THORATEC CORP
Form 10-K
March 16, 2005

Table of Contents

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

(Mark one)

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

For the fiscal year ended January 1, 2005

o 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 þ No o

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. þ

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

The aggregate market value of the voting stock held by non-affiliates computed by reference to the last sale reported of such stock on July 2, 2004, the last business day of the Registrant s second fiscal quarter, as listed on The Nasdaq National Stock Market was $517,972,797.

As of March 14, 2005, registrant had 48,198,480 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portion of Thoratec s definitive proxy statement for its 2005 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

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 within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements can be identified by the words expects, projects, hopes, believes, intends , should , estimate , will , would , may , anticipates , plans , could and other similar w could differ materially from these forward-looking statements based on a variety of factors, many of which are beyond our control. Therefore, readers are cautioned not to put undue reliance on these statements. Investors are cautioned that all such statements involve risks and uncertainties, including risks related to the development of new markets such as Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of our products, changes in the mix of our product sales and the related gross margin for such product sales, the results of clinical trials including the HeartMate II, the ability to improve financial performance, regulatory approval processes, the effect of healthcare reimbursement and coverage policies, the effects of seasonality in our product sales, the effects of price competition from any of our competitors and the effects of any merger and acquisition related activities. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the Factors That May Affect Future Results section and in other documents we file with the Securities and Exchange Commission. Actual results, events or performance may differ materially. These forward-looking statements speak only as of the date hereof. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

Thoratec, the Thoratec logo, Thoralon, TLC-II, HeartMate, HeartPak and *Vectra* are registered trademarks, and Aria, Heart Hope and IVAD are trademarks 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. We are a leading provider of circulatory support products worldwide. We sell Ventricular Assist Devices, or VADs, to virtually every leading heart transplant center in the world; marketing three out of the four VADs approved by the United States Food and Drug Administration, or FDA, as a bridge to heart transplant for adults. We are also a leading provider of point-of-care blood diagnostic test systems.

Our business is comprised of two segments; Cardiovascular and ITC. The major product lines within the Cardiovascular market are:

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

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

The major product line of our ITC segment is:

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.

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 FDA to commercially market a 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 CHF patients to perform some or all of the pumping function of the heart and we currently offer the widest range of products to serve this market. We believe that our long-standing reputation for quality and innovation and our excellent relationships with leading cardiovascular surgeons worldwide position us to capture growth opportunities in the expanding congestive heart failure market.

We currently market VADs that may be implanted or worn outside the body and that are suitable for treatments for different durations for patients of varying sizes and ages. We estimate that doctors have implanted over 9,000 of our devices in patients suffering from heart failure. Our devices are currently used primarily for patients awaiting a heart transplant or Destination Therapy implants. On November 6, 2002, the FDA approved the HeartMate 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 VAD, for Destination Therapy. Thoratec is the only company to have a ventricular assist device approved for Destination Therapy in the United States.

Destination Therapy

The FDA approval of the HeartMate VAD for Destination Therapy 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 otherwise have a life expectancy of less than two years.

The FDA s decision to approve the HeartMate 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

Table of Contents

Failure, which showed our HeartMate device nearly doubled and tripled survival over the drug therapy group at one and two years, respectively.

The Centers for Medicare & Medicaid Services, or CMS, issued a National Coverage Decision Memorandum for the use of Left Ventricular Assist System, or LVAS, for Destination Therapy, effective October 1, 2003. CMS has subsequently adjusted the relative weight and base level of reimbursement it will provide under DRG (diagnosis-related group) 103 Heart Transplant or Implant of Implantable Heart Assist Systems to raise the average payment for CMS DT-certified Centers under DRG 103 to approximately $136,000; the same reimbursement given for heart transplants. In many cases the actual payments to hospitals under DRG 103 could be higher or lower, based on geographical location and other factors.

Since December 2002, the majority of national insurance carriers, such as Aetna, Cigna, Humana, United Healthcare and UNICARE, have issued positive coverage policies to cover the use of ventricular assist devices for FDA-approved indications of our VADs, including Destination Therapy.

OUR MARKETS

Circulatory Support Products

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 of diagnosis. 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 include angioplasty, biventricular pacing, valve replacement, bypass and left ventricular reduction surgery.

Despite attempts to manage CHF through drug therapy, there is currently only one curative treatment for the disease a heart transplant. Unfortunately, the number of hearts available for transplant each year can meet the needs of only a small number of the patients requiring a heart transplant. The United Network for Organ Sharing reported that there were only 2,085 hearts available for transplant in the United States in 2003. 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 two years before receiving one of the few donor hearts available. In 2001, approximately 15% of these 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 Thoratec 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% 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 five devices approved in the United States as a bridge to transplant in adults, four 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.

Table of Contents

Destination Therapy On November 6, 2002, we received approval to market the HeartMate VAD for Destination Therapy patients with late-stage CHF who are not candidates for heart transplantation due to other degenerative illnesses or advanced age. The National Institutes for Health (NIH) estimated that the Destination Therapy application represents a long-term market opportunity of up to 100,000 additional patients annually in the United States. For these end-stage CHF patients, drug therapy is currently the only other treatment available and, even with drug therapy, the 12-month mortality rate for these patients is approximately 75%. We believe that the HeartMate will provide a significant survival benefit for this patient population. 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.

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 VAD system, in combination with other agents such as cell or drug therapies, has the potential to 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 our estimate of the percentage of patients with late-stage CHF, we believe that the patient population could be substantial. We are continuing with our strategy to add this indication to our labeling. It will require FDA approval and we will continue working with the FDA towards this goal in 2005. 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 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.

Point-of-Care Diagnostics Products

Our point-of-care, or 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.

We believe that the market growth for POC diagnostic products is fueled by convenience and ease of use to the patients and physicians, and the clinical benefits from the more frequent monitoring that Alternate Site POC products allow patients.

Vascular Graft Products

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.

Table of Contents

OUR STRATEGY

Our key strategies to maintain and expand our 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 improving and developing new products internally or acquiring or licensing new products.

Increase Cost Effectiveness of our Products. While a recent study indicates that the cost of implanting a VAD for Destination Therapy is comparable with that of a heart, liver or other major organ transplant, cost remains a significant concern for 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 work very closely with the approximately 69 centers approved by CMS in developing the Destination Therapy market, which we believe will ultimately improve the cost effectiveness of Destination Therapy. Additionally, we are expanding our market education and training programs and we continue to implement improvements that enhance the performance and cost effectiveness 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 Implantable Ventricular Assist Device, or IVAD, in countries in the European Union. In August 2004, we received FDA approval in the U.S. to market the IVAD for use in bridge-to-transplantation and post-cardiotomy recovery patients who are unable to be weaned from cardiopulmonary bypass. This makes the IVAD the only currently approved implantable cardiac assist device that can provide left, right or biventricular support.

Destination Therapy Market. In November 2002, we received approval for the HeartMate 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 was limited to approximately 69 centers in 2004, we estimate the market penetration for this indication could eventually be a meaningful portion of the 100,000 patients annually mentioned above, 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 TLC-II portable driver for home use. The TLC-II was already approved for in-hospital use in the United States, and has been approved for home therapy in Europe for several years. This approval will enable patients supported by the device to be discharged from the hospital to their home while awaiting heart transplantation or recovery of their existing heart. The TLC-II driver is the first portable driver approved for home discharge to support biventricular patients.

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 existing heart in certain patients. While our Premarket Approval, or PMA, submission for our Thoratec VAD for this indication has not yet received FDA approval, we continue to investigate this market, and believe that the patient population that could benefit from this use could be substantial.

Use of HeartMate II in U.S. clinical trial. We recently completed a Phase I clinical trial of 25 patients at 10 study sites for our HeartMate II VAD and on February 18, 2005 received FDA approval to begin the Phase II pivotal trial. We anticipate enrollment will begin before the end of the first quarter of 2005. The pivotal trial will evaluate the safety and effectiveness of the HeartMate II for use as a Bridge to Cardiac Transplantation and for Destination Therapy in patients who are ineligible for cardiac transplant due to age, malignancy or other reasons. The HeartMate II is an implantable Left Ventricular Assist Device System, or LVAS,

Table of Contents

consisting of a miniature rotary blood pump that is designed to provide long-term support. Its design is intended to be not only smaller but also simpler, quieter, and longer lasting than current generation assist devices.

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. Our Heart Hope program, designed to partner with some CMS approved Destination Therapy centers, to build the market for this new indication, and, in the process, address important issues such as reimbursement, clinical outcomes, and the building of a strong referral program for Destination Therapy patients was launched in 2004. Heart Hope is a collaboration between Thoratec and leading heart centers to advance clinical, educational and economic 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. An important element of this effort is the program s use of marketing materials such as 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, acquisitions and related business development opportunities.

OUR PRODUCTS

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

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

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

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

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

In addition to our cardiac assist products, we sell vascular access grafts, used in hemodialysis for patients with end-stage renal disease, and 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.

Our cardiac assist products represented 58%, 60%, and 62% of our product sales in 2004, 2003, and 2002, respectively. Our point-of-care blood diagnostics test systems and services amounted to 40%, 37% and 35% or our net product sales in 2004, 2003, and 2002, respectively. Sales of our vascular access grafts accounted for the remainder of our net product sales in those years.

Circulatory Support Products

Ventricular assist devices perform some or most of the pumping function of the heart in patients with severe heart failure. In most cases, a cannula connects the left ventricle of the heart to a blood pump. Blood flows from the

Table of Contents

left ventricle to the pump chamber, via the cannula, powered by an electric or air driven mechanism which drives the blood through another cannula into the aorta. From the aorta, the blood then circulates throughout the body. Mechanical or tissue valves enable unidirectional flow. Currently the power source remains outside the body for all FDA-approved VADs.

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). We estimate that between 20% and 35% of assist patients require biventricular support and therefore require a second pump for the right ventricle.

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 is less invasive than implantable VADs since only the cannula 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 approximately 50% of bridge to transplant patients treated with the Thoratec VAD 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. The Thoratec VAD is made with our proprietary biomaterial, Thoralon, which may reduce clotting.

While it is possible for most patients with paracorporeal VADs to walk or otherwise move about, the large size of the typical drive console renders movement difficult. 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 VE initially received FDA approval in September 1998 and the enhanced version of the product, called the HeartMate XVE, received FDA approval in December 2001 for bridge to transplantation. In April 2003, the HeartMate XVE version received FDA approval for Destination Therapy. The HeartMate XVE is designed for use for a duration from several months to up to two or three years. The HeartMate XVE offers only left ventricular support.

Patients with a HeartMate XVE do not require anti-coagulation drugs, because the device utilizes proprietary textured surfaces and tissue valves. As a result, we believe this device has the lowest rate of stroke incidence for patients using ventricular support. The implantable nature of this device enables patient mobility and home discharge.

Implantable VAD

We received CE Mark certification to market the Thoratec IVAD in Europe in July 2003 and FDA approval for the North American Bridge to Transplant market in August 2004. The IVAD was approved in Canada in November 2004. This makes the IVAD the only currently approved implantable cardiac assist device that can provide left, right or

biventricular support. The IVAD maintains the same blood flow path, valves and blood pump as the paracorporeal (Thoratec VAD) 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 weighs less than one pound and can be implanted in patients ranging in weight from 40 kg to over 100 kg. The small blood pump is implanted in the body. The IVAD is designed as a bridge to transplant and possibly for therapeutic recovery, but is not currently considered for Destination Therapy.

Table of Contents

HeartMate II

The HeartMate II is a next generation device intended for long-term cardiac support (5-7 years) for patients who are in end-stage heart failure. The HeartMate II is a small, implantable, electrically powered device that weighs approximately 12 ounces and is approximately 1.7 inches in diameter and 3.2 inches long. In addition to being significantly smaller than the HeartMate XVE, with only one moving part, the HeartMate II is simpler and designed to operate more quietly than pulsatile 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.

We have enrolled thirty-six patients in our European study and U.S. Phase I clinical trial of the HeartMate II device as of the end of 2004. Our Investigational Device Exemption, or IDE, supplement to the FDA seeking approval to begin a pivotal trial in the U.S. for both Bridge to Transplant and Destination Therapy was granted conditional approval in February 2005. We hope to begin enrollment in this trial in the first quarter of 2005. We also intend to seek CE Mark approval to begin commercial sales in Europe in 2005.

HeartMate III

We are also developing our third generation device, the HeartMate III, which is a centrifugal, continuous flow pump that employs a magnetically levitated rotor that eliminates wear from touching parts. The device is designed for long-term implantation (10 years or more) in 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* provides significant advantages over existing synthetic vascular access grafts that may encourage its use by surgeons who are currently using natural vessels for vascular access.

