THORATEC CORP
Form 10-K
March 17, 2004

Table of Contents

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

Form 10-K

(Mark one)

[X] ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended January 3, 2004

[ ] 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	**94-2340464**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
6035 Stoneridge Drive, Pleasanton, California	**94588**
(Address of Principal Executive Offices)	*(Zip Code)*

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

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 [X] 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. [X]

Indicate by a check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12(b)-2) Yes [X] No [ ]

The aggregate market value of the voting stock held by non-affiliates $655,742,659 computed by reference to the last sale reported of such stock on June 28, 2003 as listed on The Nasdaq National Stock Market.(1)

As of March 12, 2004, registrant had 55,849,935 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portion of Thoratec s definitive proxy statement for its 2004 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

(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.

Table of Contents

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 , hope 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;

reimbursement policies and decisions by government agencies and third party payors;

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

our plans to develop and market new products; and

our ability to improve our financial performance.

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. 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 or incorporated by reference 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, tenderfoot and IRMA are registered trademarks of International Technidyne Corporation, or ITC, our wholly-owned subsidiary.

Table of Contents

TABLE OF CONTENTS

Table of Contents

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, 4.9 million patients in the United States suffer from CHF and an additional 550,000 patients are diagnosed with this disease annually. We were the first company to receive approval from the United States Food and Drug Administration, or FDA, to commercially market a ventricular assist device, or VAD, to treat patients with late-stage heart failure, which comprises approximately 5% to 10% of the CHF patient population. Our VADs are used primarily by these CHF patients to perform some or all of the pumping function of the heart and we currently offer the widest range of products to serve this market. We believe that our long-standing reputation for quality and innovation and our excellent relationships with leading cardiovascular surgeons worldwide position us to capture growth opportunities in the expanding congestive heart failure market.

Our three major product groups are:

Circulatory Support Products. Our circulatory support products include VADs 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 using our proprietary materials to address the vascular access and coronary bypass surgery markets. 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.

Point-of-Care Diagnostics. We are a leading supplier of point-of-care blood diagnostics test systems that provide fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes.

Our VADs 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 for different durations for patients of varying sizes and ages. We estimate that our VADs have treated over 6,300 patients worldwide. Our devices are currently used primarily for patients awaiting a heart transplant or recovering from open heart surgery. On November 6, 2002, the FDA approved the HeartMate SNAP-VE VAD as the first heart assist device for Destination Therapy, or permanent support for patients suffering from end-stage heart failure who are not eligible for heart transplantation. On April 7, 2003, the FDA approved the HeartMate XVE, an enhanced version of the HeartMate SNAP-VE, for Destination Therapy. Thoratec is the only company to have a ventricular assist device approved for permanent support for end-stage heart failure patients.

On February 14, 2001, we completed our merger with Thermo Cardiosystems, Inc., (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. Immediately after the Merger the parent company of TCA, Thermo Electron Corporation, owned approximately 35% of our outstanding stock. As of the date of this report, Thermo Electron owns approximately 10% of our total outstanding common stock.

Destination Therapy

On November 6, 2002, the FDA granted us approval to market our HeartMate SNAP-VE VAD for Destination Therapy for CHF patients who are not eligible for a heart transplant. This approval marks the first time a VAD has been approved as a long-term, permanent treatment for end-stage congestive heart failure patients who do not qualify for heart transplantation due to age or extenuating health circumstances and who have a life expectancy of less than two years. While our HeartMate VAD has been used since 1998 as a bridge to heart transplantation, this new approval gives regulatory authority for the medical community s expanded use of VADs.

The FDA s decision to approve the HeartMate SNAP-VE VAD for Destination Therapy was based on data from a clinical trial called REMATCH, or Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure, which

Table of Contents

showed our HeartMate device nearly doubled and tripled survival over the drug therapy group at one and two years, respectively. The results of the trial were presented at the American Heart Association Scientific Sessions in November 2001 and the results were published in The New England Journal of Medicine.

The REMATCH trial 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. The overall purpose of the study was to evaluate the efficacy, safety and cost effectiveness of our HeartMate VAD versus maximum drug therapy. The REMATCH publication provided a detailed evaluation of survivability, device safety and impact on patient quality of life.

On April 7, 2003, the FDA approved a PMA (PreMarket Approval) Supplement allowing the use of our HeartMate XVE for Destination Therapy. The XVE is an enhanced version of the HeartMate SNAP-VE device and reflects technological advances based on the experience in the REMATCH trial. The XVE incorporates a number of significant improvements to earlier versions of the HeartMate VE, which were designed to ease implantation, provide for longer and more reliable device life and improve patient outcomes.

The Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Decision Memorandum for the use of LVAS that are approved by the FDA for Destination Therapy, effective October 1, 2003. Our HeartMate VAD is currently the only such device approved for Destination Therapy by the FDA. CMS also made technical adjustments in 2003 regarding the relative weight and base level of reimbursement it will provide under DRG (diagnosis-related group) 525 Heart Assist System Implant. This change raised the base payment under DRG 525 nearly 25% from approximately $54,000 to approximately $70,000. In many cases the actual payments to hospitals under this revised DRG will be higher, and in some cases as much as double the base payment, based on geographical location and other factors.

In December 2002, Blue Cross/Blue Shield (BC/BS) Technology Evaluation Center issued a positive decision on the use of LVADs for Destination Therapy and since then more than half of the plans around the United States have issued positive coverage polices for their beneficiaries. Aetna U.S. Healthcare, the fourth largest health insurer in the U.S. covering more than 21 million people, issued a Coverage Policy Bulletin in March 2003 indicating that it now covers the use of ventricular assist devices for FDA-approved indications, including Destination Therapy. UNICARE, an operating affiliate of WellPoint Health Networks, one of the nation s largest managed care companies serving more than 13 million members and approximately 42 million specialty members, recently made a national decision to cover LVADs for Destination Therapy. PacifiCare has also adopted coverage policy for Destination Therapy. PacifiCare insures more than three million members.

We believe that the Destination Therapy application for our HeartMate device represents a long-term market opportunity of up to 100,000 additional patients annually in the United States. For these end-stage CHF patients, maximum drug therapy is currently the only other 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.

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 4.9 million CHF patients in the United States and approximately 550,000 new cases are diagnosed each year. The AHA also estimates that approximately 70% of CHF patients under age 65 will die within eight years. We believe that the number of patients suffering from end-stage CHF who could benefit from some form of cardiac assist could be over 100,000 annually. While the number of treatment options for earlier stage 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 earlier stage CHF include angioplasty, biventricular pacing, valve replacement, bypass and left ventricular reduction surgery.

Table of Contents

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 2,275 hearts available for transplant in the United States in 2001. At any given time, there are approximately 4,000 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 2001, approximately 15% of such patients died while waiting for a donor heart.

In the United States, there are currently two FDA-approved indications for the use of VADs in patients with CHF as a bridge to heart transplant and as Destination Therapy. We are currently pursuing one additional indication for our VAD products for therapeutic recovery of the heart. Beyond the CHF markets, VADs are also approved for use during recovery following cardiac 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 patients on the waiting list for a heart transplant in the United States, we estimate that approximately 25% will receive a VAD.

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

On November 6, 2002, we received approval to market the HeartMate SNAP-VE 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. On April 7, 2003 the FDA also approved the HeartMate XVE VAD for Destination Therapy. We believe that the success in transitioning this market from maximum drug therapy to VADs is dependent on the development of VADs, like our HeartMate, with substantial longevities and proof of clinical efficacy.

This is the first VAD approved for Destination Therapy for patients suffering from late-stage CHF and we believe that the Destination Therapy 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.

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 submitted additional information in a PMA amendment in January 2003. We hope to receive approval to market our product for this indication in the United States in 2004. 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 machines - a complication that arises in approximately one 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

Table of Contents

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

In addition to the circulatory support market, we sell a device that addresses the vascular access graft market, which we market as the *Vectra* Vascular Access Graft, or *Vectra,* for patients undergoing renal hemodialysis.

Point-of-Care Diagnostics

Our point-of-care (POC) blood diagnostic test systems provide fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes. These products are sold into the Hospital POC market, and the Alternate Site POC market comprising physician s offices, long-term care facilities, clinics, visiting nurse associations, and home healthcare companies.

Market growth for POC diagnostic products is coming from the Alternate Site POC market, which is being fueled by convenience and ease of use to the patients and physicians, and the clinical benefits from the more frequent monitoring it allows patients.

Overall, we are planning for sales of our point-of-care diagnostic test systems business to grow at an annual compound growth rate of up to 10% for the next several years. The drivers for this growth assume increased patient testing, better patient outcomes, and increased decentralization of testing from central laboratories to point-of-care.

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:

Offer a broad range of products. 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 payers. An important part of our 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 improved products including next generation versions of both HeartMate and Thoratec VADs.

Increase Cost Effectiveness of our Products. While a recent study indicates that the cost of implanting a VAD is comparable with that of a heart, liver and other major organ transplant, cost remains a significant concern of our customers. In October 2003, CMS issued a favorable National Coverage decision for the use of left ventricular assist systems that are approved by the FDA for treating Destination Therapy in end-stage heart failure patients. We plan to work very closely with approximately 62 centers approved by CMS in developing the Destination Therapy market. Additionally, we are expanding our market education and training programs and we continue to implement improvements that enhance the performance of our products.

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.

Bridge to Transplant Market. On July 28, 2003, Thoratec received CE mark certification, providing approval to market the Thoratec IVAD in countries in the European Union. This makes the IVAD the only currently

approved implantable cardiac assist device that can provide left, right or biventricular support.

Destination Therapy Market. We recently received approval for the HeartMate XVE VAD for Destination Therapy in the treatment of late-stage CHF patients who are not candidates for heart transplants. While the initial CMS reimbursement approval will be limited to approximately 62 centers in 2004, we estimate the market penetration for this indication could be between 5,000 and 15,000 patients annually using current approved technologies and up to 100,000 patients annually in the United States alone as we introduce new technologies that increase the life of our VAD and improve the outcome of procedures.

Home Discharge for our TLC-II portable driver. On December 1, 2003, the FDA approved the TLCII portable driver for home discharge. The TLC II was already approved for in-hospital use in the United States, and has been approved for home

Table of Contents

discharge in Europe for several years. This approval will enable patients supported by the device to be discharged to home from the hospital while awaiting heart transplantation or recovery of the natural heart. It is the first biventricular device to receive such approval.

Obtain approval for new indications or uses of our products.

Therapeutic recovery. We believe that the use of VADs may lead to recovery of the natural heart in certain patients. While our recent PMA submission for our Thoratec VAD for this indication has not yet received approval, we continue to investigate this market, and believe that the patient population that could benefit from this use could be substantial.

Thoratec IVAD submission for the United States. We have filed with the FDA seeking approval to market the Thoratec IVAD device in the United States, and we anticipate receiving FDA approval in 2004.

Use of HeartMate II in U.S. clinical trial. We have initiated a clinical trial of the HeartMate II, a next generation axial flow design intended for the long-term cardiac support of patients who are in end-stage heart failure.

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. We have launched an important program called the Heart Hope program, designed to partner with some CMS approved Destination Therapy centers, for the purpose of building the market for this new indication, and in the process, address important issues such as reimbursement, clinical outcomes, and building a strong referral program for Destination Therapy patients. Heart Hope is a collaboration between Thoratec and leading heart centers to advance clinical, educational and economical outcomes associated with the treatment of end-stage heart failure. Underlying the Heart Hope initiative is an educational program designed to increase acceptance of Destination Therapy among heart failure cardiologists, generate physician referrals and broaden patient awareness of this new therapy. Elements of this effort include marketing materials: newsletters, direct mail pieces, education symposia, web presence, print and radio advertising and public relations materials.

Increase our presence in the heart failure and cardiovascular disease markets. In addition to increasing our presence in the heart failure and cardiovascular disease markets through internal growth, we will also be evaluating strategic alliances, joint ventures and related business development opportunities.

OUR PRODUCTS

We offer a broad product portfolio of implanted and external (paracorporeal) devices:

The Thoratec Ventricular Assist Device system is an external device for short to mid-term cardiac support, which is sold worldwide. Additionally, we sell an implantable version, called the IVAD in Europe which is the only currently approved implantable cardiac assist device providing left, right or biventricular support.

The HeartMate Left Ventricular Assist system, also called the HeartMate XVE, which is an internal device for longer-term cardiac support and the only device approved in the United States for permanent support for those patients ineligible for heart transplantation.

In addition to our cardiac assist products, we offer vascular access grafts, used in hemodialysis for patients with end-stage renal disease. Additionally, we sell point-of-care blood diagnostics test systems and services that provide fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes.

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.

Table of Contents

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.

The Thoratec VAD

The Thoratec VAD has been FDA approved since 1995 and has treated over 2,500 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 the Thoratec 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 bridge to transplant 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 are working with the FDA to gain approval for a therapeutic recovery indication for the Thoratec VAD, which we hope to receive in 2004. 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 approved in the United States in June 2001 for use in off-site excursions and was approved December 1, 2003 for home discharge use. The TLC-II has been approved for use in Europe since 1998.

The HeartMate VAD

The HeartMate has been used to treat approximately 3,800 patients worldwide. There are currently two versions of the HeartMate available on the market. 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 for bridge to transplantation. The electric HeartMate, called the HeartMate VE, received FDA approval in September 1998 for bridge to transplantation. In November 2002 the product received FDA approval for long-term, permanent treatment for end-stage congestive heart failure patients who do not qualify for heart transplantation. The enhanced version of the product, called the HeartMate XVE, received FDA approval in December 2001 for bridge to transplantation. In April 2003 the product received FDA approval for long-term, permanent treatment for end-stage congestive heart failure patients who do not qualify for heart transplantation. The HeartMate XVE accounts for over 95% of total HeartMate sales. 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. This device is currently approved for the bridge to transplant indication and for home discharge and, most recently, 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 received CE Mark certification to market the Thoratec IVAD in Europe in July 2003. This makes the IVAD the only currently approved implantable cardiac assist device that can provide left, right or biventricular support. We are seeking FDA approval to market the device in the United States and expect to have approval in 2004. As of December 2003, there have been 34 patients in the U.S. trial, reflecting more than 3,600 days of cumulative patient support. 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.

Table of Contents

HeartMate II and HeartMate III

The HeartMate II is a next generation device intended for long-term cardiac support for patients who are in end-stage heart failure. HeartMate II is an small, implantable, electrically powered device that weighs approximately 12 ounces and is approximately 1.5 inches in diameter and 2.5 inches long. In addition to being significantly smaller than currently approved devices, with only one moving part, the HeartMate II is designed to operate more simply and quietly than other approved devices.

As an axial flow device, the HeartMate II is designed to provide blood flow through the circulatory system on a continual basis and is smaller and easier to implant than pulsatile devices. A unique feature of the device is its automatic speed control mode that is designed to regulate pumping activity based on different levels of patient or cardiac activity.

We have enrolled two patients in our U.S. safety and early efficacy clinical trial of the HeartMate II device as of the end of February 2004. We are currently in the process of expanding to additional sites and continue to aggressively seek qualified patients to complete our early safety study and expand to the pivotal phase. The FDA has approved the evaluation of the HeartMate II device for an early feasibility trial for a total of seven patients at four centers and the device will be evaluated for use as a bridge to transplantation. In addition we have implanted the HeartMate II in one patient in Europe.

In addition, we are developing our third generation device, the HeartMate III. The HeartMate III is a centrifugal, continuous flow pump that employs a magnetically levitated rotor that eliminates wear from touching parts. No bearings are present and the device is completely encased in titanium. The device is designed for long-term implantation (5-10 years) for patients with end-stage heart failure including Destination Therapy, bridge-to-transplantation and therapeutic recovery. The product design is being finalized and pre-clinical studies are being performed to ready the device for clinical evaluation.

Vascular Graft Products

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

Point-of-Care Diagnostics

Through our ITC subsidiary, we design, develop, manufacture and market point-of-care diagnostic test systems that provide fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes. Our major product lines are the following:

Hemochron POC coagulation system,

IRMA POC blood gas/electrolyte and chemistry system,

ProTime coagulation monitoring system,

Hemoglobin Pro system, and

Tenderfoot, tenderlett and surgicutt incision products.

The Hemochron and IRMA products are primarily sold into the Hospital POC segment of the market, and represent about 50% of ITC s annual business.

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

Table of Contents

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

The ProTime and Hemoglobin Pro products are sold into the Alternate Site POC market comprising Physician s offices, long-term care facilities, clinics, visiting nurse associations, and home healthcare companies. Historically this segment has represented about 20% of the total ITC business. ProTime is used to monitor a patient s coagulation while they are taking oral anticoagulants such as Coumadin, and can be prescribed to be used by the patient at home or can be used in the physician s office or clinic. The system consists of a small, portable analytical instrument and disposable test cuvettes.

