 principal amount of its 4.75% subordinated convertible debentures for \$9,985,000 in cash, resulting in an extraordinary gain of \$1,212,000, net of taxes of \$743,000.

**18. Quarterly Results of Operations (Unaudited)**

The following is a summary of the unaudited quarterly results of operations for the fiscal years 2001 and 2000:

	<u>First</u>	<u>Second</u>	<u>Third</u>	<u>Fourth</u>
(In thousands, except per share data)				
Fiscal Year 2001				
Product sales	\$ 21,480	\$ 28,218	\$ 28,666	\$ 35,020
Gross profit	11,440	15,573	15,062	18,469
Net income (loss)	(82,180)	(3,103)	(2,968)	385
Basic and diluted earnings (loss) per share	\$ (1.88)	\$ (0.06)	\$ (0.05)	\$ 0.01
Fiscal Year 2000				
Product sales	\$ 19,929	\$ 22,609	\$ 19,391	\$ 21,467
Gross profit	11,769	13,209	11,092	12,496
Net income	1,770	2,639	1,494	1,621
Basic and diluted earnings per share	\$ 0.05	\$ 0.08	\$ 0.05	\$ 0.05



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**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

None.

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**PART III**

**Item 10. *Directors and Executive Officers of the Registrant***

The information regarding directors and executive officers required by Item 10 is incorporated by reference from the information under the captions Election of Directors, Directors and Executive Officers and Section 16(a) Beneficial Ownership Reporting Compliance in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2002 annual meeting of stockholders.

**Item 11. *Executive Compensation***

The information required by Item 11 is incorporated by reference from the information under the caption Executive Compensation and Other Information in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2002 annual meeting of stockholders.

**Item 12. *Security Ownership of Certain Beneficial Owners and Management***

The information required by Item 12 is incorporated by reference from the information under the caption Security Ownership of Certain Beneficial Owners and Management in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2002 annual meeting of stockholders.

**Item 13. *Certain Relationships and Related Transactions***

The information required by Item 13 is incorporated by reference from the information under the caption Certain Relationships and Related Transactions in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2002 annual meeting of stockholders.

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**PART IV**

**Item 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K**

(a) *List of documents filed as part of this report:*

1. *Financial Statements and Independent Auditors Report*

Reference is made to the Index to Financial Statements under Item 8 of Part II of this report, where these documents are included.

2. *Financial Statement Schedules*

Independent Auditors Report Deloitte & Touche LLP  
Report of Independent Public Accountants Arthur Andersen LLP  
Schedule II Valuation and Qualifying Accounts and Reserves

Other financial statement schedules are not included either because they are not required or the information is otherwise shown in the financial statements or notes thereto.

3. Exhibits filed with Annual Report on Form 10-K (numbered in accordance with Item 601 of Regulation S-K).

**(b) Reports on Form 8-K:**

The following report on Form 8-K was filed during the last quarter of our 2001 fiscal year:

1. Report on Form 8-K with the Securities and Exchange Commission on October 24, 2001 updating our unaudited pro forma combined condensed statements of operations for the year ended December 30, 2000 and for the nine months ended September 30, 2001 provided in connection with our merger with Thermo Cardiosystems Inc. on February 14, 2001.

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**INDEPENDENT AUDITORS REPORT**

To the Board of Directors and Shareholders of

Thoratec Corporation:

We have audited the financial statements of Thoratec Corporation (the Company) as of December 29, 2001, and for year then ended, and have issued our report thereon dated February 21, 2002; such report is included elsewhere in this Annual Report on Form 10-K. Our audit also included the 2001 financial statement schedule listed in Item 14(a)(2). This financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion based on our audits. In our opinion, such 2001 financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California

February 21, 2002

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**REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS**

Shareholders and Board of Directors of Thoratec Corporation:

We have audited, in accordance with generally accepted auditing standards, the consolidated financial statements as of December 30, 2000 and for the two years then ended included in this Annual Report on Form 10-K, and have issued our report thereon dated February 5, 2001. Our audits were made for the purpose of forming an opinion on those statements taken as a whole. The schedule listed in Item 14(a)2 is the responsibility of the Company's management and is presented for purposes of complying with the Securities and Exchange Commission's rules and is not part of the basic consolidated financial statements. The schedule has been subjected to the auditing procedures applied in the audits of the basic consolidated financial statements and, in our opinion, fairly states in all material respects the consolidated financial data required to be set forth therein in relation to the basic consolidated financial statements taken as a whole.