Point-of-Care Diagnostics

Through our subsidiary ITC, we design, develop, manufacture and market point-of-care diagnostic test systems that provide fast and 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;

Immediate Response Mobile Analysis (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 total annual product sales.

Hemochron is used to monitor a patient s coagulation while being administered anticoagulants in various settings, including in the cardiovascular operating room to monitor the drug Heparin and in an anticoagulation clinic to monitor the drug Coumadin. Hemochron is considered a moderately complex device

Table of Contents

and must be used by professionally trained personnel. The system consists of a small, portable analytical instrument and disposable test cuvettes.

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 physicians offices, long-term care facilities, clinics, visiting nurse associations, and home healthcare companies. Historically, this segment has represented about 20% of the ITC s total annual product sales.

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 anticoagulants, 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 product sales are generated by sales of equipment, with 70% relating to consumable products (cuvettes, cassettes, etc.) used in the testing process.

In late 2003, we acquired the IRMA product line of blood gas/electrolyte and chemistry tests from Diametrics Medical, Inc. This has significantly increased our test menu offering, and also provides us with 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 interface with a hospital s laboratory or hospital information system. This project was completed in the fourth quarter of 2004.

Our Incision products, historically representing about 30% of ITC s total annual product sales, 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 Tenderfoot, which is a heel stick used for infant testing. We market this product 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.

The drivers for continued growth in this business assume increased patient testing, better patient outcomes, and increased decentralization of testing from central laboratories to point-of-care. Our international sales have increased to approximately 26% of ITC s total sales. We expect international sales to increase from 26% currently to approximately 30% of ITC s total sales by 2007.

SALES AND MARKETING

Circulatory Support Products

The potential customers for our circulatory support products are hospitals that perform open heart surgery and heart transplants. We estimate that 130 of the approximately 1,000 hospitals in the United States that perform open-

Table of Contents

heart surgery also perform heart transplants. We actively market to these 130 heart transplant hospitals and large cardiac surgery centers in addition to approximately 100 heart transplant hospitals in Europe.

We have recruited and trained a direct sales force that, as of January 1, 2005, comprised 21 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 16 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.

In addition to our direct selling efforts, we have 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.

Hospitals or other medical institutions that acquire a VAD system generally purchase VAD pumps, related disposables and training materials, 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 usually ship the products within thirty days. We do not typically carry a backlog of orders pending shipment.

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. 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 during 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

We market the *Vectra* through C.R. Bard Corporation in the United States, and selected countries in Europe, 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 46 in the United States, who sell to hospitals as well as to third party dealers and distributors. Outside the United States, ITC has four salespeople selling principally to third party distributors. Substantially all of ITC s product sales have historically come through our distributor channels with Cardinal Healthcare as our largest distributor generating 21% of ITC s annual product sales in 2004.

As we have integrated the IRMA product line of blood gas analyzers into our business, an increasing portion of our revenue in the United States market has been generated by direct sales rather than through distributors. This shift has required 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

Competition from medical device companies and medical device subsidiaries of health care and pharmaceutical companies is intense and is expected to increase. We believe our principal competitors for the VAD system include WorldHeart Corporation, MicroMed Technology, Inc., AbioMed, Inc., and Berlin Heart in Europe. Principal

Table of Contents

competitors in the vascular graft market include W.L. Gore, Inc., C.R. Bard and Boston Scientific Corporation. Principal competitors in the hospital coagulation and blood gas monitoring equipment market include the Cardiac Surgery Division of Medtronic, Inc., iSTAT, Radiometer, Abbott Diagnostics, and Instrument Laboratories. Our primary competitor in the skin incision device market is Becton, Dickson and Company. Competitors in the alternate site (non-hospital) point-of-care diagnostics market include Roche Diagnostics and HemoSense.

We believe the key competitive factors include the relative speed with which we can:

develop products;

complete clinical testing;

receive regulatory approvals; and

manufacture and sell commercial quantities of products.

We estimate we have a majority of the VAD market domestically and more than 50% internationally. We believe that potential competitors are a few 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 competitors products result in significantly better outcomes than our products, we believe that absent any compelling reasons, cardiac centers will not generally change suppliers.

Large medical device companies dominate the markets in which our ITC business competes and we estimate our products hold anywhere from 2% to 20% market share. We expect that our growth in this market will be generated by gaining market share and from a shift of testing from the central laboratory to the point-of-care. However, this market segment is very competitive, and includes the following potential drivers:

New drug therapies under development may not require the intense monitoring of a patient s coagulation that the current anti-coagulation drug of choice, Heparin, requires. To try to mitigate this risk, we participate in clinical trials with key pharmaceutical companies so as 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 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.

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 and one patent pertaining to the TLC-II, the Thoratec VAD system is not protected by any other patents. We do not believe that this lack of patent protection will have a material adverse effect on our ability to sell our 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 include patents transferred to ITC as part of our acquisition of the IRMA 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.

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 as to which we have retained worldwide, royalty-free, exclusive rights for most medical applications. The patent license from Goldschmidt will remain in effect for the duration of the patents sold to Goldschmidt and includes medical uses that we expect are necessary for our business as now conducted or as proposed to be conducted in the future. For example, the medical applications include blood pumps, artificial hearts and cardiac assist devices of all kinds, cardiovascular products, including heart valves and prosthetic blood vessels and cannulae and blood tubing of all kinds. Aspects of our blood

Table of Contents

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 biomaterials patents ranges from 5 to 10 years, on our grafts up to 16 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 ranges from 10 to 17 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 its 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. We believe that 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 obtains 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 we settled the claim and recorded a charge of $2.3 million in the fourth quarter of 2003 and $133,000 in the first six months of 2004 for the settlement and related legal costs.

At this time, we are not a party to any other material legal proceedings that relate to patents or proprietary rights.

Table of Contents

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 *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 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 Pre-Market approval, or PMA application or a 510(k) premarket notification. There are substantial user fees that must be paid at the time of PMA or 510(k) submission to the FDA to help offset the cost of scientific data review that is required before FDA can determine if the device is approvable. 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.

A PMA Supplement is required to make modifications to a device or application approved by a PMA. A 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 ITC s 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 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 regulations, 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

Table of Contents

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, these fees could amount to hundreds of thousands of dollars per year.

In addition, any products distributed pursuant to the above authorizations are subject to thorough 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, or 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 effect 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 state 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 these 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 VAD, IVAD and HeartMate Systems. We are also certified to be in compliance with the requirements of the Canadian Medical Device Regulations (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.

Table of Contents

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.

To date, CMS and a majority of private insurers with whom we have dealt have determined to reimburse for our VADs and our diagnostic and vascular graft products. Effective October 1, 2003, CMS issued a National Coverage Decision Memorandum for the use of LVAS that are approved by the FDA for treating Destination Therapy in end-stage heart failure patients. Sixty-nine centers are now recognized by CMS as Medicare LVAD centers. Effective October 1, 2004, Medicare reimbursement payment increased with CMS LVAD centers receiving an average payment of approximately $136,000.

The change of DRG category for implantable heart assist devices from DRG 525 to 103 has raised the average payment under DRG 103 by more than 30% from approximately $90,000 to approximately $136,000. 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. Since December 2002, the majority of national insurance carriers, such as Aetna, Cigna, Humana, United Healthcare and UNICARE, have issued positive coverage policies to cover the use of ventricular assist devices for FDA-approved indications, including Destination Therapy.

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 consist 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 VADs. 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 single source third party contract manufacturers in China and Germany. 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 our 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. At the end of 2003 and during 2004, we experienced higher than normal backlog for disposable test cuvettes due to higher demand. We have expanded capacity during 2004 to accommodate the increased demand. Total backlog as of the end of fiscal 2004 and 2003 were approximately $1.3 million and $1.6 million, respectively.

RESEARCH AND DEVELOPMENT

Thoratec s research and development expenses in 2004, 2003 and 2002 were $28.7 million, $26.1 million, and $25.3 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. The primary component of our research and development costs is employee salaries and benefits. 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

Table of Contents

VAD products. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations.

MAJOR CUSTOMERS AND FOREIGN SALES

We primarily sell our products to large hospitals and distributors. No customer accounted for more than 10% of product sales in fiscal year 2004 or 2003. For fiscal year 2002, one distributor customer accounted for 11% of total product sales. No other customer accounted for more than 10% of total product sales in 2002.

Sales originating outside the United States and U.S. export sales accounted for approximately 21%, 19% and 18% for the years ended 2004, 2003 and 2002, respectively, of our total product sales. No individual foreign country accounted for a material portion of our net sales in any of the last three fiscal years.

EMPLOYEES

As of January 1, 2005, we had a total of 914 employees, consisting of 905 full-time employees and 9 part-time employees, 421 of whom worked in manufacturing, 130 in engineering, 102 in quality control and regulatory affairs, 138 in marketing and sales support, 38 in administration and finance and 85 in other support functions, including human resources, management information systems, purchasing and facilities. Out of our total employees, 894 are employed in the United States and 20 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.

ADDITIONAL INFORMATION

You can find additional information about Thoratec on our website at http://www.thoratec.com (although non of this information is, or should be deemed to be, incorporated by reference into this Annual Report on Form 10-K). We make filings of our periodic reports to the Securities and Exchange Commission (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

FACTORS THAT MAY AFFECT FUTURE RESULTS

Our business faces many risks. These risks include those related to the development of new products and markets including Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of our products, changes in the mix of our product sales, and the related gross margin for such product sales, the results of clinical trials, including those for the HeartMate II, the ability to improve financial performance, regulatory approval processes, the effect of healthcare reimbursement and coverage policies, our product sales, the effects of price competition from any of our competitors and the effects of any merger and acquisition related activities. The risks described below are what we believe to be the material risks facing our company. However, the risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risk factors actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline significantly. Investors should consider the following risks, as well as the other information included in this Annual Report on Form 10-K, and other documents we file from time to time with the SEC, 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 1, 2005, our accumulated deficit was approximately $71.5 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 as well as litigation and equity based compensation costs. Such costs could prevent us from achieving or maintaining profitability in future periods.

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

Significant uncertainty exists as to the reimbursement status of newly approved health care products such as VADs and vascular grafts, which can delay or prevent adoption in volume by hospitals. Government and other third party payors are increasingly attempting to contain health care costs. Payors are attempting to contain costs by, for example, limiting coverage and the level of reimbursement of new therapeutic products. Payors are also attempting to contain costs by refusing, in some cases, to provide any coverage for uses of approved products for disease indications other than those for which the FDA has granted marketing approval.

To date, a majority of private insurers with whom we have been involved and the CMS have determined to reimburse some portion of the cost of our VADs and our diagnostic and vascular graft products, but we cannot estimate what portion of such costs will be reimbursed and our products may not continue to be approved for reimbursement. In addition, changes in the health care system may affect the reimbursability of future products. If coverage is not expanded or if the reimbursement levels are not increased or are partially or completely reduced, our revenues would be reduced.

If we fail to obtain approval from the FDA and from foreign regulatory authorities, we cannot market and sell our products under development in the United States and in other countries, and if we fail to adhere to ongoing FDA Quality System Regulations, the FDA may withdraw our market clearance or take other action.

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

We may not obtain clearance of a 510(k) notification or approval of a PMA application with respect to any of

Table of Contents

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 sales. 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, but we have since modified or that we subsequently wish to market for new disease indications.

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

Sales of our products outside the United States are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer or shorter than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements.

The federal, state and foreign laws and regulations regarding the manufacture and sale of our products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If we fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties, which in each case would harm our business.

Certain lawsuits have been filed against us

Commencing on or about August 3, 2004, several Federal securities law putative class action suits were filed in the United States District Court for the Northern District of California on behalf of purchasers of the publicly traded securities of the Company between April 28, 2004 and June 29, 2004. These suits were consolidated in a consolidated complaint filed on or about January 18, 2005. The complaint seeks to recover unspecified damages on behalf of all purchasers of our publicly traded securities during the class period.

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

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

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

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

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

Table of Contents

with respect to these actions.

Our debt obligations expose us to risks that could adversely affect our business, operating results and financial condition.

We have a substantial level of debt. As of January 1, 2005, we had $143.8 million of outstanding indebtedness. The terms of our convertible notes do not restrict our ability to incur additional indebtedness, including indebtedness senior to the convertible notes. The level of our indebtedness, among other things, could:

- make it difficult for us to make payments on our debt;
- make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, acquisitions or general corporate purposes;
- limit our flexibility in planning for or reacting to changes in our business;
- reduce funds available for use in our operations;
- impair our ability to incur additional debt because of financial and other restrictive covenants proposed for any such additional debt;
- make us more vulnerable in the event of a downturn in our business or an increase in interest rates; or
- place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources.