Hemoglobin Pro (Hgb Pro) is used by professionals, mainly in the doctor s office to test for anemia; providing quick results on a very small blood sample. The system consists of a small, hand held test meter and disposable test strips.

Growth in the Alternate Site POC market is being fueled by convenience and ease of use to the patients and physicians. In addition, in the case of the ProTime monitoring of oral anticoagulation, clinical studies have shown that more frequent monitoring results in patients that stay in their therapeutic range more often. More frequent monitoring is made possible by patients testing themselves at home in addition to being tested in a doctor s office when appropriate.

Approximately 30% of our Hospital POC and the Alternate Site POC revenues typically relates to sales of equipment, with 70% relating to consumable products (cuvettes, cassettes, etc.) used in the testing process.

The Hospital POC and the Alternate Site POC market segments are both very competitive, and include the following potential drivers:

New drug therapies under development may not require the intense monitoring that the current drug of choice (Heparin) requires. To try to mitigate this risk, we participate in clinical trials with key pharmaceutical companies in order to be positioned to provide the hemostasis monitoring that will ultimately be required for new therapies.

New competitors that might enter the market with broader test menus. To address this risk, in late 2003 we acquired the IRMA (Immediate Response Mobile Analysis) product line of blood gas/electrolyte and chemistry tests from Diametrics. This has significantly increased our test menu offering, and also offers us the opportunity to develop the next generation system, combining the coagulation and blood gas tests into one platform, which we anticipate will take 3-5 years to complete. In the interim period, the idms data management and connectivity system, acquired as part of the IRMA acquisition, will allow the stand-alone Hemochron and IRMA systems to be interfaced together with a hospital s laboratory or hospital information system. This project is expected to be completed in mid-2004.

Our Incision products, historically representing about 30% of ITC revenues, are used to obtain a patient s blood sample for diagnostic testing. These products are sold to both the Hospital POC market and the Alternate Site POC market. Our products offer certain advantages and command a price premium over the competition, but they only capture the higher end of the market.

Our most successful Incision product is the heel stick used for infant testing, which we market based on its high-end features. Long-term, however, we believe that customers will increasingly make purchasing decisions on these types of products based on price. Therefore, we expect a gradual erosion of market share over time through 2007.

Overall, we are planning for sales of our point-of-care diagnostic test systems business to grow at an annual compound growth rate of up to 10% for the next several years. The drivers for this growth assume increased patient

testing, better patient outcomes, and increased decentralization of testing from central laboratories to point-of-care. We expect our international sales to increase from 18% currently to approximately 25% of ITC s total sales by 2007.

Other Recent Developments

During 2003, we received approval for the following products and indications by the FDA:

TLC-II Portable VAD Driver for Home Discharge. On December 1, 2003, the FDA approved the TLC-II Portable VAD Driver for home discharge. The TLC-II is a small, lightweight device that powers the Thoratec VAD (Paracorporeal VAD) as well as the investigational IVAD (Implantable/Paracorporeal VAD) The TLC-II was already approved for in-hospital use in the United States and has been approved for home discharge in Europe for several years. This approval will enable patients supported by the device to be discharged home from the hospital awaiting heart transplantation or recovery of the natural heart. It is the first biventricular support device to receive such approval.

Table of Contents

IVAD (Implantable Ventricular Assist Device). On July 28, 2003, we received CE Mark certification, providing approval to market the Thoratec IVAD in Europe. This makes the IVAD the only currently approved implantable cardiac assist device that can provide left, right or biventricular support.

HeartMate II. We initiated a clinical trial of the HeartMate II, a next generation axial flow design intended for the long-term cardiac support of patients who are in end-stage heart failure.

SALES AND MARKETING

We operate in the Cardiovascular Products and ITC business segments. Cardiovascular Products include our circulatory support products and vascular graft products. ITC includes our point-of-care blood diagnostics sales business.

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 the approximately 100 heart transplant hospitals in Europe.

We have recruited and trained a direct sales force that, as of January 3, 2004, comprised 22 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 15 direct clinical specialists who 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, perfusionists and the transplant nursing staff. We have launched an important program called the Heart Hope program, designed to partner with some CMS approved Destination Therapy centers, for the purpose of building the market for this new indication, and in the process, address important issues such as reimbursement, clinical outcomes, and building a strong referral for Destination Therapy patients. Heart Hope is a collaboration between Thoratec and leading heart centers to advance clinical, educational and economical outcomes associated with the treatment of end-stage heart failure. Underlying the Heart Hope initiative is an educational program designed to increase acceptance of Destination Therapy among heart failure cardiologists, generate physician referrals and broaden patient awareness of this new therapy. Elements of this effort include marketing materials: newsletters, direct mail pieces, education symposia, web presence, print and radio advertising and public relations materials. In addition to our direct selling effort, we have established a network of international distributors who cover those markets that represent the majority of the remaining VAD 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.

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 sales force also helps customers understand and manage reimbursement from third-party payors.

Vascular Graft Products

Table of Contents

We market the *Vectra* through Bard in the United States, Europe and selected countries in Scandinavia, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan.

Point-of-Care Diagnostics

ITC currently maintains a direct sales staff of 39 in the United States, who sell to hospitals as well as to third party dealers and distributors. Outside the United States, ITC has three salespeople selling principally to third party distributors. Substantially all of ITC s revenues have historically come through our distributor channels.

As we integrate our recently acquired IRMA product line of blood gas analyzers into our current business, an increasing portion of our revenue in the United States market will be generated by direct sales rather than through our current distributor model. This will require expanding the sales, technical service, customer service and shipping headcount at ITC in order to provide our customers with the support and service that they historically obtained from our distributors.

COMPETITION

The following represent what we believe to be our primary competition:

World Heart Corporation (WorldHeart), which manufactures and markets an implantable left ventricular assist device approved for bridge to transplant in the United States. On February 26, 2004 WorldHeart announced that it had received conditional approval from the FDA to proceed with a trial to support a PMA Supplement for use of Novacor LVAS in Destination Therapy. The approval permits enrollment at up to 40 centers and up to 50 patients in the United States. Total enrollment will be at least 225 patients. The primary end point is two-year patient survival. Secondary endpoints include health status, neurocognitive capacity, and incidence of certain adverse events, including device failure. The trial will randomize patients to receive either a Novacor LVAS or a HeartMate XVE LVAS on a 2:1 ratio.

ABIOMED Inc., which manufactures and markets biventricular assist devices approved for temporary circulatory support of patients in post-heart surgery shock and other recovery indications in the United States. In September 2003, Abiomed received FDA approval to begin commercial distribution of the AB5000 Ventricle, which provides temporary support for one or both sides of a heart that has failed but has the potential to recover.

MicroMed Technology Inc., which manufactures and markets an axial flow implantable left ventricular assist device, received approval for Destination Therapy trials in January 2004.

Arrow International, which produces and markets an implantable left ventricular assist device principally for Destination Therapy, received CE Mark certification in November 2003 to market the device in Europe.

While these companies represent today s chief competition, at the recent International Society for Heart & Lung Transplantation (ISHLT) meeting held in the fall of 2003, there were more than 20 different technologies presented in different stages of clinical trial and/or market approval. Any of these technologies could prove to be clinically superior, easier to implant, and/or less expensive than the devices currently in the market, and thus could take a leadership position in the markets in which we operate.

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 VAD. Several patents cover aspects of our HeartMate line of products.

Our patents relating to blood coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision devices are held by ITC. The rights to the blood gas, blood electrolytes and blood chemistry patents were transferred to ITC as part of the acquisition of the Immediate Response Mobile Analysis blood analysis system business from Diametrics Medical. We own or hold rights in the remainder of the U.S. patents by virtue of the merger between Thoratec and TCA, which resulted in the transfer of the ownership of the TCA patents to Thoratec.

Table of Contents

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 and Lust Antriebstechnik GmbH 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 and graft structure. Aspects of our blood coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision device products are covered by patents directed to tube-and micro-coagulation whole blood analysis, including test methods, reagents and integral (on-board) controls, thick film electrochemical analysis of blood gases, blood electrolytes, and blood chemistry, and low trauma skin incision devices for capillary blood sampling, and methods of manufacturing such devices. The duration remaining of some of our patents on our HeartMate products range from 11 to 12 years, on our biomaterials from 6 to 11 years, on our grafts up to 2 years and on our blood coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision device products from 2 to 16 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.

In addition, we hold several patents on the HeartMate II axial blood flow pump and transcutaneous energy transmission technology, the remaining duration of which range from 8 to 16 years. In August 1998, we obtained a license to incorporate technology developed by Sulzer Electronics Ltd. and Lust Antriebstechnik GmbH into the HeartMate III. HeartMate III is a miniature centrifugal pump featuring a magnetically levitated rotor with a bearingless motor that has been developed by Levitronix GmbH. The license from Sulzer and Lust gives us the exclusive right to use in our HeartMate products technology protected by several U.S. and foreign patents covering implantable bearingless motors 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 its portion of 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 hold, or have exclusive rights to, several international patents, including several biomaterial patents licensed from Goldschmidt referred to above.

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 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 and diagnostic device markets are 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, some of which could seriously harm our business.

For example, in October 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004 the Company settled the claim and recorded a charge of $2.3 million in the fourth quarter of 2003 for the settlement and related legal costs.

Table of Contents

We are not a party to any other material legal proceedings.

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 pre-clinical 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 VADs similar to those under development, the FDA requires proof of safety and efficacy in human clinical trials performed under an Investigational Device Exemption (IDE). An IDE application must contain pre-clinical 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 pre-clinical 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 the process that is used to gain FDA market clearance for most of the ITC products. 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. On October 26, 2002, the FDA signed into law The Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This law amends the FDA Act and Regulations to provide, among other things, the ability for the FDA to impose user fees for medical device reviews. Our activities require that we make many filings with the FDA that will now be subject to this new fee structure. Although the precise amount of fees that we will incur each year will be dependent upon the specific quantity and nature of our filings, such fees could amount to hundreds of thousands of dollars per year.

Table of Contents

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 Quality System 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 FDA often requires post market surveillance (PMS) requirements for significant risk devices such as VADs that require ongoing collection of clinical data during commercialization that must be gathered, analyzed and submitted to the FDA periodically for up to several years. These PMS data collection requirements are often burdensome and expensive and have an affect on the PMA approval status. 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 various state authorities, 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 and 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 13485 Series of Standards. ISO 13485 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 and ISO certification is widely regarded as essential to enter Western European markets. We obtained EN ISO 13485:2000 Certification in March 2003. 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. A prerequisite for obtaining authority to CE Mark products is to achieve full quality system certification in accordance with ISO 13485 and European Directives, such as the Medical Device Directive (MDD), In-Vitro Device Directive (IVDD) and the Active Implantable Medical Device Directive (AIMD). These are quality standards that cover design, production, installation and servicing of medical devices manufactured by us. We have the ISO 13485 and appropriate MDD, IVDD or AIMD certification and authority to CE Mark all our devices in commercial distribution including our skin incision, blood coagulation testing devices, *Vectra* graft and VAD systems such as the Thoratec PVAD, IVAD and HeartMate Systems. We are also certified to be in compliance with the requirements of the Canadian Medical Device Directive (CMDRs) at all Thoratec manufacturing sites, which is required effective January 1, 2003 to sell medical devices in Canada.

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 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 CMS, private health insurance companies and managed care organizations, reimburse part or all of the reasonable 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.

Table of Contents

To date, a majority of private insurers that we have dealt with and CMS have determined to reimburse some portion of the costs of our VADs and our diagnostic and vascular graft products. Effective October 1, 2003, CMS issued a National Coverage Decision Memorandum for the use of left ventricular assist systems (LVAS) that are approved by the FDA for treating Destination Therapy in end-stage heart failure patients. In regard to the reimbursement level, CMS also made technical adjustments, published in August 2003, regarding the relative weight and base level of reimbursement it will provide under a revised DRG (diagnosis-related group) 525 Heart Assist System Implant. This change raised the base payment under DRG 525 nearly 25% from approximately $54,000 to approximately $70,000. Since FDA approval of the HeartMate LVAS for Destination Therapy, several private payors have issued positive coverage decisions as well. In December 2002, Blue Cross/Blue Shield (BC/BS) Technology Evaluation Center issued a positive decision on the use of LVADs for Destination Therapy and since then more than half of the plans around the United States have issued positive coverage polices for their beneficiaries. Aetna U.S. Healthcare, the fourth largest insurer in the U.S. covering more than 21 million people, issued a Coverage Policy Bulletin in March 2003 indicating that it now covers the use of ventricular assist devices for FDA-approved indications, including Destination Therapy. UNICARE, an operating affiliate of WellPoint Health Networks, one of the nation s largest managed care companies serving more than 13 million members and approximately 42 million specialty members, recently made a national decision to cover LVADs for Destination Therapy. PacifiCare has also adopted coverage policy for Destination Therapy. PacifiCare insures more than three million members.

The reimbursement policies and practices of third party payors are subject to changes that might be unfavorable to our VAD systems and such unfavorable changes could seriously harm sales of our products.

MANUFACTURING

We manufacture our cardiovascular products 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 consists of the assembly of standard and custom component parts, and the testing of completed products. We rely on single sources of supply for several components of our VAD. We are aware of alternative suppliers for all single-sourced items.

Our blood coagulation testing and skin incision devices are manufactured in Edison, New Jersey, with the exception of the ProTime instrument and the hemoglobin monitor, which are manufactured through third party contract manufacturers. Our blood gas analyzer devices are manufactured in Roseville, Minnesota. The New Jersey and Minnesota facilities have been inspected, approved and licensed by the FDA and applicable State regulators. In addition, these facilities maintain ISO9001, ISO 13485 and Canadian (CMDCAS) ISO certifications. A significant amount of our manufacturing at these facilities is vertically integrated, with only limited reliance on third parties to manufacture printed circuit boards, to sterilize and to test products etc. We rely on single sources of supply for some components manufactured at out New Jersey and Minnesota facilities, and use safety stocks where there might be risk in qualifying a second supplier in a timely manner.

We typically are able to fill orders from inventory and do not have significant order backlogs. Total orders backlogged as of the end of fiscal 2003 and 2002 were approximately $1.6 million and $0.8 million, respectively.

RESEARCH AND DEVELOPMENT

Thoratec s research and development expenses in 2003, 2002 and 2001 were $26.1 million, $25.3 million and $22.1 million, respectively. Research and development costs are largely project driven, and the level of spending depends on the level of project activity planned and subsequently approved and conducted. Projects typically include efforts to develop new products such as the HeartMate II and HeartMate III, efforts to improve the operation and

performance of current products such as efforts to improve the life of various components of the HeartMate and the Thoratec VAD products. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations.

EMPLOYEES

As of January 3, 2004, we had a total of 802 employees, consisting of 792 full-time employees and 10 part-time employees, 345 of whom worked in manufacturing, 113 in engineering, 104 in quality control and regulatory affairs, 132 in marketing and sales support, 46 in administration and finance and 62 in other support functions, including human resources, management information systems, purchasing and facilities. Out of our total employees, 781 are employed in the United States and 21 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.

Table of Contents

ADDITIONAL INFORMATION

You can find additional information about Thoratec on our website at http://www.thoratec.com. We make filings of our periodic reports to the SEC, including annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as amendments to those reports, available free of charge on our website as soon as reasonably practicable following electronic filing of those reports with the SEC.

Table of Contents

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. In evaluating our company and our business before deciding to invest in our common stock 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 and other documents we file from time to time with the Securities and Exchange Commission, such as our quarterly reports on Form 10-Q, our current reports on Form 8-K and any public announcements we make from time to time.

We have a history of net losses.

We were founded in 1976 and we have a history of incurring losses from operations. As of January 3, 2004, our accumulated deficit was approximately $34.6 million. We anticipate that our expenses will increase as a result of increased pre-clinical and clinical testing, research and development and selling, general and administrative expenses. We could also incur significant additional costs in connection with our business development activities and the development and marketing of new products and indicated uses for our existing products. Such costs could prevent us from achieving or maintaining profitability in future periods.