/s/ ARTHUR ANDERSEN LLP

Boston, Massachusetts  
February 5, 2001



**Table of Contents****THORATEC CORPORATION AND SUBSIDIARIES****SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS****For the Three Fiscal Years Ended December 29, 2001**

	<b>Balance Beginning of Year</b>	<b>Additions</b>	<b>Charged (Credited) to Other Accounts(1)</b>	<b>Deductions</b>	<b>Balance End of Year</b>
(In thousands)					
Year Ended December 29, 2001:					
Allowance for doubtful accounts	\$ 939	\$337	\$	\$(725)(2)	\$ 551
Accrued product warranty	\$ 970	\$594	\$	\$(654)	\$ 910
Year Ended December 30, 2000:					
Allowance for doubtful accounts	\$1,009	\$ 25	\$(1)	\$ (94)(2)	\$ 939
Accrued product warranty	\$1,420	\$ 49	\$	\$(499)	\$ 970
Year Ended January 1, 2000:					
Allowance for doubtful accounts	\$ 951	\$120	\$(1)	\$ (61)(2)	\$1,009
Accrued product warranty	\$1,210	\$210	\$	\$	\$1,420

(1) Effects of exchange rate changes.

(2) Accounts written off, net of recoveries.

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Exhibit Number	Exhibit
3.1	Thoratec s Articles of Incorporation, as amended.(1)
3.2	Thoratec s By-Laws, as amended.(1)
4.1	Fiscal Agency Agreement dated as of May 14, 1997, among Thoratec Cardiosystems, Thermo Electron, and Bankers Trust Company as fiscal agent relating to \$70 million principal amount of 4.75% Convertible Subordinated Debentures due 2004.(2)(3)
10.1	Thoratec s 1984 Incentive Stock Option Plan, as amended.(4)
10.2	Sublease dated August 19, 1988, between Thoratec Cardiosystems and Thermedics, as amended by Amendment No. 1 dated January 1, 1990(5); and as further amended by Amendment No. 2 dated February 14, 2001.(6)
10.3	Intellectual Property Cross-license Agreement between Thermedics and the Thoratec Cardiosystems dated August 19, 1988.(7)
10.4	Form of Indemnification Agreement between Thoratec Cardiosystems and its officers and directors.(7)
10.5	Agreement for the acquisition of Th. Goldschmidt AG of Certain of the Assets of Thoratec dated March 29, 1989.(8)
10.6	Common Stock Purchase Agreement between COBE Laboratories, Inc. and Thoratec dated November 23, 1992.(9)
10.7	License Agreement between COBE Laboratories, Inc. and Thoratec dated November 23, 1992.(9)
10.8	Thoratec s 1993 Stock Option Plan.(10)
10.9	Agreement dated May 26, 1993, between The Polymer Technology Group Incorporated and the Thoratec Cardiosystems.(11)
10.10	Thoratec s 1996 Stock Option Plan.(12)
10.11	Thoratec s 1996 Nonemployee Directors Stock Option Plan, as amended.(13)
10.12	Lease Agreement dated July 25, 1996, between Main Street Associates and Thoratec, as amended.(14)
10.13	First Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(15)
10.14	Second Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(16)
10.15	Thoratec s 1997 Stock Option Plan, as amended.(17)
10.16	Amended and Restated Directors Stock Option Plan of Thoratec Cardiosystems.(18)
10.17	Amended and Restated Deferred Compensation Plan for Directors of Thoratec Cardiosystems.(18)
10.18	Amended and Restated Equity Incentive Plan of Thoratec Cardiosystems.(18)
10.19	Amended and Restated Nonqualified Stock Option Plan of Thoratec Cardiosystems.(18)
10.20	Agreement and Plan of Merger by and among Thoratec, Lightning Acquisition Corporation, Thermo Cardiosystems Inc, and Thermo Electron Corporation dated October 3, 2000.(19)
10.21	Registration Rights Agreement by and between Thoratec and Thermo Electron dated October 3, 2000.(19)
10.22	Shareholder Agreement by and between Thoratec and Thermo Electron dated October 3, 2000.(19)
10.23	Lease agreement dated August 16, 1995, between International Technidyne and BHBMC, as amended.
10.24	Transition Agreement dated February 18, 2000, between R. Michael Kleine and Thermo Electron Corporation relating to the proposed sale of Thoratec Cardiosystems.(20)