If we experience a decline in product sales due to any of the factors described in this section or otherwise, we could have difficulty paying interest or principal amounts due on our indebtedness. If we are unable to generate sufficient cash flow or otherwise obtain funds necessary to make required payments, or if we fail to comply with the various requirements of our indebtedness, including the convertible notes, we would be in default, which would permit the holders of our indebtedness to accelerate the maturity of the indebtedness and could cause defaults under our other indebtedness. Any default under our indebtedness could have a material adverse effect on our business, operating results and financial condition.

If hospitals do not conduct Destination Therapy procedures using our VAD, our product sales will be diminished.

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

The number of Destination Therapy procedures actually performed depends on many factors, most of which are out of our direct control, including:

- the number of CMS sites approved for Destination Therapy;
- the clinical outcomes of Destination Therapy procedures;
- cardiologists and referring physicians education, and their commitment to Destination Therapy;

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

the impact of changes in reimbursement rates on the timing of purchases of VADs for Destination Therapy; and

the economics for individual hospitals of not conducting a Destination Therapy procedure, including the

Table of Contents

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

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

Our VAD systems have lengthy sales cycles and we may incur substantial sales and marketing expenses and expend significant effort without making a sale. Even after making the decision to purchase our VAD systems, our customers often deploy our products slowly. For example, the length of time between initial contact with cardiac surgeons and the purchase of our VAD systems is generally between nine and eighteen months. In addition, the cardiac centers that buy the majority of our products are usually led by cardiac surgeons who are heavily recruited by competing centers or by centers looking to increase their profiles. When one of these surgeons moves between centers we sometimes experience a temporary but significant reduction in purchases by the departed center while it replaces its lead surgeon. As a result, it is difficult for us to predict the quarter in which customers may purchase our VAD systems and our product sales and operating results may vary significantly from quarter to quarter, which increases the risk of an operating loss for us for any given quarter. In particular, sales of our VADs for Destination Therapy have been lower than we had originally anticipated, and we cannot predict when, if ever, sales of our VADs for this indication will generate the level of revenues we expect.

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

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

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

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

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

The number of our employees increased from 183 on December 30, 2000 to 914 on January 1, 2005. We expect to continue increasing the number of our employees, and our business may suffer if we do not manage and train our new employees effectively. Our product sales may not continue to grow at a rate sufficient to support the costs associated with an increasing number of employees. Any future periods of rapid growth may place significant strains on our managerial, financial and other resources. The rate of any future expansion, in combination with our complex technologies and products, may demand an unusually high level of managerial effectiveness in anticipating, planning, coordinating and meeting our operational needs as well as the needs of our customers.

If we fail to successfully introduce new products, our future growth may suffer.

As part of our growth strategy, we intend to develop and introduce a number of new products and product improvements. We also intend to develop new indications for our existing products. For example, we are currently developing updated versions of our HeartMate products. If we fail to commercialize these new products, product improvements and new indications on a timely basis, or if they are not well accepted by the market, our future growth may suffer.

Table of Contents

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

As of January 1, 2005, we had $247.2 million of net intangible assets, representing 47% of our total assets and 85% of our shareholders equity. Amortization expense relating to these intangible assets for the year ended 2004 was $11.7 million. Ongoing amortization of purchased intangibles will reduce our net income or increase our net loss.

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

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

We depend on a number of custom-designed components and materials supplied by other companies including, in some cases, single source suppliers for components, instruments and materials used in our VAD products and blood testing products. For example, single sources currently manufacture and supply our ProTime and Hemoglobin instruments and the heart valves used in our HeartMate products. The suppliers of our ProTime and Hemoglobin products are located in China and Germany, respectively. We do not have long-term written agreements with most of our other vendors and from these vendors receive components on a purchase order basis only. If we need alternative sources for key raw materials or component parts for any reason, such alternative sources may not be available and our inventory may not be sufficient to fill orders before we find alternative suppliers or begin manufacturing these components or materials ourselves. Cessation or interruption of sales of circulatory support products and or our point-of-care products would seriously harm our business, financial condition and results of operations.

Alternative suppliers, if available, may not agree to supply us. In addition, we may require FDA approval before using new suppliers or manufacturing our own components or materials. Existing suppliers could also subject to an FDA enforcement action, which could also disrupt our supplies. If alternative suppliers are not available, we may not have the expertise or resources necessary to produce these materials or component parts internally.

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

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

- pay premium prices to our suppliers to keep their production lines open or to obtain alternative suppliers;
- buy substantial inventory to last through the scheduled end of life of our product, or through such time that we will have a replacement product developed and approved by the FDA; or

stop shipping the product in which the legacy component is used once our inventory of the discontinued component is exhausted.

Table of Contents

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

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

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

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

develop products;

complete clinical testing;

receive regulatory approvals; and

manufacture and sell commercial quantities of products.

Large medical device companies dominate the markets in which our ITC business competes and we estimate our products hold anywhere from 2% to 20% market share. We expect that any growth in this market will come from expanding our market share at the expense of other companies, and from testing being shifted away from 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.

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

The price of our common stock may fluctuate significantly.

The price of our common stock has been, and is likely to continue to be, highly volatile, which means that it could decline substantially within a short period of time. For example our stock price has ranged from $8.46 to $15.95 in the 12 months ended January 1, 2005. The price of our common stock could fluctuate significantly for many reasons, including the following:

future announcements concerning us or our competitors;

timing and reaction to the publication of clinical trial results;

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

Table of Contents

future;

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

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

acquisition or loss of significant customers, distributors or suppliers;

business acquisitions or divestitures;

changes in earnings estimates by analysts;

changes in third party reimbursement practices;

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

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

In addition, stock markets in general, and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations in recent years, which fluctuations have frequently been unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our stock may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

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

We may encounter problems manufacturing our products.

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

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

With the exception of Canada and the larger countries in Europe, we sell our Thoratec VAD and HeartMate systems in foreign markets through distributors. In addition, we sell our vascular access graft products through the Bard Peripheral Vascular division of C.R. Bard Corporation (which is also a competitor of ours) in the United States, and selected countries in Europe, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan. Substantially all of the international operations and a large portion of the Alternate Site domestic operations of ITC are conducted through distributors. For the year ended January 1, 2005, 21% of ITC s total product sales were through Cardinal Healthcare, a distributor of our blood coagulation testing equipment and skin incision devices.

To the extent we rely on distributors, our success will depend upon the efforts of others, over which we may have little or no control. If we lose a distributor or a distributor fails to perform to our expectations, our product sales may be harmed.

Table of Contents

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

In March 2004, we began changing our manner of distributing our Hemochron product line to our hospital pont-of-care customers in the United States from a distributor model to a direct sales model. Sales of these products represented approximately $16.1 million of our total sales for the year ended January 1, 2005.

This transition to a direct sales model necessitated 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, resulting in an increase in our sales and general and administrative costs. We expect the transition process to conclude in early 2005 when the last distributor will have been converted and the United States hospital point-of-care market will be served exclusively by ITC on a direct basis. This transition and its execution involve significant risks, including:

the alienation of distributors when they are informed of our plans;

the promotion by our former distributors of products from competitors rather than our products;

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

the challenges and costs associated with building an effective direct sales force.

If we fail to build an effective direct sales force for our hospital point-of-care product lines, our revenues may fail to increase as expected or could decrease, which could adversely affect our results of operations and financial condition.

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

We rely on patents, trade secrets, copyrights, know-how, trademarks, license agreements and contractual provisions to establish our intellectual property rights and protect our products. These legal means, however, afford only limited protection and may not adequately protect our rights. In addition, we cannot assure you that any of our pending patent applications will issue. The Patent and Trademark Office, or PTO, may deny or significantly narrow claims made under patent applications and the issued patents, if any, may not provide us with commercial protection. We could incur substantial costs in proceedings before the PTO or in any future litigation to enforce our patents in court. These proceedings could result in adverse decisions as to the validity and/or enforceability of our patents. In addition, the laws of some of the countries in which our products are or may be sold may not protect our products and intellectual property to the same extent as U.S. laws, if at all. We may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries.

Our commercially available VAD products, which account for a majority of our sales, generally are not protected by any patents. We rely principally on trade secret protection and, to a lesser extent, patents to protect our rights to our HeartMate product line. We rely principally on patents to protect our coagulation testing equipment, skin incision devices, Hemochron disposable cuvettes, IRMA analyzer, IRMA disposable cartridges, and Hgb Pro disposable test strips.

We seek to protect our trade secrets and unpatented proprietary technology, in part, with confidentiality agreements with our employees and consultants. Although it is our policy to require that all employees and consultants sign such agreements, we cannot assure you that every person who gains or has gained access to such information has done so. Moreover, these agreements may be breached and we may not have an adequate remedy.

Our products may be found to infringe prior or future patents owned by others. We may need to acquire licenses under patents belonging to others for technology potentially useful or necessary, and such licenses may not be available to us. We could incur substantial costs in defending suits brought against us on such patents or in bringing suits to protect our patents or patents licensed by us against infringement.

For example, in 2003, a patent infringement claim was filed against us by Bodycote Materials Testing Canada,

Table of Contents

Inc. and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004, we settled the claim and recorded a charge of $2.3 million in the fourth quarter of 2003 for the settlement and related legal costs.

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

Our business exposes us to an inherent risk of potential product liability claims related to the manufacturing, marketing and sale of human medical devices. We maintain a limited amount of product liability insurance. Our insurance policies generally must be renewed on an annual basis. We may not be able to maintain or increase such insurance on acceptable terms or at reasonable costs, and such insurance may not provide us with adequate coverage 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 acceptance of our products or expand our business.

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

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

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

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

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

We may acquire companies, products or technologies that we believe to be complementary to our business. If we do so, we may have difficulty integrating the acquired personnel, operations, products or technologies and we may not realize the expected benefits of any such acquisition. In addition, acquisitions may dilute our earnings per share, disrupt our ongoing business, distract our management and employees and increase our expenses, which could harm our business. We may also sell businesses or assets as part of our strategy or if we receive offers from third parties. If we do so, we may sell an asset or business for less than its full value.

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

During fiscal 2004 and 2003, sales originating outside the United States and U.S. export sales accounted for approximately 21% and 18%, respectively, of our total product sales. We anticipate that sales outside the United States and U.S. export sales will continue to account for a significant percentage of our product sales and we intend to continue to expand our presence in international markets. Non-U.S. sales are subject to a number of special risks. For example:

- we generally sell many of our products at a lower price outside the United States;
- sales agreements may be difficult to enforce;

receivables may be difficult to collect through a foreign country s legal system;

foreign customers may have longer payment cycles;

foreign countries may impose additional withholding taxes or otherwise tax our foreign income, impose tariffs or adopt other restrictions on foreign trade;

Table of Contents

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

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

Any claims relating to improper handling, storage or disposal of hazardous chemicals and biomaterials could be time consuming and costly.

Producing our products requires the use of hazardous materials, including chemicals and biomaterials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials.

We could be subject to both criminal liability and civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed our total assets. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development or production efforts or harm our operating results.

The occurrence of a catastrophic disaster or other similar events could cause damage to our facilities and equipment, which would require us to cease or curtail operations.

We are vulnerable to damage from various types of disasters, including earthquake, fire, terrorist acts, flood, power loss, communications failures and similar events. For example, in October 1989, a major earthquake that caused significant property damage and a number of fatalities struck near the area in which our Pleasanton, California facility is located. If any such disaster were to occur, we may not be able to operate our business at our facilities, in particular because our premises require FDA approval, which could result in significant delays before we can manufacture product from a replacement facility. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Therefore, any such catastrophe could seriously harm our business and results of operations.

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

Under the Sarbanes-Oxley Act of 2002, we are required to assess the effectiveness of our internal controls for financial reporting and assert that such internal controls are effective. Our independent auditors must evaluate management s assessment of the effectiveness of our internal controls over financial reporting and render an opinion on management s assessment and the effectiveness of our internal controls over financial reporting. The Act has resulted in and is likely to continue to result in increased expenses, and have required and are likely to continue to require significant efforts by management and other employees. Although we believe that our efforts will enable us to remain compliant under the Act, we can give no assurance that in the future such efforts will be successful. Our business is complex and involves significant judgments and estimates as described in our Critical Accounting Estimates. If we have material weaknesses in internal controls, we will not be able to assert that our internal controls over financial reporting are effective, which could adversely effect investor confidence in us and the market price of our common stock.

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

Table of Contents

and liabilities. However, we do not engage in hedge exposures that will arise from future sales. As a result, sales occurring in the future that are denominated in foreign currencies may be translated into 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 for talent 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.

We may be unable to repay or repurchase our convertible notes or our other indebtedness.