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

Significant uncertainty exists as to the reimbursement status of newly approved health care products such as VADs and vascular grafts, which in turn can delay or prevent adoption in volume by hospitals. Government and other third party payors are increasingly attempting to contain health care costs. Payors are attempting to contain costs by, for example, limiting coverage and the level of reimbursement of new therapeutic products. Payors are also attempting to contain costs by refusing, in some cases, to provide any coverage 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 CMS have determined to reimburse some portion of the costs of our VADs and our diagnostic and vascular graft products. Effective October 1, 2003, CMS issued a National Coverage Decision Memorandum for the use of left ventricular assist systems (LVAS) that are approved by the FDA for treating Destination Therapy in end-stage heart failure patients. Thoratec s HeartMate LVAS is currently the only such device approved for Destination Therapy by the FDA. In regard to the reimbursement level, CMS also made technical adjustments, published in August 2003, regarding the relative weight and base level of reimbursement it will provide under a revised DRG (diagnosis-related group) 525 Heart Assist System Implant. This change raised the base payment under DRG 525 nearly 25% from approximately $54,000 to approximately $70,000. Since FDA approval of the HeartMate LVAS for Destination Therapy, several private payors have issued positive coverage decisions as well. In December 2002, Blue Cross/Blue Shield (BC/BS) Technology Evaluation Center issued a positive decision on the use of LVADs for Destination Therapy and since then more than half of the plans around the United States have issued positive coverage polices for their beneficiaries. Aetna U.S. Healthcare, the fourth largest insurer in the U.S. covering more than 21 million people, issued a Coverage Policy Bulletin in March 2003 indicating that it now covers the use of ventricular assist devices for FDA-approved indications, including Destination Therapy. UNICARE, an operating affiliate of WellPoint Health Networks, one of the nation s largest managed care companies serving more than 13 million members and approximately 42 million specialty members, recently made a national decision to cover LVADs for Destination Therapy. PacifiCare has also adopted coverage policy for Destination Therapy. PacifiCare insures more than three million members. We cannot, however, estimate what portion

of such costs will be reimbursed and our products may not continue to be approved for reimbursement. In addition, changes in the health care system may affect the reimbursability of future products. If coverage is not expanded or if the reimbursement levels are not increased or are partially or completely reduced, our revenues would be reduced.

If we fail to obtain approval from the FDA and from foreign regulatory authorities, we cannot market and sell our products under development in the United States and in other countries.

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

Table of Contents

application. The process for a PMA application is lengthy, expensive and typically requires extensive pre-clinical and clinical trial data. Pre-clinical data may need to be obtained in accordance with FDA good laboratory practices.

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

The FDA also requires us to adhere to Quality System Regulations, which include production design controls, testing, quality control, storage and documentation procedures. The FDA may at any time inspect our facilities to determine whether we have adequate compliance. Compliance with Quality System Regulations for medical devices is difficult and costly. In addition, we may not be found to be compliant as a result of future changes in, or interpretations of, regulations by the FDA or other regulatory agencies. If we do not achieve compliance, the FDA may withdraw marketing clearance, require product recall or take other enforcement action, which in each case would harm our business. Any change or modification to a device is required to be made in compliance with Quality System Regulations, which 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.

If hospitals do not conduct Destination Therapy (DT) Procedures using our VAD, our revenues will be diminished

The use of our VADs as long-term therapy (Destination Therapy) in patients who are not candidates for heart transplantation was approved by the FDA in 2002, and was approved for reimbursement by the CMS in late 2003.

We estimate that the Destination Therapy application for our HeartMate device represents a market opportunity of up to 100,000 additional patients annually in the United States alone, of which we believe between 5,000 and 15,000 are treatable using current technologies.

The number of DT procedures that actually get performed is dependent on many factors, most of which are out of our direct control, including:

the number of CMS sites approved for DT;

the clinical outcomes of DT procedures;

cardiology and referring physician education, and their commitment to DT;

the economics of the DT procedure for individual hospitals, which includes the costs of the VAD and related pre- and post- operative procedures and their reimbursement; and

the economics for individual hospitals of not conducting a DT procedure, including the costs and related reimbursements of long-term hospitalization.

The different outcomes of these and other factors, and their timing, will have a significant impact on our future results.

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

Table of Contents

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

Our future revenues are impacted by the number of heart transplants conducted

A significant amount of our current revenues derive from our VADs being implanted temporarily in patients awaiting heart transplants. The number of heart transplants conducted worldwide is dependent on the number of hearts available to transplant, which is dependent on the death rate of otherwise healthy people from events such as automobile accidents. To the extent that public safety measures and technological improvements, such as automobile air bags and anti-lock brakes, are successfully implemented, the availability of these hearts to transplant may not grow significantly, and may trend downward.

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

As a result of the Merger in February 2001, the number of our employees has increased significantly, from 183 on December 30, 2000 to 802 on January 3, 2004. We expect to continue to grow and we may suffer if we do not manage and train our new employees 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 these new products, product improvements and new indications on a timely basis, or if they are not well accepted by the market, our future growth may suffer.

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

As of January 3, 2004, we had $260.9 million of net intangible assets, representing 55% of our total assets and 68% 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 2003 was $12.3 million. No amortization of goodwill was recorded in 2003 after we adopted Statement of Financial Accounting Standards No. 142 at the beginning of 2002. 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 revenue from, and 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. For example, subsequent to year-end, the Company completed its assessment of the final results from its feasibility clinical trial for the Aria CABG graft, which was ongoing through fiscal 2003. Based on the clinical trial results, the Company determined that it will not devote additional resources to the development of the Aria graft. Upon the decision to discontinue product development, the Company recorded an impairment charge of $9.0 million as of January 3, 2004 to write off purchased intangible assets

related to the Aria graft, which were recorded as a result of the Merger.

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 products and blood testing products. We do not have long-term written agreements with most of our vendors and receive components on a purchase order basis. 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.

Table of Contents

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.

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

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

- pay premium prices to our suppliers to keep their production line open or to alternative suppliers;
- buy substantial inventory to take us through the scheduled end of life of our product, or through such time that we will have a replacement product developed and approved by the FDA; or
- stop shipping product in which the legacy component is used once our inventory of the discontinued component is exhausted.

Any of these interruptions in the supply of our materials could result in substantial reductions in revenue and increases in our production costs.

If we fail to compete successfully against our existing or potential competitors, our 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 Cardiac Surgery Division of Metronic, Inc., which markets the HemoTec product line 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. Competitors in the point-of-care diagnostics market include i-STAT and Radiometer.

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 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.

We may encounter problems manufacturing our products.

We may encounter difficulties manufacturing our products. We do not have experience in manufacturing some of our products in the commercial quantities that might be required if we receive FDA approval of several or all of the products and indications currently under development. We have also recently transferred the manufacturing operations for the HeartMate to Pleasanton and received clearance from the FDA to begin manufacturing the HeartMate in this location in the first half of 2003. 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.

Table of Contents

With the exception of Canada and the larger countries in Europe, we sell our VAD and HeartMate systems in foreign markets through distributors. In addition, we sell our vascular access graft products through the Bard Peripheral Vascular division of C.R. Bard Corporation, which we refer to as Bard, in the United States, Europe and selected countries in Scandinavia, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan. Substantially all of the international operations, and a large amount of the domestic operations of our ITC subsidiary are conducted through distributors. In 2003, 9% of our total product sales were through Cardinal Healthcare, a distributor of our blood coagulation testing equipment and skin incision devices.

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

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

As we integrate our recently acquired IRMA product line of blood gas analyzers into our current business, an increasing portion of our revenue in the United States market will be generated by direct sales rather than through our current distributor model.

This transition will include expanding the sales, technical service, customer service and shipping headcount at our ITC subsidiary in order to provide our customers with the support and service that they historically obtained from our distributors. This transition and its execution involves significant risks, including:

the alienation of distributors;

the promotion by our former distributors of products from competitors;

the potential loss of customers who prefer to deal with a particular distributor; and

difficulties and delays in building an effective direct sales force.

Failure to manage this transition could significantly increase our costs while potentially reducing our revenues.

Our inability to protect our proprietary technologies or an infringement of others patents could harm our competitive position.

We rely on patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not adequately protect our rights. In addition, we cannot assure you that any of our pending patent applications will issue. The Patent and Trademark Office 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 our biomaterials patents, which are utilized in the Thoratec VAD blood pump and cannulae, and one patent covering aspects of our TLC-II, the Thoratec VAD system is not protected by any patents. We rely principally on trade secret protection and, to a lesser extent, patents to protect our rights to the HeartMate. We rely principally on patents to protect our coagulation testing equipment, skin incision devices, Hemochron disposable cuvettes, IRMA

analyzer, IRMA disposable cartridges, and Hgb Pro disposable test strips.

We seek to protect our trade secrets and unpatented proprietary technology, in part, with confidentiality agreements with our employees and consultants. Although it is our policy to require that all employees and consultants sign such agreements, we cannot assure you that every person who gains 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.

Table of Contents

For example, in October 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004 the Company settled the claim and recorded a charge of $2.3 million in the fourth quarter of 2003 for the settlement and related legal costs.

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

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

Identified quality problems can result in substantial costs and write-downs.

FDA regulations require us to track materials used in the manufacture of our products, so that any problems identified in a finished product can easily be traced back to other finished product containing the defective materials. In some instances, identified quality issues require scrapping or expensive rework of the affected lot(s), not just the tested defective product and could also require us to stop shipments.

In addition, since some of our products are used in situations where a malfunction can be life threatening, identified quality issues can result in the recall and replacement, generally free of charge, of substantial amounts of product in the field.

Any quality issue identified can therefore result in substantial costs and write offs, which could materially impact our financial results.

If we make acquisitions or divestitures, we could encounter difficulties that harm our business.

We may acquire companies, products or technologies that we believe to be complementary to our business. If we do so, we may have difficulty integrating the acquired personnel, operations, products or technologies. 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. In addition, the cardiac centers that buy the majority of our products are usually led by cardiac surgeons who are heavily recruited by competing centers or by centers looking to increase their profiles. When one of these surgeons moves between centers we sometimes experience a temporary but significant reduction in purchases by the departed center while it replaces its lead surgeon. As a result, it is difficult for us to predict the quarter in which our customers may purchase our VAD

systems and our revenue and operating results may vary significantly from quarter to quarter, which increases the risk of an operating loss for us for any given quarter.

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

During both 2003 and 2002, sales originating outside the United States and U.S. export sales accounted for approximately 19% 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;

Table of Contents

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;

terrorist activity may interrupt distribution channels or impact our customers or employees; and

fluctuations in exchange rates may affect product demand and adversely affect the profitability, in U.S. dollars, of products sold in foreign markets where payments are made in local currencies.

Any of these events could harm our operations.

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 and is likely to continue to be volatile.

The price of our common stock has been, and is likely to continue to be, highly volatile, which means that it could decline substantially within a short period of time. The price of our common stock could fluctuate significantly for many reasons, including the following:

future announcements concerning us or our competitors;

timing and reaction to the publication of clinical trial results;

quarterly variations in operating results;

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;

Table of Contents

regulatory developments, enforcement actions bearing on advertising, marketing or sales, and disclosure regarding completed ongoing or future clinical trials; or

fluctuations in the economy, world political events or general market conditions.

In addition, stock markets in general, and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years which 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, terrorist acts, flood, power loss, communications failures and similar events. For example, in October 1989, a major earthquake that caused significant property damage and a number of fatalities struck near the area in which our Pleasanton 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, in particular because our premises require FDA approval, which could result in significant delays before we can manufacture product from a replacement facility. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions.

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

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign exchange rates. At present, we use forward foreign currency contracts to hedge the gains and losses created by the remeasurement of non-functional currency denominated assets and liabilities. However, we do not currently engage in hedging exposures that will arise from future sales. As a result, sales occurring in the future that are denominated in foreign currencies may be translated to U.S. dollars at a less favorable rate than our current exchange rate environment resulting in reduced revenues and earnings.

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

Our ability to operate successfully and manage our potential future growth depends significantly upon retaining key research, technical, sales, marketing, managerial and financial personnel, and attracting and retaining additional highly qualified personnel in these areas. We face intense competition for such personnel, and we may not be able to attract and retain these individuals. We compete with numerous companies, as well as universities and nonprofit

research organizations throughout all our locations. The loss of key personnel for any reason or our inability to hire and retain additional qualified personnel in the future could prevent us from sustaining or growing our business. Our success will depend in large part on the continued services of our research, managerial and manufacturing personnel. We cannot assure you that we will continue to be able to attract and retain sufficient qualified personnel.

Arthur Andersen LLP audited certain financial information included or incorporated in this report. In the event such financial information is later determined to contain false statements, you may be unable to recover damages from Arthur Andersen LLP.

Our consolidated statements of income, comprehensive income, shareholders equity and cash flows and associated information contained in the footnotes to these financial statements for the 2000 fiscal year were audited by Arthur Andersen LLP. In 2002, Arthur

Table of Contents

Andersen ceased operations and we are unable to obtain their consent to the incorporation by reference of its report on such financial statements, dated February 5, 2001, into this Form 10-K. As a result, you may be limited in your ability to recover damages from Arthur Andersen under Section 11 of the Securities Act of 1933 if it is later determined that there are false statements contained in or incorporated by reference into any portions of this report that have been prepared in reliance on financial statements audited by Arthur Andersen.

Item 2. ***Properties***

We are headquartered in Pleasanton, California, where we lease approximately 71,000 square feet of office, manufacturing and research facilities and 4,000 square feet of warehouse space. Our leases for these facilities expire through 2012. Additionally, we lease the following facilities:

Approximately 11,000 square feet of office and research facilities in Rancho Cordova, California expiring in 2007,

Approximately 45,000 square feet of office, manufacturing, warehouse and research facilities in Edison, New Jersey expiring through 2017,

Approximately 35,000 square feet of office, manufacturing and research facilities in Roseville, Minnesota, expiring in 2008,

Approximately 39,000 square feet of office and research facilities in Burlington, Massachusetts, expiring in 2011,

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

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 at least the next year and that additional space will be available at a reasonable price to satisfy space needs thereafter.

Item 3. ***Litigation***

In October 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004 the Company settled the claim and recorded a charge of $2.3 million in the fourth quarter of 2003 for the settlement and related legal costs. We are not a party to any other 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 January 3, 2004.

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

Table of Contents

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 health care products and services company. Mr. Boylston is a Certified Public Accountant.

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.

Jeffrey W. Nelson, President - Cardiovascular Division, joined our company as President - Cardiovascular Division in August 2002. Prior to joining us, Mr. Nelson was at Philips Medical Systems (formerly ADAC Laboratories) where he spent the past eight years, most recently as general manager of the company s nuclear medicine division. He also served as a senior vice president of North American sales and general manager of ADAC Radiology Solutions and held business unit and regional sales and marketing positions at the company. Before that, he was a marketing manager for Syncor International Corporation, an associate at Cerulean Venture Fund and was in sales with Baxter Healthcare International.

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 12, there were 55,849,935 shares of our common stock outstanding with approximately 850 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.

	High	Low
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
Fiscal Year 2002		
First Quarter	$19.35	$10.24
Second Quarter	11.46	7.80
Third Quarter	8.24	5.55
Fourth Quarter	$ 9.65	$ 6.40
Fiscal Year 2003		
First Quarter	$12.21	$ 7.63
Second Quarter	14.44	11.45
Third Quarter	19.23	13.74
Fourth Quarter	$16.99	$12.35

We have not declared or paid any dividends on our common stock and we do not anticipate doing so in the foreseeable future.

Item 6. *Selected Consolidated Financial Data*

The selected consolidated financial data presented below for the five fiscal years ended January 3, 2004 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 and March 12, 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 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, 1999 ended on December 31, 1999, 2000 ended on December 30, 2000, 2001 ended on December 29, 2001, 2002 ended December 28, 2002 and 2003 ended January 3, 2004.

Table of Contents

	Fiscal Year				
	2003	2002	2001	2000 (a)	1999 (a)
	(In thousands, except per share data)				
Statement of Operations:					
Product sales	$149,916	$130,844	$113,384	$ 83,396	$ 78,611
Gross profit	88,748	75,720	60,544	48,566	45,285
Amortization of goodwill and purchased intangible assets	12,333	12,384	15,674		
In-process research and development	220		76,858		
Impairment of intangible asset	8,987				
Legal settlement, merger, restructuring and other costs	2,132	1,409	7,134	1,831	
Net income (loss)	(2,182)	511	(87,866)	7,524	9,584
Basic and diluted earnings (loss) per share	$ (0.04)	$ 0.01	$ (1.68)	$ 0.23	$ 0.30
Balance Sheet Data:					
Cash and cash equivalents	$ 62,020	$ 42,044	$ 91,726	$ 30,236	$ 418
Working capital	116,430	107,972	135,924	149,207	115,471
Total assets	476,131	468,432	530,241	176,685	169,928
Subordinated convertible debentures			54,838	54,838	58,011
Long-term deferred tax liability and other	67,123	75,454	81,020		
Total shareholders equity	$386,236	$374,340	$373,343	$105,869	$ 96,940

(a) Our financial statements for 1999 and 2000 were audited by Arthur Andersen LLP, who have ceased operations.

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 in Item 1 above 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 in Item 1 above 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, 4.9 million patients in the United States suffer from CHF and an additional 550,000 patients are diagnosed with this disease annually. We were the first company to receive approval from the United States Food and Drug Administration, or FDA, to commercially market a ventricular assist device, or VAD, to treat patients with late-stage heart failure, which comprises approximately 5% to 10% of the CHF patient population. Our VADs are used primarily by these CHF patients to perform some or all of the pumping function of the heart and we currently offer the widest range of products to serve this market. We believe that our long-standing reputation for quality and innovation and our excellent relationships with leading cardiovascular surgeons worldwide position us to capture growth opportunities in the expanding congestive heart failure market. Through our ITC subsidiary, we design, develop, manufacture and market point-of-care diagnostic test systems that provide fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes.