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Exhibit Number	Exhibit
10.25	Transition Agreement dated February 18, 2000, between Victor L. Poirier and Thermo Electron Corporation relating to the proposed sale of Thoratec Cardiosystems.(20)
10.26	Retention Agreement dated February 16, 2000, between Jay Caplan and Thermo Electron Corporation relating to Thoratec Cardiosystems.(20)
10.27	Addendum to Transition Agreement dated February 18, 2000, between R. Michael Kleine and Thermo Electron Corporation.(21)
10.28	Addendum to Transition Agreement dated February 18, 2000, between Victor L. Poirier and Thermo Electron Corporation.(21)
10.29	Employment Agreement by and between Thoratec and D. Keith Grossman, dated as of December 6, 2001.
21	Subsidiaries of Thoratec.
23.1	Independent Auditors Consent Deloitte & Touche LLP.
23.2	Independent Auditors Consent Arthur Andersen LLP.
24	Power of Attorney Reference is made to page 79 hereof.

- (1) Filed as an Exhibit with corresponding exhibit number to Thoratec's Registration Statement on Form S-1 (Registration No. 2-87293) and incorporated herein by reference. Amendment filed with the SEC on February 28, 2001 as Exhibit 3.1 to the Company's current report filed on Form 8-K (File No. 033-72502) and incorporated herein by reference.
- (2) Filed as an Exhibit to Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the fiscal quarter ended June 28, 1997 and incorporated herein by reference.
- (3) Thoratec Cardiosystems Inc. merged with and into Thoratec Corporation on July 2, 2001.
- (4) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended December 29, 1990 filed with the SEC on March 28, 1991, and incorporated herein by reference.
- (5) Filed as an Exhibit to Thoratec Cardiosystems' Annual Report on Form 10-K for the fiscal year ended December 30, 1989 and incorporated herein by reference.
- (6) Filed as an Exhibit to Annex A to Thoratec's Registration Statement on Form S-4 filed with the SEC on December 29, 2000 (Registration No. 333-49120) and incorporated herein by reference.
- (7) Filed as an Exhibit to Thoratec Cardiosystems' Registration Statement on Form S-1 (Registration No. 33-25144) and incorporated herein by reference.
- (8) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended December 30, 1989 filed with the SEC on March 30, 1990, and incorporated herein by reference.
- (9) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended January 2, 1993 filed with the SEC on March 22, 1993, and incorporated herein by reference.
- (10) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended January 1, 1994 filed with the SEC on March 22, 1994, and incorporated herein by reference.
- (11) Filed as an Exhibit to Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 1993 and incorporated herein by reference.
- (12) Filed as an Exhibit to Thoratec's Registration Statement on Form S-8 filed with the SEC on September 12, 1996, (Registration No. 333-11883) and incorporated herein by reference.
- (13) Filed as an Exhibit to Thoratec's Registration Statement on Form S-8 filed with the SEC on February 26, 2001 (Registration No. 333-56212), and incorporated herein by reference.

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- (14) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended June 29, 1996, filed with the SEC on August 13, 1996, and incorporated herein by reference.
- (15) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended June 28, 1997, filed with the SEC on July 30, 1997, and incorporated herein by reference.

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- (16) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended September 27, 1997 filed with the SEC on November 12, 1997, and incorporated herein by reference.
- (17) Filed as an Exhibit to Thoratec's Registration Statement on Form S-3 filed with the SEC on January 24, 2002 (Registration No. 333-72128), and incorporated herein by reference.
- (18) Filed as an Exhibit to Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 1999 and incorporated herein by reference.
- (19) Filed as an Annex to Thoratec's Registration Statement on Form S-4, filed with the SEC on December 29, 2000 (Registration No. 333-72128), and incorporated herein by reference.
- (20) Filed as an Exhibit to the Thoratec Cardiosystems' Annual Report on Form 10-K for the fiscal year ended January 1, 2000 and incorporated herein by reference.
- (21) Filed as an Exhibit to the Thoratec Cardiosystems' Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2000 and incorporated herein by reference.