At maturity, the entire outstanding principal amount of our convertible notes will become due and payable. Holders of the convertible notes may also require us to repurchase the convertible notes on May 16 in each of 2011, 2014, 2019, 2024 and 2029. In addition, if certain fundamental changes to our company occur, the holders of the convertible notes may require us to repurchase all or a portion of their convertible notes. We may not have sufficient funds or may be unable to arrange for additional financing to pay the principal amount due at maturity or the repurchase price of the convertible notes. Any such failure would constitute an event of default under the indenture, which could, in turn, constitute a default under the terms of our other indebtedness. Any default under our indebtedness could have a material adverse effect on our business, operating results and financial condition.

Conversion of the convertible notes or other future issuances of our stock will dilute the ownership interests of existing shareholders.

The conversion of some or all of the convertible notes will dilute the ownership interest of our existing shareholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. Further, the existence of the convertible notes may encourage short selling by market participants because the conversion of the convertible notes could depress the price of our common stock. In addition, 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. Sales of our shares and the potential for such sales could cause our stock price to decline.

Our adoption of ETIF Issue No. 04-8 in the fourth quarter of 2004, which requires the inclusion of all shares available upon conversion of our convertible notes in our diluted earnings per share, or EPS, regardless of whether the notes are then convertible, did not have a material impact on our consolidated results for the periods in which the notes were outstanding as the effect of the 7.3 million shares was anti-dilutive. However, if in future periods the shares are dilutive, then 7.3 million shares will be added to our share count used to calculate diluted earnings per share, and this inclusion could result in significantly lower diluted EPS than if the existing guidance had not been changed by EITF 04-8.

Anti-takeover defenses in our governing documents could prevent an acquisition of our company or limit the price that investors might be willing to pay for our common stock.

Our governing documents could make it difficult for another company to acquire control of our company. For example:

Our Articles of Incorporation allow our Board of Directors to issue, at any time and without shareholder approval, preferred stock with such terms as it may determine. No shares of preferred stock are currently outstanding. However, the rights of holders of any of our preferred stock that may be issued in the future may be superior to the rights of holders of our common stock.

Table of Contents

We have a rights plan, commonly known as a poison pill, which would make it difficult for someone to acquire our company without the approval of our Board of Directors.

All or any one of these factors could limit the price that certain investors would be willing to pay for shares of our common stock and could delay, prevent or allow our Board of Directors to resist an acquisition of our company, even if the proposed transaction was favored by a majority of our independent shareholders.

Item 2. ***Properties***

We are headquartered in Pleasanton, California, where we lease approximately 72,000 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 3,000 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 has 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 June of 2004, MicroMed Technology, Inc., a competitor of ours, sued us in Texas. MicroMed sought injunctive relief against us in connection with our HeartMate II Phase I clinical trial on the grounds that we had provided the HeartMate II VAD to clinical sites without charge and that doing so was a violation of Texas anti-trust law. In addition to injunctive relief, the plaintiff is seeking unspecified damages and fees, including those arising from potential sales of its VAD products which plaintiff alleges it lost due to our HeartMate II clinical trial. We have successfully defended ourselves against MicroMed s requests for injunctive relief and will continue to vigorously defend any and all of the claims made by MicroMed in this action.

Commencing on or about August 3, 2004, several Federal securities law putative class action suits were filed in the United States District Court for the Northern District of California on behalf of purchasers of the publicly traded

securities of the Company between April 28, 2004 and June 29, 2004. These suits were consolidated in a consolidated complaint filed on or about January 18, 2005. The complaint generally alleges violations of the Securities Exchange Act of 1934 by us, our Chief Executive Officer and our former Chief Financial Officer and the President of our cardiovascular division based upon, among other things, alleged false statements about the Company s expected sales and the market for HeartMate as a Destination Therapy treatment. The complaint seeks to recover unspecified damages on behalf of all purchasers of our publicly traded securities during the class period.

Table of Contents

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

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

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

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

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 1, 2005.

Our Executive 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.

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 2001. 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 also held executive management positions at Instrumentation Laboratory and Beckman Coulter Corporation. He is a past president of the Biomedical Marketing Association and was on the Board of Trustees of the National Blood Foundation from 1998 to 2004.

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 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, Related Stockholder Matters and Issuer Purchases of Equity Securities***

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 14, 2005, there were 48,198,480 shares of our common stock outstanding with approximately 775 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 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
Fiscal Year 2004		
First Quarter	$ 15.95	$ 11.75
Second Quarter	14.99	10.49
Third Quarter	11.01	9.40
Fourth Quarter	$ 10.88	$ 8.46

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

Issuer Purchases of Equity Securities

Our stock repurchase programs, which authorized us to repurchase up to $110 million of shares of the company s common stock, were announced on February 11, 2004 as a $25 million of shares program, on May 12, 2004 as a $60 million shares program, and on July 29, 2004 as an additional $25 million share program. These programs do not have an expiration date. The table below sets forth the information with respect to repurchases made under these stock repurchase programs during each month in the fourth quarter of our fiscal year ended January 1, 2005.

	Total Number Of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part Of Publicly Announced Program	Maximum Dollar Value Of Shares That May Yet Be Purchased Under The Program (in millions)
October 3, 2004 to October 30, 2004	557,000	$ 8.93	557,000	$ 15.0
October 31, 2004 to November 27, 2004	537,500	$ 9.30	537,500	$ 10.0

November 28, 2004 to January 1, 2005	277,500	$ 9.72	277,500	$	7.3
Total	1,372,000	$ 9.24	1,372,000		

Item 6. ***Selected Consolidated Financial Data***

The selected consolidated financial data presented below for the five fiscal years ended January 1, 2005 is derived from our 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 below and our audited consolidated financial statements and 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. Certain reclassifications have been made to the financial statements previously filed with the SEC to conform to current practice.

In the merger of Thoratec with TCA that 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

Table of Contents

merger. For accounting purposes, TCA is deemed to have acquired Thoratec and therefore for fiscal year 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, fiscal 2000 ended on December 30, 2000, fiscal 2001 ended on December 29, 2001, fiscal 2002 ended December 28, 2002, fiscal 2003 ended January 3, 2004 and fiscal 2004 ended January 1, 2005.

	Fiscal Year				
	2004	2003	2002	2001	2000 (a)
	(In thousands, except per share data)				
Statement of Operations:					
Product sales	$ 172,341	$ 149,916	$ 130,844	$ 113,384	$ 83,396
Gross profit	100,222	88,748	75,720	60,544	48,566
Amortization of goodwill and purchased intangible assets	11,724	12,333	12,384	15,674	
In-process research and development		220		76,858	
Impairment of intangible asset		8,987			
Litigation, merger, restructuring and other costs	733	2,132	1,409	7,134	1,831
Net income (loss)	4,974	(2,182)	511	(87,866)	7,524
Basic and diluted earnings (loss) per share	$ 0.07	$ (0.04)	$ 0.01	$ (1.68)	$ 0.23
Balance Sheet Data:					
Cash and cash equivalents and short term available-for-sale investments	$ 145,859	$ 62,020	$ 45,483	$ 91,726	$ 129,008
Working capital	206,250	116,430	107,972	135,924	149,207
Total assets	524,415	476,131	468,432	530,241	176,685
Subordinated convertible debentures	143,750			54,838	54,838
Long-term deferred tax liability and other	63,052	67,123	75,454	81,020	
Total shareholders equity	$ 292,108	$ 386,236	$ 374,340	$ 373,343	$ 105,869

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

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

With the exception of historical facts, the statements contained in this Form 10-K are forward-looking statements, within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements generally can be identified by use of statements that include words such as believe , expect , anticipate , intend , plan , foresee , may , hope , will , project , should , would , c continue or other similar words or phrases. Similarly, statements that describe our objectives, plans or goals also are forward-looking statements. All of these forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statement. See Factors That May Affect Future Results above for what we believe to be the principal factors that could cause our actual performance and future actions to differ materially from the forward-looking statements. Readers are urged to consider these factors carefully in evaluating the forward-looking statements. The forward-looking statements

included in this Form 10-K are made only as of the date of this report and we undertake no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances.

The following presentation of management s discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements included in this Form 10-K.

Overview

We are a leading manufacturer of circulatory support products for use by patients with congestive heart failure, or CHF. Our VADs are used primarily by these CHF patients to perform some or all of the pumping function of the

Table of Contents

heart and we currently offer the widest range of products to serve this market. We believe that our long-standing reputation for quality and innovation and our excellent relationships with leading cardiovascular surgeons worldwide position us to capture growth opportunities in the expanding congestive heart failure market. Through our wholly-owned subsidiary, ITC, we design, develop, manufacture and market point-of-care diagnostic test systems that provide fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes.

Our business is comprised of two segments; Cardiovascular and ITC. The major product lines within the Cardiovascular segment are:

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

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

The major product line of our ITC segment is:

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.

Growth in out ITC segment assumes increased patient testing, better patient outcomes, and increased decentralization of testing from central laboratories to point-of-care.

Our Business Model

The two product lines that represent the majority of our product sales are VAD and point-of-care diagnostic test systems and services. Historical product sales mix has been as follows:

	2004	2003	2002
Cardiovasular:			
VAD pumps including associated products and services	58%	60%	62%
Grafts	2%	3%	3%
Point-of-care diagnostic test systems	40%	37%	35%
Product Sales	100%	100%	100%

Acquisitions and Strategic Investments

On March 30, 2004, we made an investment in BioCardia, Inc. Under the terms of the investment documents, we (i) will assist BioCardia in exploring opportunities for developing devices for the surgical delivery of biotherapeutics, (ii) have limited exclusive rights to negotiate the distribution, licensing or purchase of surgical delivery technology developed by BioCardia and (iii) through an observational board seat, subject to BioCardia s authorization will be able to review relevant clinical data accumulated by BioCardia through its multiple trials. We have accounted for this investment on the cost basis as we do not have the ability to exercise significant influence over BioCardia s operating and financial policies. This investment is included on our consolidated balance sheet in other long-term assets.

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. We paid approximately $5.2 million in cash and assumed trade payables. The purchase price was allocated based on the fair value of assets acquired as determined by an independent valuation firm. There was no goodwill recorded with the transaction. As a result of the acquisition, $220,000 relating to in-process research and development was expensed in the fourth quarter of 2003.

Table of Contents

Restructuring Plan

In June 2001, following the merger with TCA, 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 recorded a total of $1.5 million in restructuring charges. These charges represent estimated employee severance costs and stock option acceleration charges.

Critical Accounting Policies and Estimates

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations are discussed below. For a more detailed discussion on the application of these and other accounting policies, see the notes to the consolidated financial statements included in this Annual Report on Form 10-K. Preparation of financial statements in accordance with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities. There can be no assurance that actual results will not differ from those estimates.

Evaluation of Purchased Intangibles and Goodwill for Impairment

In accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, we periodically evaluate the carrying value of long-lived assets to be held and used, including intangible assets subject to amortization, when events or circumstances warrant such a review. The carrying value of a long-lived asset to be held and used is considered impaired when the anticipated separately identifiable undiscounted cash flows from such an asset are less than the carrying value of the asset. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. Management must make estimates of these future cash flows and the approximate discount rate, and if any of these estimates proves incorrect, the carrying value of these assets on our consolidated balance sheet could become significantly impaired.

As of the beginning of fiscal year 2002, we adopted SFAS No. 142, Goodwill and Other Intangible Assets, and ceased amortizing purchased goodwill. We complete an impairment test of goodwill and other intangible assets subject to amortization as required by SFAS No. 142 and SFAS No. 144. Upon completion of our impairment tests as of the end of the year 2004, we determined that neither goodwill nor intangible assets were impaired.

Revenue Recognition

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

Sales of certain Cardiovascular segment products to first-time customers are recognized when it has been determined that the customer has the ability to use such products. These sales frequently include the sale of products and training services under multiple element arrangements. 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 revenue under these arrangements allocated to training is based upon fair market value of the training, which is performed principally by third party providers. The amount of product sales allocated to the Cardiovascular segment products is done on a fair value basis. Under this basis, the total value of the arrangement is allocated to the training and the Cardiovascular segment products based on the relative fair market value of the training and products. The amount of product sales allocated to training is recorded as deferred revenue and is recognized when the training is completed. As of the end of fiscal 2004, all products that had been delivered and recorded as product sales were delivered to customers for which training had been

Table of Contents

completed. There was no amount of product sales deferred related to this training not yet completed at the end of 2004; however, $20,000 of such product sales were deferred at the end of 2003 and $0.1 million at the end of 2002.

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

Management makes decisions on such things as credit worthiness and warranty reserves. If these decisions prove incorrect, the carrying value of these assets and liabilities on our consolidated balance sheet could be significantly different.