Our Business Model

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

	2001	2002	2003
VAD pumps including associated products and services	61%	62%	60%
Point-of-care diagnostic test systems	37%	35%	37%
Grafts/Other	2%	3%	3%
Net Revenues	100%	100%	100%

Ventricular Assist Devices

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

The HeartMate VAD was acquired in our 2001 merger with Thermo Cardio Systems division of Thermo Electron. This VAD is made of titanium, contains an electrically powered pump, provides a safe interface with blood through a sintering process applied to the titanium, and has an average selling price that is typically approximately $65,000 per unit. The HeartMate VAD is only approved to assist the left ventricle, and is implanted inside the body cavity. It is currently approved for use in BTT and DT.

The Thoratec VAD is made of polymers, is powered pneumatically, provides a safe interface with blood through our proprietary Thoralon coating, and has an average selling price that is approximately $35,000. The Thoratec VAD is approved to assist the left and the right ventricle, and is worn outside the body cavity. It is currently approved for use in BTT.

Table of Contents

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

The market, competition and barriers to entry - We estimate we have in excess of 90% of the VAD market domestically and more than 50% internationally. Domestic revenue growth will come from expanding the market through new indications for our current products, in particular the recent approval of Destination Therapy, and from the development and approval of new, generally smaller and longer lasting products, that can be used in a broader range of patients. Internationally we expect growth to come by taking market share from our competitors and from expanding the market.

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

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

Point-Of-Care Diagnostic Test Systems Business

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

The market, competition and barriers to entry - Large medical device companies dominate these markets and we estimate our products hold anywhere from 2% to 20% market share. Growth in this market will come from taking market share away from other companies, and from testing being shifted from the central laboratory to the point-of-care. However, this market segment is very competitive, and includes the following potential drivers:

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

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

Overall, we are planning for sales of our point-of-care diagnostic test systems to grow at an annual growth rate of up to 10% for the next several years. This growth assumes increased patient testing, better patient outcomes, and increased decentralization of testing from central laboratories to point-of-care. We expect our international sales to increase from 19% currently to approximately 25% of ITC s total sales by 2007.

Mergers

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

Table of Contents

		Life
Working capital	$1,034	
Property, plant and equipment	2,492	3-10 years
Core technology	331	10 years
Existing developed technology	1,058	10 years
Patents	317	17 years
Other intangibles	143	7-17 years
In-process research and development	220	Expensed in 2003
Acquisition costs	(395)	
Consideration paid	$5,200	

There was no goodwill recorded with the transaction. As a result of the acquisition, $220,000 relating to in-process research and development was expensed in the fourth quarter of 2003.

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 stock. 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. 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.

Restructuring Plan

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

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		
	2003	**2002**	**2001**
Sales	100%	100%	100%
Cost of sales	41	42	47

Gross profit	59	58	53
Operating expenses:			
Selling, general & administrative	30	29	29
Research & development	17	19	19
Amortization of purchased intangible assets	8	10	10
Amortization of goodwill			4
Loss on impairment of intangible asset	6		
In-process research and development			68
Litigation, merger, restructuring and other costs	1	1	6
Total operating expenses	62	59	136
Income (loss) from operations	(4)	(1)	(83)
Interest and other income - net	1	2	2
Income (loss) before income taxes	(3)	1	(81)
Income tax expense (benefit)	(1)		(3)
Net income (loss)	(2)%	1%	(78)%

Table of Contents

Fiscal Years 2003 and 2002

Sales

Product sales in 2003 were $149.9 million compared to $130.8 million in 2002. The primary components of the $19.1 million increase in revenues were as follows:

Higher VAD sales. The majority of this increase came from higher sales of the HeartMate VAD ($7.1 million)

Higher Graft Sales ($1.0 million)

Higher revenue from sales of ancillary products ($1.8 million)

Higher revenue from sales of point-of-care diagnostic test systems at our ITC subsidiary ($7.4 million)

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

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

Gross Profit

Gross profit as a percentage of sales increased from 58% in 2002 to 59% in 2003 due to the following drivers:

Higher VAD Average Selling Prices resulted in a 2.2% increase in margin. This is driven largely by sales in 2003 of our HeartMate VAD representing a higher percentage of our revenue when compared to the lower priced Thoratec VAD. The HeartMate VAD typically sells at an ASP of between $60,000 and $70,000, while the Thoratec VAD typically sells at an ASP between $30,000 and $40,000.

Lower margins on ITC product lines resulted in a 0.8% decline in the Company s overall margins. This includes the impact of the IRMA product line we acquired in the fourth quarter of 2003 which currently operates with margins in the 30% range, compared to the margins on other products sold by our ITC division which typically sell at margins in the 50% range, and the impact of higher scrap, higher freight, and lower ASP s in our Incision product line.

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

Selling, General and Administrative

Selling, general and administrative expenses in 2003 were $44.4 million, or 30% of product sales, compared to $37.4 million, or 29% of product sales, in 2002. Underlying the $7.0 million increase in spending were the following drivers:

Increased headcount from 125 at the end of 2001 to 139 at the end of 2002 to 174 at the end of 2003, together with annual salary increases aggregating 4% effective January 2003.

Higher spending on Medicare reimbursement activities and market research and related activities, primarily associated with Destination Therapy, and costs associated with the IRMA product line acquired in Q4, 2003.

Higher insurance premiums

Higher facilities costs related to higher headcount.

These higher costs were offset by lower legal costs associated with filing an S-3 in 2002 that did not recur in 2003, and lower meeting expense related to a customer event in 2002 that did not recur in 2003. We anticipate that selling, general and administrative costs will generally increase each year as our business grows, with some quarterly and annual spending around events such as product introductions, and with spending as a percentage of revenue trending downward as revenues from current products increase, in particular as we realize revenue associated with Destination Therapy.

Research and Development

Research and development expenses in 2003 were $26.1 million, or 17% of product sales, compared to $25.3 million, or 19% of product sales, in 2002. Research and development costs are largely project driven, and the level of spending depends on the level of

Table of Contents

project activity planned and subsequently approved and conducted. Projects typically include efforts to develop new products such as the HeartMate II and HeartMate III, efforts to improve the operation and performance of current products such as efforts to improve the life of various components of the HeartMate and the Thoratec VAD products. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations. We anticipate that Research and Development costs will generally increase modestly each year as our business grows, with some quarterly and annual spikes in spending around events such as product introductions and regulatory approvals, and with spending as a percentage of revenue trending downward as revenues from current products increase, in particular as we realize revenue associated with Destination Therapy.

Amortization of Purchased Intangible Assets

Amortization of purchased intangible assets in 2003 was $12.3 million compared to $12.4 million in 2002. We anticipate that amortization of intangible assets in 2004 will total approximately $11.7 million.

Amortization of Goodwill

Beginning in 2002, we have stopped amortizing goodwill in accordance with SFAS No. 142.

Impairment of Intangible Asset

Subsequent to year-end, the Company completed its assessment of the final results from its feasibility clinical trial for the Aria CABG graft, which was ongoing through fiscal 2003. Based on the clinical trial results, the Company determined that it will not devote additional resources to the development of the Aria graft. Upon the decision to discontinue product development, the Company recorded an impairment charge of $9.0 million as of January 3, 2004 to write off purchased intangible assets related to the Aria graft, which were recorded as a result of the Merger.

In-process Research and Development Costs

In-process research and development expense in 2003 was $0.2 million related to our acquisition of the IRMA product line.

Legal Settlement, Merger, Restructuring and Other Costs

Legal settlement, merger, restructuring and other charges in 2003 were $2.1 million compared to $1.4 million in 2002. The 2003 expense is primarily comprised of $2.3 million to settle a patent infringement claim filed against us by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D related to materials used in the Company s HeartMate® LVAS.

Interest and Other Income - Net

Interest and other income - net in 2003 was $1.8 million compared to $1.6 million in 2002. This increase was primarily due to $1.1 million less interest paid due to the redemption of our debentures in March 2002, offset partially by the impact of lower interest rates on invested cash in 2003, which resulted in a decrease in interest income of $0.4 million from $1.9 million in 2002 to $1.5 million in 2003, and the impact of our foreign exchange hedging program commenced in 2003.

Income Taxes

Our effective tax rate was 39% in 2003 compared to an effective tax rate of 42% in 2002. This reduction reflects the relatively larger impact of various tax incentives, nondeductible expenses and tax credits in 2002 when net income subject to tax was less than $1 million. Based on a pre tax loss in 2003 of $3.6 million, the impact of these tax differences is proportionately lower.

Fiscal Years 2002 and 2001

Product Sales

Product sales in 2002 were $130.8 million compared to $113.4 million in 2001, an increase of $17.4 million or 15%. This increase was primarily attributable to an increase in VAD product sales of $10.5 million resulting from higher unit sales and average selling prices, an increase in vascular graft product sales of $2.1 million due to higher unit sales, and an increase in ITC sales of $4.8 million.

Table of Contents

Product sales in 2001 included Thoratec sales for the post-merger period from February 14, 2001 through December 29, 2001 whereas product sales in 2002 included Thoratec sales for the full 12 months of 2002.

The increase in ITC sales $4.8 million was primarily due to increases in sales of our blood coagulation testing products of $4.4 million.

Gross Profit

Gross profit in 2002 was $75.7 million, representing approximately 58% of product sales, compared to $60.5 million, representing approximately 53% of product sales in 2001. This increase in gross profit as a percentage of sales was primarily due to higher average selling prices for our VAD products and lower manufacturing and product service costs as a percentage of sales in 2002 compared to 2001.

Selling, General and Administrative

Selling, general and administrative expenses in 2002 were $37.4 million, or 29% of product sales, compared to $32.3 million, or 29% of product sales, in 2001. While selling, general and administrative expenses were consistent as a percentage of product sales from period to period, they increased as a result of promotional activities, new product introductions and costs to expand markets for our blood coagulation testing equipment and VADs as well as higher insurance costs, costs associated with computer systems installed in 2002 and business development activities.

Research and Development

Research and development expenses in 2002 were $25.3 million, or 19% of product sales, compared to $22.1 million, or 19% of product sales, in 2001. This increase resulted from an increase in spending for certain VAD product development programs partially offset by lower spending related to the REMATCH trials.

Amortization of Purchased Intangible Assets

Amortization of purchased intangible assets in 2002 was $12.4 million compared to $11.3 million in 2001. As of January 3, 2004, intangible assets of $207.0 million have been recorded as a result of our Merger and are being amortized over their estimated useful lives of eight to twenty years. In accordance with SFAS No. 142, at the beginning of 2002 we reclassified our purchased intangible asset related to acquired workforce in the net amount of $1.3 million to goodwill and ceased amortization of that asset. The increase in the amortization of purchased intangible assets from 2001 is due to the inclusion of a full year of amortization in 2002 compared to only ten months of amortization in 2001.

Amortization of Goodwill

Amortization of goodwill in 2001 was $4.4 million. Beginning in 2002, we have stopped amortizing goodwill in accordance with SFAS No. 142.

In-process Research and Development Costs

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

One of the projects was completed in 2001. There have been no significant developments subsequent to the Merger related to the current status of any of the remaining 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 regulated and technical nature of our products, current estimates remain materially consistent with our initial estimates.

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.

Table of Contents

Legal Settlement, Merger, Restructuring and Other Costs

Legal settlement, merger, restructuring and other charges in 2002 were $1.4 million compared to $7.1 million in 2001. The 2002 amount included costs consisting mainly of executive waiver agreement costs of $0.4 million, restructuring costs of $0.5 million representing estimated severance costs related to the consolidation of our VAD manufacturing operations, and other costs of $0.5 million related to the termination of a European distribution agreement. The 2001 amount included 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 our VAD manufacturing operations, and costs of $0.7 million related to the events of September 11, 2001.

Interest and Other Income Net

Interest and other income - net in 2002 was $2.1 million compared to $2.4 million in 2001. This decrease was primarily due to a decrease of $3.2 million in interest income caused by both lower cash balances and a reduction in interest rates during 2002. The decrease in interest income was partially offset by a reduction of interest expense due to the redemption of our subordinated convertible debentures in the first quarter of 2002 and an increase in other income primarily related to foreign currency translation gains.

Income Taxes

Our effective tax provision rate was 42% in 2002 compared to an effective tax benefit rate of 4% in 2001. For 2002, the effective tax provision rate exceeded the federal statutory income tax rate primarily due to the impact of state income taxes. 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.

Liquidity and Capital Resources

At the end of 2003, we had working capital of $116.4 million compared with $108.0 million at the end of 2002. Cash and cash equivalents at the end of 2003 were $62.0 million compared to $42.0 million at the end of 2002, an increase of $20.0 million.

Cash provided by operating activities was $30.7 million in 2003. In addition we had cash flows from financing activities of $10.6 million in 2003 from the sale of stock, through the exercising of stock options and stock issued under the newly implemented Employee Stock Purchase Plan. This total of $41.3 million of cash inflows was offset by $8.9 million net purchases of available for sale investments, $6.9 million paid to acquire property, plant and equipment which primarily consisted of $5.0 million of equipment additions and $1.7 million of leasehold improvements, and $5.2 million used in the acquisition of the IRMA product line.

In February 2004, we announced a stock repurchase program under which up to $25 million of our common stock could be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of purchases were based on several conditions, including the price of our stock, general market conditions and other factors.

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

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

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

Table of Contents

On September 30, 2003, we completed an asset purchase of the Immediate Response Mobile Analysis, or IRMA, point-of-care blood analysis system product line from Diametrics Medical, Inc. (Diametrics). We paid $5.2 million in cash and assumed trade payables. The purchase price was allocated based on the fair value of assets acquired and liabilities assumed as determined by an independent valuation firm. As a result of the acquisition, $220,000 relating to in-process research and development was expensed in the fourth quarter of 2003.

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. 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. Due to the reverse acquisition, Thoratec s assets and liabilities were recorded based upon their estimated fair values at the date of acquisition. The purchase price is also allocated to intangible assets, including goodwill. Approximately $309.0 million of the total purchase price of $346.2 million was 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 IPR&D was expensed in the first quarter of 2001. The write-off of IPR&D was 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 regulated and technical nature of the Company s products, current estimates remain materially consistent with the Company s initial estimates.

Evaluation of Goodwill and Purchased Intangibles for Impairment

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which we adopted as of the beginning of fiscal year 2002, we periodically evaluate the carrying value of long-lived assets to be held and used including intangible assets, when events or circumstances warrant such a review. The carrying value of a long-lived asset to be held and used is considered impaired when the anticipated separately identifiable undiscounted cash flows from such an asset are less than the carrying value of the asset. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved.

As of the beginning of fiscal year 2002, we adopted SFAS No. 142, Goodwill and Other Intangible Assets, and ceased the amortization of purchased goodwill. In addition, we reevaluated the useful lives of our identifiable intangible assets and determined that the remaining useful lives were appropriate. Each year we complete an impairment test of goodwill as required by SFAS No. 142. Upon completion of our impairment tests as of the end of fiscal 2003, we determined that our goodwill was not impaired.

Revenue Recognition

We recognize revenue from product sales when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectibility is reasonably assured. Sales to distributors are recorded when title transfers upon shipment. One distributor has certain limited

product return rights. A limited number of other distributors have certain rights of return upon termination of their distribution agreement. A reserve for sales returns is recorded for these customers applying reasonable estimates of product returns based upon significant historical experience in accordance with SFAS No. 48, Revenue Recognition when Right of Return Exists. No other direct sales customers or distributors have return rights or price protection.

Sales of certain Cardiovascular segment products to first-time customers are recognized when it has been determined that the customer has the ability to use such products. These sales frequently include the sale of products and training services under multiple element arrangements. For most customers, training is not essential to the functionality of the products as the customers already possess sufficient expertise and experience to use the products. In these situations, training is provided as a best practice to optimize the use

Table of Contents

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 2003, $0.1 million 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 $20,000 at the end of 2003, $100,000 at the end of 2002 and $38,000 at the end of 2001.

We also rent certain medical devices to customers on a month-to-month or as-used basis. Rental income is based on utilization and is included in product sales as earned. Included in product sales for 2003, 2002 and 2001 are $4.6 million, $3.8 million and $3.5 million, respectively, of income earned from the rental of these medical devices.

The majority of our products are covered by a one-year limited manufacturer s warranty from the date of installation. Estimated contractual warranty obligations are recorded when related sales are recognized and any additional amounts are recorded when such costs are probable and can be reasonably estimated. The change in accrued warranty expense in 2003 and 2002 is summarized in the following table (in thousands):

	Balance Beginning of Year	Charges to Costs and Expenses	Warranty Expenditures	Balance End of Year
Year ended 2003	$695	$193	$ (59)	$829
Year ended 2002	$910	$ 45	$(260)	$695
Year ended 2001	$970	$594	$(654)	$910

Reserves

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make payments owed to us for product sales. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

In June 2001, we approved a Restructuring Plan to consolidate all of our VAD manufacturing operations to our manufacturing facilities and headquarters in Pleasanton, California. Through the completion date of the Restructuring Plan in April 2003, we have recorded $1.5 million of restructuring charges in accordance with Emerging Issues Task Force 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity and Staff Accounting Bulletin 100, Restructuring and Impairment Charges. These charges represent estimated employee severance costs and stock option acceleration charges. We completed the relocation of the Woburn, Massachusetts manufacturing operations to our Pleasanton facility in the first quarter of 2003 and in February 2003 the FDA inspected the Pleasanton facility related to this transfer. We received FDA approval in April 2003. As of the completion date of the Restructuring Plan, we have paid approximately $1.3 million in severance payments to 78 employees.

Contractual Obligations

As of January 3, 2004, we have the following contractual obligations (in millions):

	Total	2004	2005	2006	2007	2008	Thereafter
Operating lease obligations	$22.2	$ 2.5	$2.5	$2.5	$2.4	$2.1	$ 10.2
Purchase obligations	10.2	10.2					
Total	$32.4	$12.7	$2.5	$2.5	$2.4	$2.1	$ 10.2

Our purchase obligations of $10.2 million include $6.4 million of supply agreements and $3.8 million of purchase orders open at January 3, 2004.

Recent Accounting Pronouncements

In April 2002, the FASB issued SFAS No. 145, which, among other things, changed the presentation of gains and losses on the extinguishment of debt. Any gain or loss on extinguishment of debt that does not meet the criteria in APB Opinion 30, Reporting the

Table of Contents

Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, is to be included in operating earnings and not presented separately as an extraordinary item. We adopted SFAS No. 145 at the beginning of fiscal year 2003 and therefore, we reclassified in the first quarter of 2003 the extraordinary loss incurred in 2002 of $0.5 million to interest and other income-net.

In June 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. The Company will apply the provisions of SFAS No. 146 for any restructuring activities initiated after December 31, 2002.

In November 2002, the Emerging Issues Task Force, or EITF, reached a consensus regarding EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. The guidance provided is effective for contracts entered into on or after July 1, 2003. The adoption of this guidance did not have a material effect upon our consolidated financial statements.

In November 2002, the FASB issued Interpretation, or FIN, No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. We adopted the disclosure provisions of FIN No. 45 effective as of fiscal year end 2002. We do not expect that the recognition provisions of FIN 45 will have a material impact upon our consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure which amends FASB Statement No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements of the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We adopted the disclosure provisions of SFAS No. 148 at the beginning of fiscal 2003. We do not expect to change to use the fair value based method of accounting for stock-based employee compensation.

In January 2003, the FASB issued FIN No. 46, Consolidation of Variable Interest Entities. The provisions of FIN 46 are effective for any arrangements entered into after January 31, 2003. Since January 31, 2003, the Company has not invested in any entities it believes are variable interest entities. In December 2003, the FASB issued a revised interpretation of FIN 46, FIN 46-R. The Company does not expect the adoption of FIN 46-R to have a material impact upon our consolidated financial statements.

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. This statement is effective for contracts entered into or modified after June 30, 2003. We adopted SFAS No. 149 effective July 1, 2003. The adoption of this statement did not have a material effect upon our consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003 and was effective at the beginning of the first interim period beginning after June 15, 2003. In November 2003, the FASB issued FASB Staff Position No. 150-3, Effective Date, Disclosures, and Transition for Madatorily Redeemable Noncontrolling Interests under SFAS No. 150, which defers the effective date for various provisions of SFAS 150. The adoption of this statement is not expected to have an impact upon our consolidated financial statements.

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

Interest Rate Risk

Our investment portfolio is made up of cash equivalent and marketable security investments in money market funds and debt instruments of government agencies and high quality corporate issuers. All investments are carried at market value and are treated as available-for-sale. All investments mature within two years or less from the date of purchase. The holdings of any one issuer, except government agencies, do not exceed 10% of the portfolio. We are exposed to market risk related to changes in interest rates. The market value of these investments may fall if market interest rates increase. If market interest rates were to increase by 10% from the levels at January 3, 2004, absent other factors, we estimate the fair market value of our investment portfolio would decline by an immaterial amount. We do not utilize derivative financial instruments to manage interest rate risks.

Table of Contents

Foreign Currency Rate Fluctuations

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

Commencing in September of 2003, the Company began using forward foreign currency contracts to hedge the gains and losses generated by the remeasurement of these non-functional currency assets and liabilities. Changes in the fair value of the forward foreign currency contracts are included in Interest and Other Income-Net , and typically offset the foreign currency exchange gains and losses described above. These derivatives are not designated as cash flow or fair value hedges under SFAS No. 133 and typically have maturities of three months or less. At January 3, 2004, the Company had forward foreign currency contracts to exchange Pounds Sterling and Euros for US Dollars with a notional value of $4.3 million and a negligible fair value. There were no forward foreign currency contracts outstanding at the end of 2002. Net foreign currency exchange gain was negligible in 2003 compared to $0.5 million for 2002. Net foreign currency exchange loss was approximately $0.1 million in 2001.

Table of Contents

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

THORATEC CORPORATION AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

INDEPENDENT AUDITORS REPORT

To the Shareholders and Board of Directors of Thoratec Corporation:

We have audited the accompanying consolidated balance sheets of Thoratec Corporation and subsidiaries as of January 3, 2004 and December 28, 2002 and the related consolidated statements of operations, comprehensive income (loss), shareholders equity and cash flows for the years ended January 3, 2004, December 28, 2002 and December 29, 2001. 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 audits.

We conducted our audits 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 audits provide 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 January 3, 2004 and December 28, 2002 and the results of their operations and their cash flows for the years ended January 3, 2004, December 28, 2002 and December 29, 2001 in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 1 to the consolidated financial statements, in 2002 the Company changed its method of accounting for goodwill and other intangible assets to conform to Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California

March 12, 2004

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	2003	2002
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 62,020	$ 42,044
Short-term available-for-sale investments		3,439
Receivables, net of allowances of $486 in 2003 and $238 in 2002	27,969	27,593
Inventories	36,417	38,835
Deferred tax asset	9,717	12,182
Prepaid expenses and other assets	3,079	2,517
Total current assets	139,202	126,610
Property, plant and equipment, net	28,492	24,715
Long-term available-for-sale investments	41,179	30,051
Goodwill	96,065	96,492
Purchased intangible assets, net	164,865	184,282
Long-term deferred tax asset	4,796	5,244
Other assets	1,532	1,038
Total Assets	$476,131	$468,432
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 6,952	$ 6,319
Accrued compensation	8,851	6,372
Accrued merger, restructuring and other		1,208
Estimated liabilities for warranty, legal and other	1,463	1,304
Accrued legal settlement	2,000	
Accrued income taxes	1,637	1,393
Other accrued liabilities	1,869	2,042
Total current liabilities	22,772	18,638
Long-term deferred tax liability and other	67,123	75,454

Total Liabilities	89,895	94,092
Commitments		
Shareholders equity:		
Common shares: authorized 100,000; issued and outstanding 56,242 in 2003 and 55,037 in 2002	423,045	410,266
Deferred compensation	(2,630)	(3,735)
Accumulated deficit	(34,594)	(32,412)
Accumulated other comprehensive income (loss):		
Unrealized gain on investments	51	130
Cumulative translation adjustments	364	91
Total accumulated other comprehensive income (loss)	415	221
Total Shareholders Equity	386,236	374,340
Total Liabilities and Shareholders Equity	$476,131	$468,432

See notes to consolidated financial statements.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Fiscal Years Ended		
	2003	**2002**	**2001**
	(In thousands, except per share data)		
Product sales	$149,916	$130,844	$113,384
Cost of product sales	61,168	55,124	52,840
Gross profit	88,748	75,720	60,544
Operating expenses:			
Selling, general and administrative	44,437	37,413	32,346
Research and development	26,052	25,251	22,082
Amortization of purchased intangible assets	12,333	12,384	11,321
Amortization of goodwill			4,353
Impairment of intangible asset	8,987		
In-process research and development	220		76,858
Legal settlement, merger, restructuring and other costs	2,132	1,409	7,134
Total operating expenses	94,161	76,457	154,094
Loss from operations	(5,413)	(737)	(93,550)
Interest and other income - net	1,837	1,631	2,359
Income (loss) before taxes	(3,576)	894	(91,191)
Income tax expense (benefit)	(1,394)	383	(3,325)
Net income (loss)	$ (2,182)	$ 511	$ (87,866)
Basic and diluted earnings (loss) per share	$ (0.04)	$ 0.01	$ (1.68)
Shares used to compute earnings (loss) per share:			
Basic	55,583	56,184	52,336
Diluted	55,583	56,762	52,336

See notes to consolidated financial statements.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	For the Fiscal Years Ended		
	2003	**2002**	**2001**
		(In thousands)	
Net income (loss)	$(2,182)	$511	$(87,866)
Other net comprehensive income (loss):			
Unrealized gain (loss) on available-for-sale investments (net of taxes of $(54), $87 and $22 in 2003, 2002 and 2001, respectively)	(79)	130	39
Foreign currency translation adjustments	273	108	(26)
Comprehensive income (loss)	$(1,988)	$749	$(87,853)

See notes to consolidated financial statements.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

	Common Shares	Stock $	Retained Earnings (Accumulated Deficit)	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Total Shareholders Equity
			(In thousands)			
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
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 taxes of $22)					39	39
Foreign currency translation adjustment					(26)	(26)
Net Loss			(87,866)			(87,866)
BALANCE, FISCAL YEAR ENDED 2001	56,114	$409,081	$(31,166)	$ (4,555)	$ (17)	$373,343
Issuance of common shares, net of costs	1,055	16,120				16,120
Non-cash compensation for services		100				100
Exercise of common stock options for cash	93	829				829
		334				334

Tax benefit related to employees and directors stock plans						
Common stock issued under restricted common stock award	50	328		(328)		
Repurchase of common stock	(2,275)	(16,526)	(1,757)			(18,283)
Amortization of deferred compensation				1,148		1,148
Other comprehensive income:						
Unrealized gain on available-for-sale investments (net of taxes of $87)					130	130
Foreign currency translation adjustment					108	108
Net Income			511			511
BALANCE, FISCAL YEAR ENDED 2002	55,037	$410,266	$(32,412)	$ (3,735)	$ 221	$374,340
Non-cash compensation for services		30				30
Exercise of common stock options for cash	1,082	9,494				9,494
Issuance of common shares under Employee Stock Purchase Plan	123	1,107				1,107
Tax benefit related to employees and directors stock plans		2,148				2,148
Amortization of deferred compensation				1,105		1,105
Other comprehensive income:						
Unrealized loss on available-for-sale investments (net of taxes of $(54))					(79)	(79)
Foreign currency translation adjustment					273	273
Net Loss			(2,182)			(2,182)
BALANCE, FISCAL YEAR ENDED 2003	56,242	$423,045	$(34,594)	$ (2,630)	$ 415	$386,236

See notes to consolidated financial statements.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Fiscal Years Ended		
	2003	**2002**	**2001**
		(In thousands)	
Cash flows from operating activities:			
Net income (loss)	$ (2,182)	$ 511	$ (87,866)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	18,914	17,076	19,845
Impairment of intangible asset	8,987		
In-process research and development	220		76,858
Non-cash compensation expense	30	100	303
Amortization of deferred compensation	1,105	1,148	677
Income tax (benefit) expense	(1,394)	383	(3,325)
Changes in assets and liabilities:			
Receivables	565	(420)	(5,892)
Inventories	3,666	(12,640)	(560)
Prepaid expenses and other assets	(1,043)	(1,035)	814
Accounts payable and other liabilities	5,153	(1,806)	(4,326)
Change in net deferred tax liability	(3,362)	(1,092)	332
Net cash provided by (used in) operating activities	30,659	2,225	(3,140)
Cash flows from investing activities:			
Purchases of available-for-sale investments	(24,848)	(34,060)	(120,267)
Sales and maturities of available-for-sale investments	15,891	700	218,989
Reclassification from (to) restricted cash and cash equivalents		45,884	(45,884)
Capitalized transaction costs	(395)		(5,838)
Purchases of property, plant and equipment	(6,926)	(7,528)	(7,947)
Cash and equivalents acquired in business acquisition			16,199
Acquisition of IRMA product line	(5,200)		
Net cash provided by investing activities	(21,478)	4,996	55,252
Cash flows from financing activities:			
Proceeds from stock option exercises, net	9,494	829	11,077
Proceeds from common stock offering		15,335	
Proceeds from stock issued under employee stock purchase plan	1,107		

Repurchase of common stock		(18,283)	(1,703)
Repurchase of convertible debentures		(54,838)	
Net cash provided by (used in) financing activities	10,601	(56,957)	9,374
Effect of exchange rate changes on cash and cash equivalents	194	54	4
Net increase (decrease) in cash and cash equivalents	19,976	(49,682)	61,490
Cash and cash equivalents at beginning of period	42,044	91,726	30,236
Cash and cash equivalents at end of period	$ 62,020	$ 42,044	$ 91,726
Supplemental disclosure of cash flow information:			
Cash paid for taxes	$ 889	$ 347	$ 470
Cash paid for interest	$	$ 839	$ 2,604
Supplemental disclosure of Non-cash investing and financing activities:			
Issuance of restricted stock for services	$	$ 328	$ 4,140
Tax benefit related to stock option exercises	$ 2,148	$ 334	$ 5,402
Reclassification of acquired workforce, net of taxes	$	$ 1,334	$

See notes to consolidated financial statements.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Operations and Significant Accounting Policies

Operations - Thoratec Corporation, referred to as we, our, Thoratec or our Company, is headquartered in Pleasanton, California and is a leading manufacturer of circulatory support products for use by patients with congestive heart failure. We develop, manufacture and market products that are used by physicians and hospitals for cardiac assist, vascular and diagnostic applications. We organize and manage our business by functional operating entities, which operate in two business segments: our Cardiovascular segment and our ITC segment. Our Cardiovascular segment develops, manufactures and markets proprietary medical devices used for circulatory support and vascular graft applications. Our ITC segment designs, develops, manufactures and markets point-of-care diagnostic test systems. We conduct business both domestically and internationally. In February 2001, we merged with Thermo Cardiosystems, Inc. (TCA). Prior to the merger (the Merger), TCA was a subsidiary of Thermo Electron Corporation (Thermo Electron). In September 2003, ITC acquired the Immediate Response Mobile Analysis, (IRMA), point-of-care blood analysis system product line from Diametrics Medical, Inc., (Diametrics), in an asset purchase.

Fiscal Year - We report on a 52-53 week fiscal year, which ends on the Saturday closest to December 31. The fiscal years ended December 29, 2001, (2001) and December 28, 2002, (2002) included 52 weeks and the fiscal year ended January 3, 2004, (2003) included 53 weeks.

Principles of Consolidation - The consolidated financial statements include the accounts of our Company and our 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 our 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 - We primarily sell our products to large hospitals and distributors. No customer accounted for more than 10% of product sales in fiscal year 2003. For fiscal years 2002 and 2001, one distributor customer accounted for 11% and 12% of total product sales, respectively. Accounts receivable for this same distributor customer accounted for 11% and 10% of total accounts receivable as of the end of 2003 and 2002, respectively. No other customer accounted for more than 10% of total product sales in 2003, 2002 or 2001 or had an accounts receivable balance greater than 10% of total accounts receivable at the end of 2003 or 2002.

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, we maintain allowances for potential credit losses.

Additionally, we are potentially subject to concentrations of credit risk in our investments. To mitigate this credit risk, we invest in high-grade instruments and limit our exposure to any one issuer.

Certain Risks and Uncertainties - We are subject to certain risks and uncertainties and believe that changes in any of the following areas could have a material adverse effect on our future financial position or results of operations: the ability to achieve and maintain profitability; the ability of third party payors to cover and provide appropriate levels of

reimbursement for our products; the ability to receive Food and Drug Administration, or FDA, and foreign regulatory authorities approval to manufacture, market and sell our products; the ability to direct and manage current and future growth, including the growth of the number of Destination Therapy, or DT, procedures performed and the integration of any current and future acquisitions of companies or technologies; new product development and introduction, including FDA approval and market receptiveness; the ability to realize the full value of our intangible assets; the reliance on specialized suppliers; competition from other products; the ability to manufacture products on an efficient and timely basis and at a reasonable cost and in sufficient volume, including the ability to obtain timely deliveries of parts from suppliers; the dependence upon distributors and any changes made to our method of distribution; the ability to protect our proprietary technologies or an infringement of others patents; product liability or other claims; our ability to identify and correct quality issues in a timely manner and at a reasonable cost; the ability to maintain compliance with changing federal and state regulations; the long and variable sales and deployment cycle of our ventricular assist device (VAD) products; worldwide demand for circulatory support and

Table of Contents

graft products and blood coagulation testing and skin incision devices and the management of risks inherent in selling in foreign countries; claims relating to the handling, storage or disposal of hazardous chemicals and biomaterials; stock price volatility due to general economic conditions or future issuances and sales of our stock; the occurrence of natural catastrophic disasters; foreign currency fluctuations; the ability to attract and retain talented employees; and other risks as detailed from time to time in our filings with the Securities and Exchange Commission, referred to as the SEC.