Reserves

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

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

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		
	2004	**2003**	**2002**
Product sales	100%	100%	100%
Cost of product sales	42	41	42
Gross profit	58	59	58
Operating expenses:			
Selling, general & administrative	31	30	29
Research and development	17	17	19
Amortization of purchased intangible assets	7	8	10
Loss on impairment of intangible asset		6	
Litigation, merger, restructuring and other costs		1	1
Total operating expenses	55	62	59
Income (loss) from operations	3	(4)	(1)
Other income and (expense):			
Interest expense	(1)		
Interest income and other	1	1	2
Income (loss) before taxes	3	(3)	1
Income tax expense (benefit)	(1)	(1)	

Net income (loss)	2%	(2)%	1%

Fiscal Years 2004 and 2003

Product Sales

Product sales in 2004 were $172.3 million compared to $149.9 million in 2003. The primary components of the $22.4 million, or 15%, increase in product sales were the following:

Point-of-care diagnostic sales increased $9 million, including $4.5 million in revenue from the IRMA product line acquired in the fourth quarter of 2003.

Alternate site sales increased $4.7 million, primarily due to increased sales of the ProTime product line.

Higher VAD sales of $4.5 million. The majority of this increase came from higher sales of the HeartMate VAD.

Table of Contents

Other ancillary product sales, (drivers, cannulae, service, rentals and spares) increased $5.9 million, including an increase in TLC II driver revenue principally from Home Discharge , which was approved by the FDA toward the end of the second quarter of 2004; partially offset by

$1.7 million in lower graft revenue.

Our sales of Destination Therapy implants were lower in 2004 than we had originally anticipated, and we expect product sales for this indication to increase more slowly than we had originally projected.

Gross Profit

Gross profit as a percentage of sales for 2004 and 2003 was 58% and 59%, respectively. Within these essentially flat margins were the following significant fluctuations:

A 1% higher margin on cardiovascular products resulting from a shift in sales mix from lower to higher margin products, partially offset by higher manufacturing costs.

A 3% lower margin on point-of-care revenue, primarily related to the IRMA product line, plus higher manufacturing and shipping costs associated in part with the shift in sales from distributor to direct channels.

Selling, General and Administrative

Selling, general and administrative expenses in 2004 were $54.1 million, or 31% of product sales, compared to $44.4 million, or 30% of product sales, in 2003. The $9.7 million increase in spending was primarily attributable to the following:

Increased headcount from 139 employees at the end of 2002 to 174 at the end of 2003 to 207 at the end of 2004, together with annual salary, fringe benefit and other cost increases of $4.7 million.

Higher spending on marketing and related activities, primarily associated with our HeartHope Center Program, Destination Therapy, and costs associated with the IRMA product line of $3.9 million.

Higher professional fees, including legal, audit and financial consulting services relating primarily to our compliance with the Sarbanes-Oxley Act of 2002 of an additional $0.9 million.

Higher insurance premiums for 2004 compared to 2003 of $0.2 million.

Research and Development

Research and development expenses in 2004 were $28.7 million, or 17% of product sales, compared to $26.1 million, or 17% of product sales, in 2003. Research and development costs are largely project driven, and the level of spending depends on the level of project activity planned and subsequently approved and conducted. The primary component of our research and development costs is employee salaries and benefits. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations.

Amortization of Purchased Intangible Assets

Amortization of purchased intangible assets in 2004 was $11.7 million compared to $12.3 million in 2003 as there were no new acquisitions coupled with the $9.0 million write-off of the Aria assets at the end of fiscal year 2003.

In-process Research and Development Costs

We had no in-process research and development charges in 2004. In-process research and development expense in 2003 was $0.2 million related to our acquisition of the IRMA product line.

Table of Contents

Litigation, Merger, Restructuring and Other Costs

Litigation, merger, restructuring and other charges in 2004 were $0.7 million compared to $2.1 million in 2003. The 2004 expense is primarily comprised of costs associated with a putative Federal securities law class action, and a shareholder derivative action entitled *Wong v. Grossman* that were filed in the third quarter of 2004. The 2003 expense is primarily comprised of $2.3 million to settle a patent infringement claim.

Interest Expense

Interest expense in 2004 was $2.5 million compared to none in 2003. This expense in 2004 includes $2.1 million in interest payments and $0.4 million in amortization of the debt issuance costs related to our convertible notes. We did not have these notes or any other debt instrument in 2003.

Interest Income and Other

Interest income and other in 2004 was $2.2 million compared to $1.8 million in 2003. This increase was primarily due to higher interest income earned on our portfolio based on increased cash balances in 2004 compared 2003.

Income Taxes

Our effective tax rate was 24% in 2004 compared to 39% in 2003. The reduction in our effective tax on a comparative basis was due primarily to a combination of reduced tax basis profitability in the current year; increased interest income from tax favorable investments; increased research and development credits; offset in part by increased expenditures for non-deductible expenses.

Fiscal Years 2003 and 2002

Product Sales

Product sales in 2003 were $149.9 million compared to $130.8 million in 2002. The primary components of the $19.1 million, or 15%, increase in product sales were as follows:

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

Higher graft sales of $1.0 million.

Higher revenue from sales of ancillary products of $1.8 million.

Higher revenue from ITC sales of point-of-care diagnostic test systems of $7.4 million

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

Gross Profit

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

Higher VAD average selling prices resulted in a 2.2% increase in margin, largely as a result of 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 had an average selling price of between $60,000 and $70,000,

while the Thoratec VAD typically sold for between $30,000 and $40,000.

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

Table of Contents

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. The $7.0 million increase in spending was primarily attributable to the following:

Increased headcount from 125 employees 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 the fourth quarter of 2003.

Higher insurance premiums

Higher facilities costs related to higher headcount.

These higher costs were offset in part by lower legal costs in 2003 due to our filing with the SEC a registration statement in 2002 that did not recur in 2003, and lower meeting expenses related to a customer event in 2002 that did not recur in 2003.

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 project activity planned and subsequently approved and conducted. The primary component of our research and development costs are employee salaries and benefits. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations.

Amortization of Purchased Intangible Assets

Amortization of purchased intangible assets in 2003 was $12.3 million compared to $12.4 million in 2002. The expense was flat year over year as there were no acquisitions or changes in amortization values through the year ended 2003.

Amortization of Goodwill

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

Impairment of Intangible Asset

Subsequent to the year ended 2003, we completed an assessment of the final results from our feasibility clinical trial for the Aria CABG graft, which was ongoing through fiscal 2003. Based on the clinical trial results, we determined that it would not devote additional resources to the development of the Aria graft. Upon the decision to discontinue product development, we 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 with TCA.

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. There were no in-process research and development expenses in 2002.

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

Table of Contents

by Bodycote Materials Testing Canada, Inc. and David C. MacGregor, M.D related to materials used in the Company s HeartMate ® LVAS, partially offset by a reversal of a restructuring reserve.

Interest Expense

There was no interest expense in 2003 and $1.1 million in 2002. This decrease was due to less interest paid due to the redemption of our debentures in March 2002. We had no debt in 2003.

Interest Income and Other

Interest income and other in 2003 was $1.8 million compared to $2.7 million in 2002. This decrease was primarily due to the impact of lower interest rates on invested cash in 2003, which resulted in a decrease in interest income, 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 $1.0 million. Based on a pre-tax loss in 2003 of $3.6 million, the impact of these tax differences was proportionately lower.

Liquidity and Capital Resources

At January 1, 2005, we had working capital of $206.3 million compared with $116.4 million at January 3, 2004. Cash and cash equivalents and short-term available-for-sale investments at January 1, 2005 were $145.9 million compared to $62.0 million at January 3, 2004. The increase is due primarily to unexpended proceeds from our convertible debt offering in the second quarter of 2004.

Cash provided by operating activities for the year ended January 1, 2005 was $18.2 million, after payments of litigation expenses for a settled litigation matter and annual bonuses accrued at January 3, 2004 totaling $5.2 million. In addition, investing activities used $61.4 million, with $55.6 million net purchases of investments and $5.8 million to acquire property, plant and equipment. The purchases of property, plant and equipment consisted of $5.0 million for equipment and $0.8 million for leasehold improvements. Cash provided by financing activities for the year was $40.5 million, including $139.4 million net proceeds from the issuance of our convertible notes and an additional $3.8 million from proceeds related to stock option exercises and our Employee Stock Purchase Plan, partially offset by $102.7 million paid to repurchase 8.3 million shares of stock under our stock repurchase programs.

A portion of the debt offering proceeds were used to purchase and pledge $9.8 million to the trustee under the indenture for the exclusive benefit of the holders of the convertible notes, U.S. government securities to provide for the payment, in full, of the first six scheduled interest payments. Additional net proceeds were used to repurchase 4.2 million shares of our outstanding common stock for $60.0 million. The remaining net proceeds will be used for general corporate purposes, which may include additional stock repurchases, strategic investments or acquisitions. The convertible notes were issued at an issue price of $580.98 per note, which is 58.098% of the principal amount at maturity of the notes. The convertible notes bear interest at a rate of 1.3798% per year on the principal amount at maturity, payable semi-annually in arrears in cash on May 16 and November 16 of each year, from November 16, 2004 until May 16, 2011. Beginning on May 16, 2011, the original issue discount will accrue daily at a rate of 2.375% per year on a semi-annual bond equivalent basis and, on the maturity date, a holder will receive $1,000 per note. As a result, the aggregate principal amount of the notes at maturity will be $247.4 million.

In February 2004 and July 2004, the Board of Directors authorized stock repurchase programs under which up to an aggregate of $50.0 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. In May 2004, in conjunction with our convertible notes offering, the Board of Directors authorized the repurchase of an additional $60.0 million of our common stock. As of January 1, 2005, we had repurchased and retired 8.3 million shares with an aggregate purchase price of $102.7 million under these combined programs.

Table of Contents

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

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

Contractual Obligations

As of January 1, 2005, we had the following contractual obligations (in millions):

	Total	2005	2006	2007	2008	2009	Thereafter
Long-Term Debt Obligations (a)	$ 269.1	3.4	3.4	3.4	3.4	3.4	252.1
Operating Lease Obligations	19.5	2.5	2.5	2.4	2.3	1.8	8.0
Purchase Obligations	19.8	2.2	2.2	2.2	2.2	1.8	9.2
Total	$ 308.4	8.1	8.1	8.0	7.9	7.0	269.3

Our operating lease obligations of $19.5 million were comprised of our various leased facilities and office equipment. Our purchase obligations of $19.8 million were comprised of supply agreements in effect at January 1, 2005.

(a) Includes interest of $21.8 million and original issue discount of $103.7 million. See note 8 to our audited consolidated financial statements in this report for data related to long-term debt.

Letter of Credit

In the third quarter of 2004 we obtained an Irrevocable Standby Letter of Credit for $390,000 as part of our worker s compensation insurance program. The Letter of Credit is not collateralized. The Letter of Credit expires on June 30, 2005 and is scheduled to automatically renew each year on June 30th.

Accounting Pronouncements

In December 2004, the FASB issued statement 123® Share-Based Payment This statement requires that stock-based compensation be recognized as a cost in the financial statements and that such cost be measured based on the fair value of the stock-based compensation. Our adoption of this statement, which we expect to occur in the third quarter of 2005, will have a material, although non-cash, impact on our consolidated statements of operations.

In March 2004, the Emerging Issues Task Force (EITF) reached a final consensus on Issue 03-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments* , to provide additional guidance in determining whether investment securities have an impairment which should be considered other-than-temporary. On September 15, 2004 the FASB issued proposed FSP EITF Issue 03-1-a to address the application of the EITF Issue 03-1 to debt securities that are affected by interest rate and/or sector-spread changes only. On September 30, 2004, the FASB issued FSP EITF Issue 03-1-1, which delayed the effective date of certain paragraphs of the EITF until EITF 03-1-a is issued. We did however, adopt the disclosure provisions in the fourth quarter of 2004, the adoption had no effect on our operating results or financial condition. Management expects that the adoption of the delayed portions of this Issue and the related FSP s will not have a significant effect on our operating results or financial condition once

adopted.

In April 2004, the FASB issued FSP FAS No. 129-1, *Disclosure of Information about Capital Structure, Relating to Contingently Convertible Securities* to provide disclosure guidance for contingently convertible securities. We adopted the disclosure provisions in the second quarter of 2004 as they apply to the convertible notes. The 7.3 million shares underlying our convertible notes are reportable under this new disclosure are antidilutive and, therefore, have been excluded from the calculation of diluted net income per share. See note 15.