Cash and Cash Equivalents - Cash and cash equivalents are defined as short-term highly liquid investments with original maturities of 90 days or less.

Short-Term and Long-Term Available-For-Sale Investments - Our investments are primarily held in corporate bonds and U.S. government obligations and are classified as available-for-sale and are reported at fair value based upon quoted market price. Any temporary difference between cost and fair value of an investment is presented as a separate component of accumulated other comprehensive income. The specific identification method is used to determine realized gains and losses on investments.

Inventories - Inventories are stated at the lower cost or market. Cost is based on the first in, first out method.

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. Amortization expense of all rental equipment included in our rental program is recognized ratably over 2 to 3 years and is recorded in cost of product sales.

Capitalized Software Costs - We capitalize 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. We expense costs related to preliminary project assessment, research and development, re-engineering, training and application maintenance as incurred. Through fiscal year 2002, costs capitalized for a new enterprise resource planning software system, (ERP System), were $3,666,000. No additional costs were capitalized in 2003 related to this ERP System. Depreciation expense related to this ERP System of $494,000 and $413,000 were recorded in 2003 and 2002, respectively. All capitalized software costs are depreciated on a straight-line method over a period of eight years upon being placed in service.

Valuation of Long-Lived Assets In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, which we adopted as of the beginning of fiscal year 2002, we periodically evaluate the carrying value of long-lived assets to be held and used including intangible assets, when events or circumstances warrant such a review. The carrying value of a long-lived asset to be held and used is considered impaired when the anticipated separately identifiable undiscounted cash flows from such an asset are less than the carrying value of the asset. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved.

Purchased Intangible Assets and Goodwill - As of the beginning of fiscal year 2002, we adopted SFAS No. 142, Goodwill and Other Intangible Assets, and ceased the amortization of purchased goodwill. In addition, we reevaluated the useful lives of our identifiable intangible assets and determined that the remaining useful lives were appropriate. Each year we complete an impairment test of goodwill as required by SFAS No. 142. Upon completion of our impairment tests as of the end of fiscal 2003, we determined that our goodwill was not impaired.

The following table presents the impact of adopting SFAS No. 142 on net income (loss) and net income (loss) per share had the standard been in effect for fiscal year 2001 (in thousands, except per share amounts):

Table of Contents

	For Fiscal Year Ended 2001
Net income (loss) as reported	$(87,866)
Add back:	
Amortization of goodwill, net of tax	4,194
Adjusted net income (loss)	$(83,672)
As reported basic and diluted net income (loss) per share	$ (1.68)
Impact of amortization of goodwill, net of tax	0.08
Adjusted basic and diluted net income (loss) per share	$ (1.60)

The change in the carrying amount of goodwill, which is only attributable to our Cardiovascular business segment, for fiscal years 2003 and 2002 were as follows (in thousands):

	As of Fiscal Years	
	2003	2002
Balance at the beginning of year	$96,492	$95,209
Adjustment to reflect realization of acquired foreign deferred tax asset	(427)	
Reclassification of assembled workforce, net of taxes		1,334
Adjustment to reflect resolution of pre-merger contingency		(51)
Balance as of January 3, 2004	$96,065	$96,492

In 2003, goodwill related to the Merger of Thoratec with TCA was adjusted to reflect the utilization of tax net operating loss, (NOL), benefits related to our subsidiary in the United Kingdom, (UK). At the time of the Merger, a deferred tax asset related to these NOL tax benefits was established with a corresponding valuation allowance for the full amount. As our UK subsidiary more likely than not will begin utilizing a portion of this NOL benefit, a portion of the original valuation allowance has been reversed against goodwill.

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

	Fiscal Year 2003		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and Trademarks	$ 37,815	$(10,416)	$ 27,399
Core Technology	37,485	(5,353)	32,132
Developed Technology	122,782	(17,535)	105,247
Non-compete Agreement	90	(3)	87
Total Purchased Intangible Assets.	$198,172	$(33,307)	$ 164,865

	Fiscal Year 2002		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and Trademarks	$ 37,478	$ (6,789)	$ 30,689
Core Technology	37,181	(3,486)	33,695
Developed Technology	132,301	(12,403)	119,898
Total Purchased Intangible Assets	$206,960	$(22,678)	$ 184,282

As of the beginning of fiscal 2002, the purchased intangible asset associated with the assembled workforce in the amount of $1,334,000, net of accumulated amortization of $381,000 and taxes of $897,000, was reclassified to goodwill in accordance with SFAS No. 142.

Subsequent to year-end, the Company completed its assessment of the final results from its feasibility clinical trial for the Aria CABG graft which was ongoing through fiscal 2003. Based on the clinical trial results, the Company determined that it will not

Table of Contents

devote additional resources to the development of the Aria graft. Upon the decision to discontinue product development, the Company recorded an impairment charge of $9.0 million as of January 3, 2004 to write off purchased intangible assets related to the Aria graft, which were recorded as a result of the Merger.

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

Amortization expense related to identifiable intangible assets for fiscal 2003, 2002 and 2001 was $12,333,000, $12,384,000, and $11,321,000, respectively. Amortization expense is expected to be approximately $11,700,000 for each of the next five years. The purchased intangible assets have estimated useful lives of eight to twenty years.

Fair Value of Financial Instruments - Financial instruments include cash and cash equivalents, short-term and long-term available-for-sale investments, customer receivables, accounts payable and certain other accrued liabilities. The fair value of short-term and long-term investments are assessed using current market quotations from major investment brokers. The carrying amounts of these investments are adjusted to market value monthly. The carrying amounts of all other financial investments are reasonable estimates of their fair values.

Foreign Currency Translation - All assets and liabilities of our non-United States operations are translated into United States dollars at period-end exchange rates, and the resulting translation adjustments are included in other 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 our 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.

Commencing in September 2003, the Company began using forward foreign currency contracts to hedge the gains and losses generated by the remeasurement of these non-functional currency assets and liabilities. Changes in the fair value of the forward currency contracts are included in Interest and Other Income-Net, and typically offset the foreign currency exchange gains and losses described above. These derivatives are not designated as cash flow or fair value hedges under SFAS No. 133 and typically have maturities of three months or less. At January 3, 2004, the Company had forward foreign currency contracts to exchange Pounds Sterling and Euros for US Dollars with a notional value of $4.3 million and negligible fair value. Net foreign currency exchange gain was negligible in 2003 compared to $0.5 million for 2002. Net foreign currency exchange loss was approximately $0.1 million on 2001.

Repurchases of Common Stock - In April 2001, the Board of Directors authorized a stock repurchase program under which up to $20,000,000 of our common stock could be acquired. We completed this stock repurchase program in the third quarter of 2002. From the inception of the program through the third quarter of 2002, we repurchased 2,467,600 shares of our common stock for $20,000,000. For each share repurchased, we reduced the common stock account by the average value per share reflected in the account prior to the repurchase with the excess allocated to retained earnings. All repurchased shares have been retired.

In February 2004, the Board of Directors authorized a stock repurchase program under which up to $25.0 million of our common stock could be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of purchases were based on several conditions, including the price of our stock, general market conditions and other factors.

Revenue Recognition and Product Warranty - We recognize revenue from product sales when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is

fixed or determinable and collectibility is reasonably assured. Sales to distributors are recorded when title transfers upon shipment. One distributor has certain limited product return rights. A limited number of other distributors have certain rights of return upon termination of their distribution agreement. A reserve for sales returns is recorded for these customers applying reasonable estimates of product returns based upon significant historical experience in accordance with SFAS No. 48, Revenue Recognition when Right of Return Exists. No other direct sales customers or distributors have return rights or price protection.

Table of Contents

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 2003, $128,000 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 $20,000 at the end of 2003, $148,000 at the end of 2002 and $38,000 at the end of 2001.

We also rent certain medical devices to customers on a month-to-month or as-used basis. Rental income is based on utilization and is included in product sales as earned. Included in product sales for 2003, 2002 and 2001 are $4,727,000, $3,884,000 and $3,456,000, respectively, of income earned from the rental of these medical devices.

The majority of our products are covered by a one-year limited manufacturer s warranty. Estimated contractual warranty obligations are recorded when related sales are recognized and any additional amounts are recorded when such costs are probable and can be reasonably estimated. The change in accrued warranty expense in 2003 and 2002 is summarized in the following table (in thousands):

	Balance Beginning of Year	Charges to Costs and Expenses	Warranty Expenditures	Balance End of Year
Fiscal year ended 2003	$ 695	$ 193	$ (59)	$829
Fiscal year ended 2002	$ 910	$ 45	$(260)	$695
Fiscal year ended 2001	$ 970	$ 594	$(654)	$910

Stock-Based Compensation - We account 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. 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. The fair value of each option granted is estimated using the Black-Scholes option pricing model. If compensation cost for our stock-based plans had been determined based on the fair value at the grant dates for awards under those plans, consistent with the method of FASB Statement No. 123, our reported net income (loss) would have been adversely affected, as shown in the following table (in thousands, except per share data):

	For Fiscal Year Ended		
	2003	2002	2001
Net income (loss):			

As reported	$(2,182)	$ 511	$(87,866)
Add: Stock-based compensation expense included in reported net income, net of related tax effects	693	726	812
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(8,465)	(9,788)	(9,421)
Pro forma	$(9,954)	$(8,551)	$(96,475)
Basic and diluted earnings (loss) per share:			
As reported	$ (0.04)	$ 0.01	$ (1.68)
Pro forma	$ (0.18)	$ (0.15)	$ (1.84)

Table of Contents

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:

	Stock Option Plans			Employee Stock Purchase Plan	
	For Fiscal Year Ended			For Fiscal Year Ended	
	2003	2002	2001	2003	2002
Risk-free interest rate	3.69%	4.79%	5.08%	1.16%	1.39%
Expected volatility	67%	69%	71%	67%	69%
Expected option life	3.88 years	3.85 years	2.85 years	0.50 years	0.50 years
Dividends	None	None	None	None	None

Earnings (Loss) Per Share - Basic earnings (loss) per share were computed using the weighted average number of common shares outstanding for each respective year. Diluted earnings (loss) per share amounts reflect the weighted average impact from the date of issuance of all potentially dilutive securities during the years presented unless the inclusion would have had an antidilutive effect.

Other 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 available-for-sale investments and foreign currency translation adjustments.

Recently Issued Accounting Standards - In June 2001, the FASB issued SFAS No. 143, Accounting for Asset Retirement Obligations. We adopted SFAS No. 143 at the beginning of fiscal 2003. The adoption of this statement did not materially impact our consolidated financial statements.

In April 2002, the FASB issued SFAS No. 145, which, among other things, changed the presentation of gains and losses on the extinguishment of debt. Any gain or loss on extinguishment of debt that does not meet the criteria in APB Opinion 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, is to be included in operating earnings and not presented separately as an extraordinary item. We adopted SFAS No. 145 at the beginning of fiscal year 2003 and therefore, we reclassified in the first quarter of 2003 the extraordinary loss incurred in 2002 of $0.5 million to interest and other income-net.

In June 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. The Company will apply the provisions of SFAS No. 146 for any restructuring activities initiated after December 31, 2002.

In November 2002, the Emerging Issues Task Force, or EITF, reached a consensus regarding EITF Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. The guidance provided is effective for contracts entered into on or after July 1, 2003. The adoption of this guidance did not have a material effect upon our consolidated financial statements.

In November 2002, the FASB issued Interpretation, or FIN, No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others. We adopted the disclosure provisions of FIN No. 45 effective as of fiscal year end 2002. We do not expect that the recognition provisions of FIN 45 will have a material impact upon our consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure. SFAS No. 148 amends FASB Statement No. 123, Accounting for Stock-Based Compensation, to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements of the method of accounting for stock-based employee compensation and the effect of the method used on reported results. We adopted the disclosure provisions of SFAS No. 148 at the beginning of fiscal 2003. We do not currently plan to change to use the fair value based method of accounting for stock-based employee compensation.

In January 2003, the FASB issued FIN No. 46, Consolidation of Variable Interest Entities. The provisions of FIN 46 are effective for any arrangements entered into after January 31, 2003. Since January 31, 2003, the Company has not invested in any entities it believes are variable interest entities. In December 2003, the FASB issued a revised interpretation of FIN 46, FIN 46-R. The Company does not expect the adoption of FIN 46-R to have a material impact upon our consolidated financial statements.

Table of Contents

In April 2003, the FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. The statement is effective for contracts entered into or modified after June 30, 2003. We adopted SFAS No. 149 effective July 1, 2003. The adoption of this standard did not have a material effect on our consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003 and was effective at the beginning of the first interim period beginning after June 15, 2003. In November 2003, the FASB issued FASB Staff Position No. 150-3, Effective Date, Disclosures, and Transition for Mandatorily Redeemable Noncontrolling Interests under SFAS No. 150, which defers the effective date for various provisions of SFAS 150. The adoption of this statement is not expected to have an impact on our consolidated financial statements.

Presentation Certain 2002 and 2001 amounts have been reclassified to conform to the presentation in the 2003 financial statements.

2. Merger and Acquisitions

Merger of Thoratec and TCA

On February 14, 2001, we completed our Merger with TCA. Pursuant to the Merger agreement between us and TCA dated October 3, 2000, we issued 32,226,074 new 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 shares of our stock for each share of TCA 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 our 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 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. Approximately $309,025,000 of the total purchase price of $346,193,000 was 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 one-time write-off of IPR&D related to four technology projects that were in development, had not reached technological feasibility, had no alternative future use and for which successful development was uncertain. One of the projects was completed in 2002. There have been no significant developments subsequent to the Merger related to the current status of any of the three remaining 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 regulated and technical nature of our products, current estimates remain materially consistent with our initial estimates.

Acquisition of Immediate Response Mobile Analysis (IRMA)

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

acquired as determined by an independent valuation firm as follows (in thousands):

Table of Contents

		Life
Working capital	$1,034	
Property, plant and equipment	2,492	3-10 years
Core technology	331	10 years
Existing developed technology	1,058	10 years
Patents	317	17 years
Other intangibles	143	7-17 years
In-process research and development	220	Expensed in 2003
Acquisition costs	(395)	
Consideration paid	$5,200	

There was no goodwill recorded with the transaction. As a result of the acquisition, $220,000 relating to in-process research and development was expensed in the fourth quarter of 2003.

On a pro-forma basis, consolidating historic financial information of Thoratec and the IRMA product line and making pro forma consolidation adjustments, as if the acquisition had occurred on December 30, 2001, unaudited pro forma revenue for 2002 and 2003 would have been $143.2 million and $154.8 million respectively. On the same basis, 2002 net loss and loss per share would have been $0.4 million $0.01 respectively, and 2003 net loss and loss per share would have been approximately $2.7 million and $0.05 respectively.

3. Investments

Our 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 as a separate component of accumulated other comprehensive income. We classify investments that mature in less than one year of the purchase date as short-term investments. Investments that mature greater than one year from the purchase date are classified as long-term investments. At the end of 2003 and 2002, we had no investments with maturities greater than two years from the date of purchase.

The aggregate market value, cost basis and gross unrealized gains and losses of short-term and long-term available-for-sale investments for 2003 and 2002 by major security type are as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As of Fiscal Year 2003:				
Long-term investments:				
Corporate bonds	$37,095	$ 105	$ (19)	$37,181
US government obligations	4,000		(2)	3,998

	$41,095	$ 105	$ (21)	$41,179
As of Fiscal Year 2002:				
Short-term investments:				
Corporate bonds	$ 3,438	$ 1	$	$ 3,439
Long-term investments:				
Corporate bonds	29,834	218	(1)	30,051
	$33,272	$ 219	$ (1)	$33,490

The contractual maturities of available-for-sale investments as of January 3, 2004 and December 28, 2002, regardless of the consolidated balance sheet classifications, are as follows (in thousands):

Table of Contents

	Amortized Cost	Fair Value
As of Fiscal Year 2003		
Due within one year	$23,790	$23,876
Due after one year through two years	17,305	17,303
	$41,095	$41,179
As of Fiscal Year 2002		
Due within one year	$11,879	$11,922
Due after one year through two years	21,393	21,568
	$33,272	$33,490

The cost of available-for-sale investments that are sold is based on specific identification in determining recorded realized gains and losses. In 2003 and 2002 there were no significant gains or losses recorded.

4. Inventories

Inventories consist of the following (in thousands):

	As of Fiscal Year	
	2003	2002
Finished goods	$15,504	$14,692
Work-in-process	9,089	6,645
Raw materials	11,824	17,498
Total	$36,417	$38,835

5. Financial Instruments

In 2003 we initiated a foreign currency exchange risk management program principally designed to mitigate the change in value of assets and liabilities that are denominated in non-functional currencies. Forward foreign exchange contracts that generally have terms of three months or less are used to hedge these non-functional currency exposures. The derivatives used in the foreign currency exchange risk management program are not designated as cash flow or fair value hedges under SFAS No. 133, Accounting for Derivative Investments and Hedging Activities. These

contracts are recorded on the balance sheet at fair value in current assets. Changes in the fair value of the contracts and of the underlying exposures being hedged are included in Interest and Other Income Net. As of the end of fiscal year 2003, the notional value of outstanding contracts was $4.3 million and their fair value was negligible.

6. Property, Plant and Equipment

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

	As of Fiscal Year	
	2003	**2002**
Land	$ 341	$ 341
Building	2,445	2,445
Building lease	2,285	2,285
Equipment	34,606	28,897
Rental equipment	6,493	6,095
Leasehold improvements	11,853	9,292
Total	58,023	49,355
Accumulated depreciation and amortization	(29,531)	(24,640)
	$ 28,492	$ 24,715

Depreciation expense in 2003, 2002 and 2001 was $5,717,000, $5,187,000 and $4,523,000, respectively.

Table of Contents

7. Commitments and Contingencies

Leases

We lease manufacturing, office, research facilities and equipment under various operating lease agreements. Future minimum lease payments as of the end of 2003 are noted below (in thousands):

Fiscal year:	
2004	$ 2,542
2005	2,451
2006	2,452
2007	2,438
2008	2,106
Thereafter	10,176
Total	$22,165

Rent expense for all operating leases was $2,149,000 in 2003, $1,808,000 in 2002 and $1,778,000 in 2001.

Commitments

We had various purchase order commitments totaling approximately $10,162,000 and $11,032,000 as of the end of fiscal years 2003 and 2002, respectively.

Contingencies

We are involved in various other litigation matters in the normal course of business. We believe that the ultimate resolution of these matters will not have a material effect on our financial position or results of operations.

8. Subordinated Convertible Debentures

On March 11, 2002 we completed the redemption of our outstanding subordinated convertible debentures using restricted cash, cash and cash equivalents of approximately $54,800,000. Loss in the amount of $515,000 and a tax benefit of $206,000 was recorded on the date of the redemption related to the write-off of the capitalized debt issuance costs. Restricted cash had been pledged as collateral for a letter of credit guarantee to Thermo Electron related to Thermo Electron s guarantee of our subordinated debentures. As a result of the redemption, the letter of credit guarantee to Thermo Electron was extinguished.

Table of Contents

9. Common and Preferred Stock

We have 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. We may redeem the Series A preferred stock at any time for our 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 January 3, 2004, 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 us 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 January 3, 2004, no shares of Series B preferred stock were outstanding.

On May 2, 2002, we adopted a shareholder rights plan, which we call the Rights Plan. Under the Rights Plan, we distributed one purchase right for each share of common stock outstanding at the close of business on May 17, 2002. If a person or group acquires 15% or more of our common stock in a transaction not pre-approved by our Board of Directors, each right will entitle its holder, other than the acquirer, to buy our common stock at 50% of its market value for the right s then current exercise price (initially $70.00). In addition, if an unapproved party acquires more than 15% of our common stock, and our Company or our business is later acquired by the unapproved party or in a transaction in which all shareholders are not treated alike, shareholders with unexercised rights, other than the unapproved party, will be entitled to purchase common stock of the merger party or asset buyer with a value of twice the exercise price of the rights. Each right also becomes exercisable for one one-thousandth of a share of our Series RP preferred stock at the right s then current exercise price ten days after an unapproved third party makes, or announces an intention to make, a tender offer or exchange offer that, if completed, would result in the unapproved party acquiring 15% or more of our common stock. Our Board of Directors may redeem the rights for a nominal amount before an event that causes the rights to become exercisable. The rights will expire on May 2, 2012.

In connection with the Rights Plan, we designated 100,000 no par shares of Series RP preferred stock. These shares, if issued, will be entitled to receive quarterly dividends and liquidation preferences. There are no shares of Series RP preferred stock issued and outstanding and we do not anticipate issuing any shares of Series RP preferred stock except as may be required under the Rights Plan.

We filed a Registration Statement on Form S-3 with the SEC to register for sale 1,055,000 newly issued shares of our 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. We received $15,335,000, net of underwriting discounts, fees and 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. We received no proceeds from the sale of these over-allotment shares.

Table of Contents

10. Stock-Based Compensation

Restricted Common Stock

In 2001, an award of 250,000 shares of restricted common stock was made to one of our executive officers under our 1997 Stock Option Plan. This award was valued at $4,140,000, recorded as deferred compensation and is being amortized over the restriction lapse period. In 2002, a similar award of 50,000 shares was made to another of our executive officers. This award was valued at $328,000, was recorded as deferred compensation and is being amortized over the restriction lapse period. As of the end of fiscal 2003, none of the restrictions on these shares have lapsed.

Stock Option Plans

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. There were no grants under any of TCA s plans during 2003, 2002 or 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 of our 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.

In 1993, our Board of Directors approved the 1993 Stock Option Plan (1993 SOP), which permits us to grant options to purchase up to 666,667 shares of common stock. No options were granted under this plan in 2003 or 2002.

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 us to grant options to purchase up to 500,000 shares of common stock. During both 2003 and 2002 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 us to grant non-qualified options to the CEO to purchase up to 333,333 shares of common stock, which were granted in 1996. The Directors Option Plan, as amended, permits us to grant up to 550,000 shares and provides for an initial grant to a Director to purchase 15,000 shares upon appointment to the Board , and annual grants thereafter to purchase 7,500 shares (granted in four equal installments). Provisions also include immediate vesting of both initial and annual grants and a five year life on the options. In addition, the plan administrator has been provided with the discretion to impose any repurchase rights in our favor on any optionee. We currently have seven non-employee directors, each of whom is eligible to participate in the Directors Option Plan. There were 61,875 and 45,000 options granted in 2003 and 2002, respectively, 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 our shareholders in February 2001, amended by the Board of Directors in December 2001, and amended again by approval of a vote of our shareholders in May 2003. The 1997 SOP allows us to grant up to 13,700,000 shares of stock in the form of stock options, restricted stock awards, and stock bonuses. During 2003 and 2002, 2,240,673 options and 2,780,200 options, respectively, were granted at fair market value under this plan. During 2003 and 2002, no shares and 50,000 shares, respectively, were granted as restricted stock awards under this plan.

We have four common stock option plans with options still outstanding at January 3, 2004. Options may be granted by the Board of Directors at the fair market value on the date of grant and generally become exercisable within five years of grant and expire between five and ten years from the date of grant. At the end of 2003, options to purchase 4,211,966 common shares remain available for grant under all the plans.

Table of Contents

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 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 and expired	(527)	12.35
Exercised	(1,378)	8.04
Options assumed during Merger	3,696	8.09
Outstanding at fiscal year end 2001 (2,615 exercisable at $9.99 weighted average price per share)	5,585	10.51
Granted ($9.45 weighted average fair value per share)	2,825	13.31
Cancelled and expired	(582)	13.19
Exercised	(93)	8.90
Outstanding at fiscal year end 2002 (3,392 exercisable at $9.94 weighted average price per share)	7,735	$ 11.36
Granted ($6.57 weighted average fair value per share)	2,302	12.74
Cancelled and expired	(801)	13.51
Exercised	(1,082)	8.74
Outstanding at fiscal year end 2003 (3,566 exercisable at $10.76 weighted average price per share)	8,154	$ 11.88

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. This acceleration of vesting was provided in the terms of the original Thoratec grants. Of the options that accelerated, agreements involving substantially all of the underlying shares were entered into whereby certain option holders agreed not to sell or transfer any of their shares for a period of up to 18 months and to remain employed with us for a period of 12 months after the effective date of the Merger. In exchange, the options holders received cash payments totaling $810,000 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.

Options outstanding as of the end of 2003 are summarized as follows:

Exercise Price Range		Options Outstanding			Options Exercisable	
		Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Exercise Price
$ 4.38	$ 6.38	927,252	5.76	$ 5.69	693,245	$ 5.68
6.40	8.78	1,167,527	7.14	8.31	586,858	8.16
8.81	11.97	2,127,879	6.87	9.91	1,243,573	9.98
11.98	15.48	1,751,690	8.43	14.10	382,871	14.17
15.55	17.77	2,005,391	8.04	15.96	538,082	16.09
17.80	20.85	113,625	6.77	19.09	61,198	19.24
29.40	33.05	60,516	2.89	32.35	60,516	32.35
$ 4.38	$33.05	8,153,880	7.37	$11.88	3,566,343	$10.76

Table of Contents

Employee Stock Purchase Plan

In May 2002, our shareholders approved the Company s Employee Stock Purchase Plan (ESPP) under which 500,000 shares of common stock had been reserved for issuance. In addition, the ESPP provides for an annual increase of up to 250,000 shares in the total number of shares available for issuance under the ESPP on March 1 of each year. No increase in shares available for issuance under the ESPP was made during 2003. Eligible employees may purchase a limited number of shares of the Company s stock at 85% of the lower of the market value at the offering date or market value on the purchase date. Approximately 123,000 shares of common stock were issued in 2003 for $1,100,000. No shares of common stock were issued under this plan in 2002. As of the end of fiscal year 2003, approximately 377,000 shares are available for issuance under this plan.

11. Related Parties

Corporate Service Agreement

We had a corporate services agreement with Thermo Electron, which terminated upon completion of the Merger in 2001. Thermo Electron s corporate staff provided to us certain administrative and financial services. We paid Thermo Electron an annual amount equal to 0.8% of our revenues for these services. In addition, we incurred direct charges that Thermo Electron paid directly on our behalf. Included in the 2001 statement of operations is $124,000 of expense for these administrative and financial services and direct charges.

Operating Leases

We subleased manufacturing, office and research facilities from Thermedics Inc. in connection with the development and manufacturing of our VADs in Woburn, Massachusetts. Thermedics was a division of Thermo Electron until November 21, 2001 when it was divested by Thermo Electron and became an unrelated third party. We were charged for actual square footage occupied at approximately the same rent paid per square foot by Thermedics under its lease. The accompanying statements of income include expenses from the sublease when Thermedics was owned by Thermo Electron of $193,600 in 2001.

Purchases

We purchased 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 $2,931,000 to Tecomet for product purchases in 2001, and continue to purchase products from Tecomet, Inc. under substantially the same terms and conditions.

12. Taxes on Income

The provisions for income tax expenses (benefits) are as follows (in thousands):

	For Fiscal Year Ended		
	2003	**2002**	**2001**
Current:			
Federal	$ 232	$ 661	$
State	873	1,103	420

Foreign	13	14	
	1,118	1,778	420
Deferred:			
Federal	(2,175)	(930)	(2,915)
State	(764)	(465)	662
Foreign	427		
	(2,512)	(1,395)	(2,253)
Total provision before valuation allowance	(1,394)	383	(1,833)
Reduction of valuation allowance			(1,492)
Total provision	$(1,394)	$ 383	$(3,325)

Table of Contents

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 due to the following (in thousands):

	For Fiscal Year Ended					
	2003		2002		2001	
U.S. federal statutory income tax expense (benefit)	$(1,251)	35.0%	$ 313	35.0%	$(31,916)	(35.0)%
State income tax expense (benefit), net of federal tax expense (benefit)	(126)	3.5	177	19.8	(794)	(0.9)
Non-deductible amortization of goodwill					1,524	1.7
Non-deductible acquired IPR&D	77	(2.2)			26,900	29.5
Non-deductible merger expenses					175	0.2
Export benefits	(166)	4.6	(334)	(37.3)	(50)	(0.1)
Federal research and development credits	(177)	4.9	(118)	(13.2)	(100)	(0.1)
Non-deductible amortization of deferred compensation	68	(1.9)	101	11.3	82	0.1
Meals and entertainment	105	(2.9)	101	11.3	63	0.1
Expiration of net operating losses			154	17.2	154	0.2
Foreign earnings permanently reinvested	(72)	2.0				
Other	148	(4.0)	(11)	(1.3)	637	0.7
	$(1,394)	39.0%	$ 383	42.8%	$ (3,325)	(3.6)%

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 our net deferred taxes are as follows (in thousands):

	As of Fiscal Year	
	2003	2002
Deferred tax assets:		
Write-off of acquired technology	$ 1,043	$ 1,173
Reserves and accruals	2,265	1,895
Depreciation and amortization	368	1,536
Inventory basis difference	2,621	2,196

Research and development credit carryforwards	2,324	1,997
Net operating loss carryovers	5,570	8,339
Other, net	322	290
Total deferred tax assets	14,513	17,426
Deferred tax liabilities:		
Purchased intangibles	(65,845)	(74,081)
Net deferred tax liabilities	$(51,332)	$(56,655)

At the end of 2003, we had recognized a benefit of $72,000 related to $1.4 million of foreign earnings considered to be permanently invested in operations outside the United States.

At the end of 2003, we had federal, state and foreign net operating loss (NOL) carryforwards of approximately $15.6 million, $2.0 million and $2.8 million, respectively, which expire from 2011 through 2021. The foreign NOL has no expiration date and will be treated as a post acquisition purchase price adjustment when utilized. Use of $0.9 million of the federal NOL carryforwards, which arose prior to a greater than 50% change in ownership in 1992, is limited to approximately $0.4 million per year.

At the end of 2003, we had available carryforward research and experimentation tax credits for federal and state income tax purposes of approximately $1.7 million and $0.6 million, respectively. Federal tax credit carryforwards expire from 2009 through 2023. State tax credits carry forward indefinitely.

Table of Contents

The federal and state provisions do not reflect the tax savings resulting from reductions associated with our various stock option plans. These savings were $2.1 million, $0.3 million and $5.4 million in 2003, 2002 and 2001, respectively.

13. Enterprise and Related Geographic Information

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

Business segments (in thousands):

	For the Fiscal Years Ended		
	2003	**2002**	**2001**
Product sales:			
Cardiovascular	$ 94,382	$ 84,442	$ 71,809
ITC	55,534	46,402	41,575
Total product sales	$149,916	$130,844	$113,384
Income (loss) before income taxes:			
Cardiovascular	$ 13,604	$ 8,392	$ (177)
ITC	10,586	9,680	8,953
Corporate	(5,931)	(5,016)	(2,660)
Amortization of goodwill and purchased intangibles	(12,333)	(12,384)	(15,674)
In-process research and development	(220)		(76,858)
Impairment of intangible asset	(8,987)		
Legal settlement, merger, restructuring and other costs	(2,132)	(1,409)	(7,134)
Total operating loss	(5,413)	(737)	(93,550)
Interest and other income, net	1,837	1,631	2,359
Total income (loss) before taxes	$ (3,576)	$ 894	$ (91,191)
Total assets:			
Cardiovascular	$ 67,607	$ 71,234	$ 57,299
ITC	29,881	23,464	19,883

Corporate	117,713	92,960	159,242
Goodwill and purchased intangible assets	260,930	280,774	293,817
Total assets	$476,131	$468,432	$530,241
Depreciation and amortization:			
Cardiovascular	$ 6,508	$ 4,766	$ 3,634
ITC	1,178	1,074	1,214
Amortization of goodwill and purchased intangible assets	12,333	12,384	15,674
Total depreciation and amortization	$ 20,019	$ 18,224	$ 20,522
Capital expenditures:			
Cardiovascular	$ 4,785	$ 6,321	$ 6,789
ITC	4,634	1,207	1,158
Total capital expenditures	$ 9,419	$ 7,528	$ 7,947

Corporate primarily represents general and administrative items not specifically allocated to any particular business segment.

2003 ITC capital expenditures include $2,493 of property, plant and equipment acquired through our acquisition of the IRMA product line.

Table of Contents

Geographic Areas (in thousands):

	For the Fiscal Years Ended		
	2003	**2002**	**2001**
Product Sales:			
Domestic	$121,831	$106,983	$ 90,678
Europe	18,433	15,188	13,000
All other international	9,652	8,673	9,706
Total international.	28,085	23,861	22,706
Total	$149,916	$130,844	$113,384

14. Retirement Savings Plan

Substantially all of our 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 25% of their eligible compensation to the Retirement Plan with Thoratec making discretionary matching contributions, subject to certain IRS limitations. In 2003, 2002 and 2001 our 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 us. For 2003, 2002 and 2001, we made contributions to the Retirement Plan of approximately $827,000, $806,000 and $674,000, respectively.