In October 2004, EITF Issue No. 04-8, *Accounting Issues Related to Certain Features of Contingently Convertible Debt and the Effect on Diluted Earnings per Share* was issued. Issue No. 04-8 states that shares

Table of Contents

available under contingently convertible debt should be included in diluted earnings per share, or EPS, in all periods, since the notes were issued, except when inclusion is anti-dilutive, regardless of whether the contingency is met and regardless of whether the market price contingency is substantial. Our adoption of this proposed interpretation, in the fourth quarter of 2004, did not have a material impact on our most recent consolidated results as the effect of the 7.3 million shares issuable upon conversion of the notes was anti-dilutive. If in future periods the shares would be dilutive, then 7.3 million shares will be added to our share count used to calculate diluted earnings per share, and this inclusion could result in lower diluted EPS than if the existing guidance had not been changed by EITF 04-8.

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

Interest Rate Risk

Our investment portfolio is made up of cash equivalent and marketable investments in auction rate securities, money market funds, debt instruments of government agencies, U.S. Treasuries, local municipalities, 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, except for some investments in U.S. Treasuries held as restricted investments as collateral for future interest payments related to our convertible debt, which mature within three years from the date of purchase. Our holdings of the securities of any one issuer, except government agencies, do not exceed 10% of the portfolio. If interest rates rise, the market value of our investments may decline which could result in a loss if we are forced to sell an investment before the scheduled maturity. If interest rates were to rise or fall from current levels by 25 basis points the change in our net unrealized loss on investments would be nominal. We do not utilize derivative financial instruments to manage interest rate risks.

Our convertible notes do not bear interest rate risk as the notes were issued at a fixed rate of interest.

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 to our U.S. sales and marketing group and are internally reported as part of that group. All assets and liabilities of our non-U.S. operations are translated into U.S. dollars at the period-end exchange rates and the resulting translation adjustments are included in comprehensive income. The period-end translation of the non-functional currency assets and liabilities (primarily assets and liabilities on our UK subsidiary consolidated balance sheet that are not denominated in UK Pounds) at the period-end exchange rates result in foreign currency gains and losses, which are included in Interest Income and Other.

We use forward foreign currency contracts to hedge the gains and losses generated by the revaluation of these non-functional currency assets and liabilities. These derivatives are not designated as cash flow or fair value hedges under SFAS No. 133. As a result, changes in the fair value of the forward foreign currency contracts are included as Interest Income and Other. The change in the fair value of the forward foreign currency contracts typically offsets the change in value from revaluation of the non-functional currency assets and liabilities. These contracts typically have maturities of three months or less. At January 1, 2005 and January 3, 2004, we had forward foreign currency contracts in Pounds Sterling and Euros with a notional value of $6.9 million and $4.3 million, respectively. These contracts had an average exchange rate of Euros to Pounds Sterling of .6939 and Pounds Sterling to the U.S. dollar of .4763 as of January 1, 2005. The impact of foreign currency revaluation, net of forward foreign currency contracts, was $0.2 million for the year ended January 1, 2005 and was negligible for the year ended January 3, 2004.

Table of Contents

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

THORATEC CORPORATION AND SUBSIDIARIES

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

MANAGEMENT REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Management assessed our internal control over financial reporting as of January 1, 2005, the end of our fiscal year. Management based its assessment on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management s assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, our overall control environment and took into consideration the situation which resulted in the restatement of the pro forma stock compensation fair value disclosures for the years ended January 3, 2004 and December 28, 2002 . This assessment is supported by testing and monitoring performed by our internal accounting and finance organization.

Based on our assessment, management has concluded that our internal control over financial reporting was effective as of January 1, 2005 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principles. The results of management s assessment were reviewed with the Audit Committee.

Our independent registered public accounting firm, Deloitte & Touche LLP, has issued an attestation report on management s assessment of our internal control over financial reporting, which is included in this Item 8 of this Annual Report on Form 10-K.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Thoratec Corporation:

We have audited management s assessment, included in the accompanying Management s Report on Internal Control Over Financial Reporting, that Thoratec Corporation and subsidiaries (the Company) maintained effective internal control over financial reporting as of January 1, 2005, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of January 1, 2005, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 1, 2005, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and financial statement schedules as of and for the year ended January 1, 2005 of the Company and our report dated March 16, 2004 expressed an unqualified opinion on those

financial statements and financial statement schedules and included an explanatory paragraph concerning the restatement of the pro forma stock compensation fair value disclosures for the years ended January 3, 2004 and December 28, 2002.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California

March 16, 2005

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Thoratec Corporation:

We have audited the accompanying consolidated balance sheets of Thoratec Corporation and subsidiaries (the Company) as of January 1, 2005 and January 3, 2004, and the related consolidated statements of operations, comprehensive income (loss), stockholders equity, and cash flows for the years ended January 1, 2005, January 3, 2004, and December 28, 2002. Our audits also included the financial statement schedules listed in the Index to this Annual Report of Form 10-K at Part VI Item 15 (a) 2. These financial statements and financial statement schedules are the responsibility of the Company s management. Our responsibility is to express an opinion on the financial statements and financial statement schedules based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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 1, 2005 and January 30, 2004, and the results of their operations and their cash flows for the years ended January 1, 2005, January 2, 2004 and December 28, 2002, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such financial statement schedules, when considered in relation to the basic consolidated financial statements taken as a whole, present fairly, in all material respects, the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, the pro forma stock compensation fair value disclosures for the years ended January 3, 2004 and December 28, 2002 have been restated.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of January 1, 2005, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2005 expressed an unqualified opinion on management s assessment of the effectiveness of the Company s internal control over financial reporting and an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California
March 16, 2005

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	For the Fiscal Year Ended	
	2004	2003
	(In thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,017	$ 18,270
Short-term available-for-sale investments	129,842	43,750
Restricted short-term investments	3,362	
Receivables, net of allowances of $708 in 2004 and $486 in 2003	33,051	27,969
Inventories	39,141	36,417
Deferred tax asset	6,470	9,717
Prepaid expenses and other assets	3,873	3,079
Total current assets	231,756	139,202
Property, plant and equipment, net	27,584	28,492
Long-term available-for-sale investments		41,179
Restricted long-term investments	4,845	
Goodwill	94,097	96,065
Purchased intangible assets, net	153,141	164,865
Long-term deferred tax asset	6,381	4,796
Other assets	6,611	1,532
Total Assets	524,415	$ 476,131
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 7,699	$ 6,952
Accrued compensation	9,507	8,851
Accrued liabilities for legal, audit and warranty	1,610	1,463
Accrued legal settlement		2,000
Accrued income taxes	2,299	1,637
Other accrued liabilities	4,391	1,869
Total current liabilities	25,506	22,772
Senior subordinated convertible notes	143,750	
Long-term deferred tax liability and other	63,051	67,123
Total Liabilities	232,307	89,895
Commitments		
Shareholders equity:		

Common shares: authorized 100,000; issued and outstanding 48,375 in 2004 and 56,242 in 2003	364,775	423,045
Deferred compensation	(1,586)	(2,630)
Accumulated deficit	(71,514)	(34,594)
Accumulated other comprehensive income:		
Unrealized gain (loss) on investments	(325)	51
Cumulative translation adjustments	758	364
Total accumulated other comprehensive income	433	415
Total Shareholders Equity	292,108	386,236
Total Liabilities and Shareholders Equity	$ 524,415	$ 476,131

See notes to consolidated financial statements.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Fiscal Years Ended		
	2004	2003	2002
	(In thousands, except per share data)		
Product sales	$ 172,341	$ 149,916	$ 130,844
Cost of product sales	72,119	61,168	55,124
Gross profit	100,222	88,748	75,720
Operating expenses:			
Selling, general and administrative	54,134	44,437	37,413
Research and development	28,657	26,052	25,251
Amortization of purchased intangible assets	11,724	12,333	12,384
Impairment of intangible asset		8,987	
In-process research and development		220	
Litigation, merger, restructuring and other costs	733	2,132	1,409
Total operating expenses	95,248	94,161	76,457
Income (loss) from operations	4,974	(5,413)	(737)
Other income and (expense):			
Interest expense	(2,460)		(544)
Interest income and other	2,176	1,837	2,175
Income (loss) before taxes	4,690	(3,576)	894
Income tax expense (benefit)	1,126	(1,394)	383
Net income (loss)	$ 3,564	$ (2,182)	$ 511
Basic and diluted earnings (loss) per share	$ 0.07	$ (0.04)	$ 0.01
Shares used to compute earnings (loss) per share:			
Basic	52,187	55,583	56,184
Diluted	53,160	55,583	56,762

See notes to consolidated financial statements.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	For the Fiscal Years Ended		
	2004	2003	2002
	(In thousands)		
Net income (loss)	$ 3,564	$ (2,182)	$ 511
Other net comprehensive income (loss):			
Unrealized gain (loss) on available-for-sale investments (net of taxes of $(130), $(54), and $87 in 2004, 2003, and 2002, respectively)	(376)	(79)	130
Foreign currency translation adjustments	394	273	108
Comprehensive income (loss)	$ 3,582	$ (1,988)	$ 749

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 (In thousands)	Accumulated Other Comprehensive Income (Loss)	Total Shareholders Equity
BALANCE, DECEMBER 29, 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
Tax benefit related to employees and directors stock plans		334				334
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, DECEMBER 28, 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
		2,148				2,148

Tax benefit related to employees and directors stock plans						
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, JANUARY 3, 2004	56,242	$ 423,045	$ (34,594)	$ (2,630)	$ 415	$ 386,236
Exercise of common stock options for cash	266	2,432				2,432
Issuance of common shares under Employee Stock Purchase Plan	147	1,341				1,341
Tax benefit related to employees and directors stock plans		485				485
Repurchase of common stock	(8,255)	(62,200)	(40,484)			(102,684)
Restricted Stock Forfeiture	(25)	(328)		134		(194)
Amortization of deferred compensation				910		910
Other comprehensive income:						
Unrealized loss on available-for-sale investments (net of taxes of $(130)					(376)	(376)
Foreign currency translation adjustment					394	394
Net Income			3,564			3,564
BALANCE, JANUARY 1, 2005	48,375	$ 364,775	$ (71,514)	$ (1,586)	$ 433	$ 292,108

See notes to consolidated financial statements.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Fiscal Years Ended		
	2004	2003	2002
		(In thousands)	
Cash flows from operating activities:			
Net income (loss)	$ 3,564	$ (2,182)	$ 511
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	18,782	18,785	17,076
Investment premium amortization	948	18	77
Unrealized (gain)/loss on available-for-sale investments	130	54	130
Impairment of intangible asset		8,987	
In-process research and development		220	
Non-cash interest and other expenses	778	32	409
Tax benefit related to stock options	485	2,148	334
Amortization of deferred compensation	715	1,105	1,148
Loss on disposal of asset	122	55	2
Change in net deferred tax liability	(2,178)	(4,756)	(836)
Changes in assets and liabilities:			
Receivables	(5,082)	565	(420)
Inventories	(3,116)	3,525	(13,026)
Prepaid expenses and other assets	(30)	(1,043)	(1,521)
Accounts payable and other liabilities	3,372	3,004	(1,836)
Other	(255)		
Net cash provided by operating activities	18,235	30,517	2,048
Cash flows from investing activities:			
Purchases of available-for-sale investments	(197,015)	(33,897)	(84,267)
Sales of available-for-sale investments	119,782	1,200	89,850
Maturities of available-for-sale investments	21,620	15,891	700
Reclassification from (to) restricted cash and cash equivalents			45,884
Capitalized transaction costs		(395)	
Purchases of property, plant and equipment, net	(5,812)	(6,785)	(7,144)
Acquisition of product line		(5,200)	
Net cash provided by (used in) investing activities	(61,425)	(29,186)	45,023
Cash flows from financing activities:			
Net proceeds from issuance of convertible notes	139,454		
Proceeds from stock option exercises, net	2,432	9,494	829
Proceeds from common stock offering			15,335
Proceeds from stock issued under employee stock purchase plan	1,341	1,107	

Repurchase of common stock	(102,684)		(18,283)
Repurchase of convertible debentures			(54,838)
Net cash provided by (used in) financing activities	40,543	10,601	(56,957)
Effect of exchange rate changes on cash and cash equivalents	394	194	54
Net increase (decrease) in cash and cash equivalents	(2,253)	12,126	(9,832)
Cash and cash equivalents at beginning of period	18,270	6,144	15,976
Cash and cash equivalents at end of period	$ 16,017	$ 18,270	$ 6,144
Supplemental disclosure of cash flow information:			
Cash paid for taxes	$ 1,114	$ 889	$ 347
Cash paid for interest	$ 1,631	$	$ 839
Supplemental disclosure of Non-cash investing and financing activities:			
Purchases of equipment from Inventory	$ 392	$ 142	$ 386
Issuance of restricted stock	$	$	$ 328
Cancellation of restricted stock	$ (328)	$	$
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 in these Notes as we , our , us , Thoratec or the Company , is headquartered in Pleasanton, California and is a 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: Cardiovascular and ITC. 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 with TCA (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 28, 2002, (2002) included 52 weeks and the fiscal years ended January 3, 2004, (2003) and January 1, 2005 (2004) 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 2004 or 2003. For fiscal year 2002, one distributor customer accounted for 11% of total product sales. 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 2004, 2003, or 2002 or had an accounts receivable balance greater than 10% of total accounts receivable at the end of 2004 or 2003.

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; our 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; our 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

Table of Contents

reasonable cost; the ability to maintain compliance with changing federal and state regulations; the long and variable sales and deployment cycle of our ventricular assist device (VAD) products; worldwide demand for circulatory support and graft products and blood coagulation testing and skin incision devices and the management of risks inherent in selling in foreign countries; claims relating to the handling, storage or disposal of hazardous chemicals and biomaterials; stock price volatility due to general economic conditions or future issuances and sales of our stock; the occurrence of natural catastrophic disasters; foreign currency fluctuations; and the ability to attract and retain talented employees.

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 auction rate securities, corporate and municipal bonds and U.S. government obligations and are classified as available-for-sale and are reported at fair value based upon quoted market price. 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. Short-term investments generally mature between three months and two years from the purchase date. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature or due to the frequency in which the interest rate is reset such as with auction rate securities, in addition these securities represent the investment of cash that is available and intended for current operations. Investments that are not intended for use in current operations are classified as long-term investments.

Restricted Short-Term and Long-Term Investments - Our investments are primarily held in U.S. Treasuries as collateral for future interest payments related to our convertible debt. These securities are classified as restricted and are reported at fair value based upon quoted market price. In the fourth quarter of 2004 we adopted the disclosure provisions of EITF 03-01, which provides additional guidance in determining whether investment securities have an impairment which should be considered other-that-temporary. Under this new guidance we determined that we had no impairments that were other-than temporary. 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 include 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.

The Company leases certain facilities for administration, manufacturing and warehousing under long term operating leases. Any scheduled rent increases, rent holidays and other related incentives are recognized on a straight-line basis over the term of the lease.

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 2003, costs capitalized for a new enterprise resource planning software system (ERP System) were

$3.7 million. No additional costs were capitalized in 2004 related to this ERP System. Depreciation expense related to this ERP System of $0.5 million was recorded in each 2004 and 2003 and an additional $0.4 million was recorded in 2002. 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

Table of Contents

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. We complete an impairment test of goodwill and other intangible assets subject to amortization as required by SFAS No. 142 and SFAS No. 144. Upon completion of our impairment tests as of the end of fiscal 2004, we determined that neither goodwill nor intangible assets were impaired.

Fair Value of Financial Instruments - Financial instruments include cash and cash equivalents, short-term and long-term available-for-sale investments, restricted short-term and long-term investments, customer receivables, accounts payable, convertible notes and certain other accrued liabilities. The fair values 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.

Debt Issuance Costs Costs incurred in connection with the issuance of our senior subordinated convertible notes have been capitalized and are included in other assets on the consolidated balance sheet. These costs are amortized on a straight line basis until May 2011, the point at which we can redeem the debt, and such amortization expense is reflected in Interest expense on the consolidated statement of operations.

Foreign Currency Translation We conduct business in foreign countries. 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 and expense 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 U.K. subsidiary into United States dollars are recorded in the statements of operations as foreign currency transaction gains or losses and are included in Interest Income and Other .

In September 2003, the Company began using forward foreign currency contracts to hedge the gains and losses generated by the remeasurement of non-functional currency assets and liabilities (primarily assets and liabilities on our UK subsidiary s consolidated balance sheet that are not denominated in UK pounds). Changes in the fair value of the forward currency contracts are included in Interest Income and Other, 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 1, 2005, the Company had forward foreign currency contracts to exchange Pounds Sterling and Euros for U.S. Dollars with a notional value of $6.9 million and negligible fair value. Net foreign currency exchange loss was $0.2 million in 2004 and negligible in 2003. Net foreign currency exchange gain was approximately $0.5 million on 2002.

Repurchases of Common Stock - In February 2004, the Board of Directors authorized a stock repurchase program under which up to $25.0 million of our common stock could be acquired in the open market or in privately negotiated transactions. The number of shares to be purchased and the timing of purchases were based on several conditions, including the market price of our stock, general market conditions and other factors. The Board of Directors subsequently authorized the repurchase of an additional $60.0 million in May 2004 and an additional $25.0 million in July 2004. Through December 2004, we repurchased 8.3 million shares of our common stock for $102.7 million under these three combined programs. 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.

Revenue Recognition and Product Warranty - We recognize revenue from product sales of our Cardiovascular and ITC segments when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectibility is reasonably assured. Sales to distributors are recorded when title transfers upon shipment. One distributor has certain limited product return rights. One other distributor has certain rights of return upon termination of its distribution agreement. A reserve for sales returns is recorded for these customers applying reasonable estimates of product returns based upon 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 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

Table of Contents

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 fair value basis. Under this basis, the total value of the arrangement is allocated to the training and the Cardiovascular segment products based on the relative fair market value of the training and 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 2004, all products that had been delivered and recorded as product sales were delivered to customers for which training had been completed. There was no amount of product sales deferred related to this training not yet completed for the year ended 2004; however, $20,000 of such product sales were deferred at the end of 2003 and $0.1 million at the end of 2002.

On December 29, 2004 we modified our distributor agreement with BARD Medical to continue the exclusive distribution of our *Vectra* product line until December 31, 2005. We received a payment of $1.8 million which will be recognized over the remaining term of the agreement.

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 2004, 2003, and 2002 are $5.8 million, $4.7 million, and $3.9 million, respectively, of income earned from the rental of these medical devices.

The majority of our products are covered by up to a two-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 and are included in Cost of Product Sales . The change in accrued warranty expense in 2004, 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 2004	$ 829	$ 173	$ (384)	$ 618
Fiscal year ended 2003	$ 695	$ 193	$ (59)	$ 829
Fiscal year ended 2002	$ 910	$ 45	$ (260)	$ 695

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		
	2004	2003 (Restated)	2002 (Restated)
Net income (loss):			

As reported	$ 3,564	$ (2,182)	$ 511
Add: Stock-based compensation expense included in reported net income, net of related tax effects	793	693	726
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(12,524)	(7,363)	(7,883)
Pro forma	$ (8,167)	$ (8,852)	$ (6,646)
Basic and diluted earnings (loss) per share:			
As reported	$ 0.07	$ (0.04)	$ 0.01
Pro forma	$ (0.16)	$ (0.16)	$ (0.12)

Subsequent to the issuance of our 2003 consolidated financial statements, management determined that total stock based employee compensation expense determined under the fair value based method, net of related tax effects, for 2003 and 2002 had been calculated incorrectly. Accordingly, such pro forma amounts presented above have been restated. The effect was to decrease pro forma stock-based compensation expense, net of tax and pro

Table of Contents

forma net loss by $1.1 million for 2003 and by $1.9 million for 2002. Pro forma earnings per share increased $0.02 per share for 2003 and $0.03 per share in 2002. This correction did not impact the Company s consolidated financial position, results of operations, or cash flows for any of the periods presented.

The increase in stock-based employee compensation expense, net of tax effects, in 2004 was primarily due to the decreased effective tax rates offset by an increase in the number of options granted in 2004.

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 For Fiscal Year Ended		
	2004	**2003**	**2002**
Risk-free interest rate	4.36%	3.69%	4.79%
Expected volatility	62%	67%	69%
Expected option life	3.36 years	3.88 years	3.85 years
Dividends	None	None	None

	Employee Stock Purchase Plan For Fiscal Year Ended		
	2004	**2003**	**2002**
Risk-free interest rate	1.32%	1.16%	1.39%
Expected volatility	61%	67%	69%
Expected option life	0.50 years	0.50 years	0.50 years
Dividends	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 December 2004, the FASB issued statement 123® Share-Based Payment This statement requires that stock-based compensation be recognized as a cost in the financial statements and that such cost be measured based on the fair value of the stock-based compensation. Our adoption of this statement, which we expect to occur in the third quarter of 2005, will have a material, although non-cash, impact on our consolidated statements of operations.

In March 2004, the Emerging Issues Task Force (EITF) reached a final consensus on Issue 03-1, *The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments* , to provide additional guidance in determining whether investment securities have an impairment which should be considered other-than-temporary. On September 15, 2004, the FASB issued proposed FSP EITF Issue 03-1-a to address the application of the EITF Issue 03-1 to debt securities that are affected by interest rate and/or sector-spread changes only. On September 30, 2004, the

FASB issued FSP EITF Issue 03-1-1, which delayed the effective date of certain paragraphs of the EITF until EITF 03-1-a is issued. We did however, adopt the disclosure provisions in the fourth quarter of 2004, the adoption had no effect on our operating results or financial condition. Management expects that the adoption of the delayed portions of this Issue and the related FSP s will not have a significant effect on our operating results or financial condition.

In April 2004, the FASB issued FSP FAS No. 129-1, *Disclosure of Information about Capital Structure, Relating to Contingently Convertible Securities* to provide disclosure guidance for contingently convertible securities. We adopted the disclosure provisions in the second quarter of 2004 as they apply to the convertible notes. The 7.3 million shares underlying our convertible notes that are reportable under this new disclosure are antidilutive and, therefore, have been excluded from the calculation of diluted net income per share. See note 15.

In October 2004, EITF Issue No. 04-8, *Accounting Issues Related to Certain Features of Contingently Convertible Debt and the Effect on Diluted Earnings per Share* was issued. Issue No. 04-8 states that shares available under contingently convertible debt should be included in diluted earnings per share, or EPS, in all periods,

Table of Contents

since the notes were issued, except when inclusion is anti-dilutive, regardless of whether the contingency is met and regardless of whether the market price contingency is substantial. Our adoption of this proposed interpretation, in the fourth quarter of 2004, did not have a material impact on our most recent consolidated results as the effect of the 7.3 million shares was anti-dilutive. If in future periods the shares would be dilutive, then 7.3 million shares will be added to our share count used to calculate diluted earnings per share, and this inclusion could result in lower diluted EPS than if the existing guidance had not been changed by EITF 04-8.

Presentation Certain 2003 and 2002 amounts have been reclassified to conform to the presentation in the 2004 financial statements.

In prior years, auction rate securities were classified in Cash and cash equivalents . These securities have been reclassified for all periods presented from Cash and cash equivalents to Short term available-for-sale investments . These auction rate securities have an underlying component of a long-term debt or equity instrument; however, these are traded or mature on a shorter term based on an auction bid that resets the interest rate over time intervals of 28 to 49 days. These resets allow for a much higher level of liquidity than typical long term investments. We have reclassified these securities to short-term available-for-sale investments based on the period from purchase date to the reset date and as they are not intended to be held to the maturity date. The tables below summarize the effect of this reclassification:

	Cash and cash equivalents	Short-term available-for-sale investments
Year Ended 2003:		
As previously reported	$ 62,020	$
Auction rate securities	(43,750)	43,750
As adjusted	$ 18,270	$ 43,750

2. Acquisition and Strategic Investment

On September 30, 2003, we completed an asset purchase of the IRMA point-of-care blood analysis system product line from 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:

		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, $0.2 million relating to in-process research and development was expensed in the fourth quarter of 2003.

On a pro-forma basis, consolidating historical 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.

On March 30, 2004, we made an investment in BioCardia, Inc. Under the terms of the investment documents, we (i) will assist BioCardia in exploring opportunities for developing devices for the surgical delivery of biotherapeutics, (ii) have limited exclusive rights to negotiate the distribution, licensing or purchase of surgical delivery technology developed by BioCardia and (iii) through an observational board seat, subject to BioCardia s authorization will be able to review relevant clinical data accumulated by BioCardia through its multiple trials. We have accounted for this investment on the cost basis as we do not have the ability to exercise significant influence over BioCardia s operating and financial policies. This investment is included on our consolidated balance sheet in other long-term assets.

Table of Contents

3. Investments

Short-term investments consist of available-for-sale securities that are carried at fair value and generally mature or reset interest rates between three months and two years from the purchase date. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature and because such marketable securities represent the investment of cash that is available for current operations. Investments that are not intended for use in current operations are classified as long-term investments. We include any unrealized gains and losses on short-term investments, net of tax, in shareholders equity as a component of other comprehensive income.

As required by the terms of the convertible notes during the second quarter of 2004 (See Note 8) we purchased an aggregate of $9.8 million in U.S. government securities that were pledged to the trustee under the indenture. These funds are for the exclusive benefit of the holders of the convertible notes to provide for the payment, in full, of the first six semi-annual interest payments. The investments that relate to interest payments due within one year have been classified as restricted short-term investments and the investments that relate to interest payments due after one year have been classified as restricted long-term investments.