15. Legal Settlement, Merger, Restructuring and Other Costs

During 2003, 2002 and 2001, the following legal settlement, merger, restructuring and other costs were recorded in expense (in thousands):

	For the Fiscal Years Ended		
	2003	**2002**	**2001**
Legal Settlement	$2,256	$	$
Merger		356	5,326
Restructuring	(118)	524	1,093
Other	(6)	529	715

Total	$2,132	$1,409	$7,134

Legal Settlement

In October 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004 the Company settled the claim and recorded a charge of $2.3 million in the fourth quarter of 2003 for the settlement and related legal costs.

Merger Costs

All Merger activities and related expenses were completed in the third quarter of 2002. Merger costs recorded during 2002 and 2001 consisted principally 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, certain Thoratec executives stock options accelerated according to their terms. In exchange for a waiver of their rights to immediately exercise these options and to sell the related stock, we 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 2002 (in thousands):

Table of Contents

	2002
Accrued Merger Costs:	
Beginning balance	$ 472
Add:	
Accruals pursuant to executive waiver agreement	337
Less:	
Payments pursuant to executive waiver agreement	(809)
Ending balance	$

Certain 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 $19,000 for 2002. All of these expenses have been paid.

Restructuring Costs

In June 2001, we initiated a restructuring plan (the Restructuring Plan) to consolidate all of our VAD manufacturing operations to our facilities in Pleasanton, California. This plan required the closure of our Chelmsford, Massachusetts office and research facility and the relocation of the Woburn, Massachusetts manufacturing operations. We continue to perform some marketing, research and development, and administrative functions at the Woburn facility. 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 and all relocation activities were completed under the Restructuring Plan in the first quarter of 2003. In February 2003, the FDA inspected the Pleasanton facility related to the relocation of the manufacturing operations and we received FDA approval to begin manufacturing our HeartMate product line in Pleasanton in April of 2003. Through the completion date of the Restructuring Plan in April 2003, we have recorded $1,495,000 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 employee severance costs and stock option acceleration charges. As of the completion date of the Restructuring Plan, we have paid approximately $1,297,000 in severance payments to 78 employees. The following is a summary of our accrued restructuring costs activity in 2003 and 2002 (in thousands):

	Fiscal Year	
	2003	2002
Accrued Restructuring Costs:		
Beginning balance	$ 679	$ 863
Employee severance accrual		425
Reduction of severance accrual	(122)	
Payments of employee severance	(557)	(609)

Ending balance	$	$ 679

In addition to the employee severance costs, estimated restructuring costs includes expense related to the acceleration of stock options granted to employees who have been or will be terminated under the Restructuring Plan. In the fiscal years ended 2003 and 2002, $4,000 and $99,000, respectively, of stock options acceleration expense was recorded.

Other Costs

Other costs of $529,000 were incurred in the fourth quarter of 2002 related to the termination of a European distribution agreement. In the first quarter of 2003 $523,000 of this amount was paid. The remaining $6,000 of the original accrual was reversed from expense in the second quarter of 2003 as an adjustment to estimated settlement 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 costs have been paid.

16. Earnings (Loss) Per Share

Table of Contents

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 3,257,000, 4,165,000 and 5,585,000 shares of common stock were not included in the computations of diluted earnings and losses per share for 2003, 2002 and 2001, respectively, as their inclusion would be antidilutive. In addition, the computation of diluted earnings per share for all years presented excluded the effect of assuming the conversion of our 4.75% subordinated convertible debentures, convertible at $37.62 per share, because their effect would have been antidilutive.

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

	2003	2002	2001
Net income (loss)	$ (2,182)	$ 511	$(87,866)
Weighted average number of common shares-Basic	55,583	56,184	52,336
Dilutive effect of stock-based compensation plans		578	
Weighted average number of common shares-Diluted	55,583	56,762	52,336
Basic and diluted earnings (loss) per common share	$ (0.04)	$ 0.01	$ (1.68)

17. Quarterly Results of Operations (Unaudited)

The following is a summary of our unaudited quarterly results of operations for the fiscal years 2003 and 2002:

	First	Second	Third	Fourth
	(In thousands, except per share data)			
Fiscal Year 2003				
Product sales	$36,062	$36,156	$35,250	$42,448
Gross profit	21,171	21,505	20,994	25,078
Net income (loss)	1,418	1,023	887	(5,510)
Basic and diluted earnings (loss) per share	$ 0.03	$ 0.02	$ 0.02	$ (0.10)
Fiscal Year 2002				
Product sales	$29,639	$31,034	$31,105	$39,066
Gross profit	16,475	17,753	18,050	23,442

Net income (loss)	(1,758)	(556)	237	2,588
Basic and diluted earnings (loss) per share	$ (0.03)	$ (0.01)	$ 0.00	$ 0.05

The fourth quarter of 2003 included charges of $2.3 million relating to a settlement of a patent infringement claim and $9.0 million to write off purchased intangibles both of which are described in Note 18.

18. Subsequent Events

In October 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D. related to materials used in the HeartMate LVAs. On February 3, 2004 the Company settled the claim and recorded a charge of $2.3 million in the fourth quarter of 2003 for the settlement and related legal costs.

Subsequent to year-end, the Company completed its assessment of the final results from its feasibility clinical trial for the Aria CABG graft which was ongoing through fiscal 2003. Based on the clinical trial results, the Company determined that it will not devote additional resources to the development of the Aria graft. Upon the decision to discontinue product development, the Company recorded an impairment charge of $9.0 million as of January 3, 2004 to write off purchased intangible assets related to the Aria graft, which were recorded as a result of the Merger.

Table of Contents

On February 11, 2004 the company announced that the board of directors authorized a stock repurchase program under which Thoratec common stock with a market value of up to $25 million may be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of such activity will be dependent on several conditions, including the price of Thoratec stock, general market conditions and other factors. As of the end of fiscal 2003, Thoratec had approximately 56 million shares outstanding. The purchases will be funded from available cash and cash equivalents. The stock repurchase program will be effective immediately and purchases may continue until the authorized limit is reached or the Company discontinues the program. Through March 12, 2004, we have repurchased 465,000 shares at an average price of $13.25 per share for an aggregate outlay of $6.2 million including 250,000 shares purchased from Thermo Electron Corporation in a privately arranged transaction executed through a third party broker at the then current market price.

Table of Contents

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

None.

Item 9A. ***Controls and Procedures***

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

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

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

Table of Contents

PART III

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

The information regarding directors and executive officers required by Item 10 is incorporated by reference from the information under the captions Election of Directors, Section 16(a) Beneficial Ownership Reporting Compliance, Code of Ethics, and in other applicable sections in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2004 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 in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2004 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 2004 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 Transactions in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2004 annual meeting of stockholders.

Item 14. ***Principal Accountant Fees and Services***

The information required by Item 14 is incorporated by reference from the information under the caption Independent Public Accountants in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2004 annual meeting of stockholders.

Table of Contents

PART IV

Item 15. ***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

   Schedule II - Valuation and Qualifying Accounts and Reserves for each of the three fiscal years ended January 3, 2004.

   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

   Reference is made to the Exhibit Index on page 74 of this report, where these documents are included.

(b) Reports on Form 8-K:

On November 10, 2003, Thoratec filed a report on Form 8-K/A dated September 29, 2003 for the purpose of filing financial statements required by Item 7(a) and proforma financial information required by Item 7(b) of Diametrics Medical Inc. s Intermittent Testing Operations (a business unit of Diametrics Medical, Inc,) which was acquired by Thoratec s subsidiary, International Technidyne Corporation.

On October 21, 2003, Thoratec filed a report on form 8-K dated October 21, 2003 relating to the results of its third fiscal quarter ended September 27, 2003. Under the Form 8-K, Thoratec furnished (not filed) pursuant to Item 12 under Item 7 the press release entitled, Thoratec Reports Third Quarter 2003 Financial Results; Fourth Consecutive Quarter of Double Digit Sales Growth relating to the results of its third fiscal quarter ended September 27, 1003, as well as related non-GAAP financial information and GAAP financial statements for the quarter as an exhibit under Item 7.

On September 30, 2003, Thoratec filed a report on form 8-K dated September 29, 2003 disclosing the completion of the acquisition of the assets relating to the intermittent testing business products of Diametrics Medical, Inc. by Thoratec s subsidiary, International Technidyne Corporation under Item 2. Thoratec also filed the related press release entitled, Thoratec Subsidiary Announces Closing of Previously Announced IRMA® Product Line Acquisition as an exhibit under Item 7.

Table of Contents

INDEPENDENT AUDITORS REPORT

To the Board of Directors and Shareholders of
Thoratec Corporation:

We have audited the financial statements of Thoratec Corporation as of January 3, 2004 and December 28, 2002, and for the years ended January 3, 2004, December 28, 2002 and December 29, 2001 and have issued our report thereon dated March 12, 2004 (which report expresses an unqualified opinion and includes an explanatory paragraph concerning the adoption of a new accounting principle in 2002); such report is included elsewhere in this Annual Report on Form 10-K. Our audits also included the financial statement schedules of Thoratec Corporation listed in Item 15 (a)(2). These financial statement schedules are the responsibility of the Company s management. Our responsibility is to express an opinion based on our audits. In our opinion, such financial statement schedules, when considered in relation to the basic financial statements taken as a whole, present fairly in all material respects the information set forth therein.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California
March 12, 2004

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

SCHEDULE II - VALUATION AND QUALIFYING ACCOUNTS
For Each of the Three Fiscal Years for the Period Ended January 3, 2004

	Balance Beginning of Year	Additions	Deductions	Balance End of Year
		(In thousands)		
Year Ended January 3, 2004:				
Allowance for doubtful accounts	$ 238	$361	$(113)(1)	$ 486
Accrued product warranty	$ 695	$193	$ (59)(2)	$ 829
Year Ended December 28, 2002:				
Allowance for doubtful accounts	$ 551	$154	$(467)(1)	$ 238
Accrued product warranty	$ 910	$ 45	$(260)(2)	$ 695
Year Ended December 29, 2001:				
Allowance for doubtful accounts	$ 939	$337	$(725)(1)	$ 551
Accrued product warranty	$ 970	$594	$(654)(2)	$ 910

(1) Accounts written off, net of recoveries.

(2) Warranty expenditures incurred.

Table of Contents

EXHIBIT INDEX

Exhibit Number	Exhibit
3.1	Thoratec s Articles of Incorporation, as amended.(1)
3.2	Thoratec s By-Laws, as amended.
4.1	Rights Agreement between Thoratec Corporation and Computershare Trust Company, Inc. as Rights Agent dated as of May 2, 2002.(2)
10.1	Thoratec s 1984 Incentive Stock Option Plan, as amended.(3)
10.2	Sublease dated August 19, 1988, between Thoratec Cardiosystems and Thermedics, as amended by Amendment No. 1 dated January 1, 1990(4); and as further amended by Amendment No. 2 dated as of February 14, 2001.(1)
10.3	Intellectual Property Cross-license Agreement between Thermedics and the Thoratec Cardiosystems dated August 19, 1988.(5)
10.4	Form of Indemnification Agreement between Thoratec Cardiosystems and its officers and directors.(5)
10.5	Agreement for the acquisition of Th. Goldschmidt AG of Certain of the Assets of Thoratec dated March 29, 1989.(6)
10.6	Thoratec s 1993 Stock Option Plan.(7)
10.7	Agreement dated May 26, 1993, between The Polymer Technology Group Incorporated and the Thoratec Cardiosystems.(8)
10.8	Thoratec s 1996 Stock Option Plan.(9)
10.9	Thoratec s 1996 Nonemployee Directors Stock Option Plan, as amended.
10.10	Lease Agreement dated July 25, 1996, between Main Street Associates and Thoratec, as amended.(10)
10.11	First Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(11)
10.12	Second Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(12)
10.13	Thoratec s 1997 Stock Option Plan, as amended.(13)
10.14	Amended and Restated Directors Stock Option Plan of Thoratec Cardiosystems.(14)
10.15	Amended and Restated Nonqualified Stock Option Plan of Thoratec Cardiosystems.(14)

10.16	Agreement and Plan of Merger by and among Thoratec, Lightning Acquisition Corporation, Thermo Cardiosystems Inc, and Thermo Electron Corporation dated October 3, 2000.(15)
10.17	Registration Rights Agreement by and between Thoratec and Thermo Electron dated October 3, 2000.(15)
10.18	Shareholder Agreement by and between Thoratec and Thermo Electron dated October 3, 2000.(15)
10.19	Lease agreement dated August 16, 1995, between International Technidyne and BHBMC, as amended.(16)
10.20	Employment Agreement by and between Thoratec and D. Keith Grossman, amended as of December 6, 2001.(16)
10.21	Thoratec s 2002 Employee Stock Purchase Plan.(17)
10.22	Amended and Restated Thoratec Corporation Executive Severance Benefits Plan as amended February 26, 2004.
10.23	Thoratec s Deferred Compensation Plan effective as of January 1, 2004.
10.24	Grantor Trust Agreement between Thoratec and Wachovia Bank, National Association effective as of January 1, 2003.
10.25	Asset Purchase Agreement by and between Diametrics Medical, Inc. and International Technidyne Corporation dated as of July 17, 2003.(18)
10.26	Lease Agreement between International Technidyne Corporation and Roseville Properties Management Company dated September 26, 2003.
21	Subsidiaries of Thoratec.(16)
23.1	Independent Auditors Consent - Deloitte & Touche LLP.

Table of Contents

Exhibit Number	Exhibit
24	Power of Attorney Reference is made to page 77 hereof.
31.1	Section 302 Certification of Chief Executive Officer and Chief Financial Officer
32.1	Section 906 Certification of Chief Executive Officer and Chief Financial Officer

(1) Filed as an Exhibit to Thoratec s Annual Report on Form 10-K for the fiscal year ended December 28, 2002 filed with the SEC on March 20, 2003 and incorporated herein by reference.

(2) Filed as an Exhibit to Thoratec s Form 8-A12G filed with the SEC on May 3, 2002 (Registration No. 000-49798), and incorporated herein by reference.

(3) 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.

(4) 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.

(5) Filed as an Exhibit to Thoratec Cardiosystems Registration Statement on Form S-1 (Registration No. 33-25144) and incorporated herein by reference.

(6) 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.

(7) 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.

(8) 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.

(9) 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.

(10) 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.

(11) 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.

(12) 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.

(13) Filed as an Exhibit to Thoratec s Registration Statement on Form S-8 filed with the SEC on June 18, 2003 (Registration No. 333-106238), and incorporated herein by reference.

(14) 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.

(15) Filed as an Annex to Thoratec s Registration Statement on Form S-4/A, filed with the SEC on December 29, 2000 (Registration No. 333-72128), and incorporated herein by reference.

Table of Contents

(16) Filed as an Exhibit to Thoratec s Form 10-K405 filed with the SEC on March 15, 2002 (Registration No. 033-72502), and incorporated herein by reference.

(17) Filed as an Exhibit to Thoratec s Form S-8 POS filed with the SEC on July 1, 2002 (Registration No. 333-90768), and incorporated herein by reference.

(18) Filed as an Exhibit to Thoratec s Form 8-K filed with the SEC on July 21, 2003

Table of Contents

SIGNATURES

In accordance with Section 13 or Section 15(d) of the Exchange Act, as amended, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 17th day of March 2004.

THORATEC CORPORATION

By: /s/ D. KEITH GROSSMAN

D. Keith Grossman
Chief Executive Officer

Date: March 17, 2004

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each person whose signature appears below constitutes and appoints D. Keith Grossman and M. Wayne Boylston, and each of them, his true and lawful attorney-in-fact, with full power of substitution and resubstitution, to act for him and in his name, place and stead, in any and all capacities to sign any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing which they, or any of them, may deem necessary or advisable to be done in connection with this annual report as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or any substitute or substitutes for any or all of them, may lawfully do or cause to be done by virture hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Thoratec Corporation and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ D. KEITH GROSSMAN D. Keith Grossman	Chief Executive Officer, President and Director	March 17, 2004
/s/ M. WAYNE BOYLSTON M. Wayne Boylston	Senior Vice President, Chief Financial Officer and Secretary (Principal Financial and Accounting Officer)	March 17, 2004
/s/ J. DONALD HILL J. Donald Hill	Director and Chairman of the Board of Directors	March 17, 2004
/s/ HOWARD E. CHASE Howard E. Chase	Director	March 17, 2004
/s/ J. DANIEL COLE	Director	March 17, 2004

J. Daniel Cole /s/ NEIL F. DIMICK	Director	March 17, 2004
Neil F. Dimick /s/ WILLIAM M. HITCHCOCK	Director	March 17, 2004
William M. Hitchcock /s/ GEORGE W. HOLBROOK, JR.	Director	March 17, 2004
George W. Holbrook, Jr. /s/ DANIEL M. MULVENA	Director	March 17, 2004
Daniel M. Mulvena		