Individual securities with a fair value below the costs basis at January 1, 2005 were evaluated to determine if they were other-than-temporarily impaired. These securities were determined to be only temporarily impaired because the decline in value was related entirely to changes in market interest rates. No securities have been in a continuous loss position for 12 months or longer.

The aggregate market value, cost basis and gross unrealized gains and losses of short-term and long-term available-for-sale investments and restricted short-term and long-term investments for 2004 and 2003 by major security type are as follows (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
As of Fiscal Year 2004 Short-term investments:				
Corporate bonds	$ 24,435	$	$ (118)	$ 24,317
Municipal bonds and auction rate securities	92,300	1	(149)	92,152
U.S. government obligations	13,500		(126)	13,374
Restricted investments in U.S. Government obligations	3,375		(13)	3,362
	133,610	1	(406)	133,205
Long-term investments:				
Restricted Investments in U.S. Government obligations	4,862		(17)	4,845
	$ 138,472	$ 1	$ (423)	$ 138,050
As of Fiscal Year 2003 Short-term investments:				
Municipal bonds and auction rate securities	$ 43,750	$	$	$ 43,750
	43,750			$ 43,750

Long-term investments:

Corporate bonds	$ 37,095	$ 105	$ (19)	$ 37,181
US government obligations	4,000		(2)	3,998
	$ 84,845	$ 105	$ (21)	$ 84,929

The contractual maturities of available-for-sale investments and restricted investments as of January 1, 2005 and January 3, 2004, regardless of the consolidated balance sheet classifications, are as follows (in thousands):

	Amortized Cost	**Fair Value**
As of Fiscal Year 2004:		
Due within one year	$ 91,301	$ 91,126
Due after one year through two years	45,583	45,337
Due after two years through three years	1,588	1,587
	$ 138,472	$ 138,050
As of Fiscal Year 2003:		
Due within one year	$ 67,540	$ 67,626
Due after one year through two years	17,305	17,303
	$ 84,845	$ 84,929

Table of Contents

The cost of available-for-sale investments and restricted investments that are sold is based on specific identification in determining recorded realized gains and losses. In 2004 and 2003 there were no significant gains or losses recorded.

4. Inventories

Inventories consist of the following (in thousands):

	As of Fiscal Year	
	2004	**2003**
Finished goods	$ 18,562	$ 15,504
Work-in-process	4,582	9,089
Raw materials	15,997	11,824
Total	$ 39,141	$ 36,417

5. Purchased Intangible Assets and Goodwill

The change in the carrying amount of goodwill, which is only attributable to our Cardiovascular business segment, for fiscal years 2004 and 2003 was as follows (in thousands):

	As of Fiscal Years	
	2004	**2003**
Balance at the beginning of year	$ 96,065	$ 96,492
Adjustment to reflect realization of acquired deferred tax asset	(1,153)	(427)
Reversal of accrual for securities registration costs	(815)	
Balance as of January 1, 2005	$ 94,097	$ 96,065

In 2003 and again in 2004, 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.

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

The components of 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 2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and Trademarks	$ 37,815	$ (14,051)	$ 23,764
CoreTechnology	37,485	(7,242)	30,243
Developed Technology	122,782	(23,721)	99,061
Non-compete Agreement	90	(17)	73
Total Purchased Intangible Assets	$ 198,172	$ (45,031)	$ 153,141

	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

Table of Contents

Subsequent to year-end 2003, the Company completed its assessment of the final results from its feasibility clinical trial for the Aria CABG graft which was ongoing through fiscal 2003. Based on the clinical trial results, the Company determined that it would not devote additional resources to the development of the Aria graft. Upon the decision to discontinue product development, the Company recorded an impairment charge of $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. 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 2004, 2003, and 2002 was $11.7 million, $12.3 million and $12.4 million, respectively. Patents and trademarks have useful lives of eight to twenty years, core technology assets have useful lives ranging from nine to twenty years, developed technology have a useful life range of nine to twenty years and the useful life of the non-compete agreement is approximately six years.

6. Property, Plant and Equipment

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

	As of Fiscal Year	
	2004	**2003**
Land	$ 341	$ 341
Building	2,445	2,445
Building lease	2,285	2,285
Equipment	38,728	34,606
Rental equipment	6,810	6,493
Leasehold improvements	11,061	11,853
Total	61,670	58,023
Accumulated depreciation and amortization	(34,086)	(29,531)
	$ 27,584	$ 28,492

Depreciation expense in 2004, 2003, and 2002 was $7.1 million, $5.7 million and $5.2 million, respectively.

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 2004 are noted below (in thousands):

Fiscal year:	
2005	$ 2,463
2006	2,453

2007	2,432
2008	2,257
2009	1,849
Thereafter	8,032
Total	$ 19,486

Rent expense for all operating leases was $2.5 million in 2004, $2.1 million in 2003 and $1.8 million in 2002.

Commitments

We had various purchase order commitments, which were comprised of supply agreements, totaling approximately $19.8 million and $10.2 million as of the end of fiscal years 2004 and 2003, respectively.

Contingencies

We are involved in various litigation matters (See Note 14).

Table of Contents

8. Long-Term Debt

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

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

The deferred debt issuance costs of $4.3 million are included in other assets on the consolidated balance sheet. The deferred debt issuance costs are amortized on a straight line basis until May 2011 at which point the Company can redeem the debt. These charges are included in Interest expense on our consolidated statements of operations.

	Fiscal Year 2004 (in millions)
Long Term Debt Offering Proceeds:	
Principal amount of convertible notes at maturity	$ 247.4
Original issue discount	(103.7)
Debt issuance costs	(4.3)
Net proceeds	$ 139.4

Holders of the convertible notes may convert their convertible notes into shares of our common stock at a conversion rate of 29.4652 shares per $1,000 principal amount of convertible notes, which represents a conversion price of $19.72 per share, subject to adjustments upon the occurrence of certain events. Holders were able to convert their convertible notes at any point after the close of business on September 30, 2004 if, as of the last day preceding the calendar quarter, the closing price of our common stock for at least 20 trading days in a period of 30 consecutive trading days ending on the last trading day of such preceding calendar quarter is more then 120% of the accreted conversion price per share of our common stock. Holders may surrender their convertible notes on or prior to May 16, 2029 during the five business day period after any five consecutive trading day period in which the trading price per note for each day of that period was less than 98% of the product of the closing sale price of our common stock and the conversion rate on each such day; provided that if on the day prior to any conversion the closing sale price of our common stock is greater than the accreted conversion price but less than or equal to 120% of the accreted conversion price, then holders will receive upon conversion, in lieu of shares of common stock based on the conversion rate, cash or common stock, or a combination of cash and common stock, at our option, with a value equal to the accreted

principal amount of the notes plus accrued but unpaid interest as of the conversion date. Additionally, holders may convert their convertible notes if we call them for redemption or if specified corporate transactions or significant distributions to holders of our stock have occurred. As of the year ended January 1, 2005 no notes have been converted or called.

Holders may require us to repurchase all or a portion of their convertible notes on each of May 16, 2011, 2014, 2019, 2024 and 2029 at a repurchase price equal to 100% of the issue price, plus accrued original issue discount, if any. In addition, if we experience a change in control or a termination of trading each holder may require us to purchase all or a portion of such holder s notes at the same price, plus, in certain circumstances, a make whole premium. The fair value of the make whole premium at January 1, 2005 was zero. We may redeem any of the convertible notes at any time beginning May 16, 2011, by giving the holders at least 30 days notice, either in whole or in part at a redemption price equal to the sum of the issue price and the accrued original issue discount, plus accrued and unpaid interest and liquidation damages, if any.

Table of Contents

The convertible notes are subordinated to all of our senior indebtedness and structurally subordinated to all indebtedness of our subsidiaries. Therefore, in the event of a bankruptcy, liquidation or dissolution of us or one or more of our subsidiaries and acceleration of or payment default on our senior indebtedness, holders of the convertible notes will not receive any payment until holders of any senior indebtedness we may have outstanding have been paid in full.

The aggregate fair value of the convertible notes at January 1, 2005, based on market quotes, was $126.0 million.

On March 11, 2002, we completed the redemption of then outstanding subordinated convertible debentures using restricted cash, cash and cash equivalents of approximately $54.8 million. A loss in the amount of $0.5 million and a tax benefit of $0.2 million 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.

9. Common and Preferred Stock

We have authorized 100 million no par common shares, and 2.5 million 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 1, 2005, 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 1, 2005, 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.

In 2002, we sold 1.1 million newly issued shares of our common stock for $15.3 million, net of underwriting discounts, fees and other expenses of the offering.

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 $4.1 million, 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 $0.3 million, was recorded as deferred compensation and was being amortized over the restriction lapse period. The second award was forfeited in December 2004 upon the resignation of the executive officer and the previously recognized amortization of deferred compensation of $0.2 million was reversed. In addition 25,000 shares were granted as a consultant award in December 2004. This award was valued at $0.2 million and amortizes over the restriction lapse period of three years. As of the end of fiscal 2004, none of the restrictions on the remaining 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 2004, 2003, or 2002. 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 2004 or 2003.

In 1996, the Board of 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 2004 and 2003 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 52,500 and 61,875 options granted in 2004 and 2003, respectively, at fair market value under the Directors Option Plan.

In 1997, the Board of 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 13.7 million shares of stock in the form of stock options, restricted stock awards, and stock bonuses. During 2004 and 2003, 3.1 million and 2.2 million options, respectively, were granted at fair market value under this plan. During 2004 and 2003, 25,000 shares and no shares, respectively, were granted as restricted stock awards, noted above, under this plan.

We have four common stock option plans with options still outstanding at January 1, 2005. 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 2004, options to purchase 1.8 million 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 2001 (2,615 exercisable at $9.99 weighted average price per share)	5,585	$ 10.51
Granted ($7.19 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
Granted ($5.72 weighted average fair value per share)	3,140	12.33
Cancelled and expired	(752)	13.53
Exercised	(266)	8.99
Outstanding at fiscal year end 2004 (5,111 exercisable at $11.38 weighted average price per share)	10,276	$ 11.97

Options outstanding as of the end of 2004 are summarized as follows:

	Options Outstanding			Options Exercisable	
Exercise Price Range	Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number Outstanding	Weighted Average Exercise Price
$4.38 $5.60	344,286	3.69	5.23	316,540	5.19
5.75 6.38	526,559	5.65	5.99	405,749	6.05
6.40 9.25	1,187,542	6.25	8.39	749,617	8.30
9.25 11.80	1,979,107	6.29	9.89	1,391,547	9.88
11.85 - 14.40	3,736,476	8.86	12.88	793,954	13.02
14.42 - 17.60	2,322,554	6.99	15.73	1,310,800	15.68
17.63 - 20.85	141,216	5.57	18.78	103,968	18.84
29.92 - 33.05	38,389	3.29	31.98	38,389	31.98

$4.38 - $33.05	10,276,129	7.24	11.97	5,110,564	11.38

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 2004. 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 147,000 shares of common stock were issued in 2004 for $1.4 million. Approximately 123,000 shares of common stock were issued in 2003 for $1.1 million. As of the end of fiscal year 2004, approximately 230,000 shares are available for issuance under this plan.

11. Taxes on Income

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

	For Fiscal Year Ended		
	2004	**2003**	**2002**
Current:			
Federal	$ 401	$ 232	$ 661
State	529	873	1,103
Foreign	1,126	13	14
	2,056	1,118	1,778

Table of Contents

	For Fiscal Year Ended		
	2004	2003	2002
Deferred:			
Federal	(112)	(2,175)	(930)
State	(818)	(764)	(465)
Foreign		427	
	(930)	(2,512)	(1,395)
Total income tax provision (benefit)	$ 1,126	$ (1,394)	$ 383

The domestic and foreign components of income (loss) before income taxes are as follows (in thousands):

	For the Fiscal Years ended		
	2004	2003	2002
Domestic	$ 1,470	$ (5,123)	$ 576
Foreign	3,220	1,547	318
Income (loss) before income taxes	$ 4,690	$ (3,576)	$ 894

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 (loss) before taxes due to the following (in thousands):

	For Fiscal Year Ended					
	2004		2003		2002	
U.S. federal statutory income tax expense (benefit)	$ 1,641	35.0%	$ (1,251)	35.0%	$ 313	35.0%
State income tax expense (benefit), net of federal tax expense (benefit)	(5)	(.1)	(126)	3.5	177	19.8
Non-deductible expenses	547	11.5	398	(11.0)	191	21.3
Research and development and other credits	(798)	(16.9)	(343)	9.5	(452)	(50.5)
Expiration of net operating losses					154	17.2
Foreign earnings permanently reinvested			(72)	2.0		
Tax advantaged investment income	(259)	(5.5)				
	$ 1,126	24.0%	$ (1,394)	39.0%	$ 383	42.8%

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	
	2004	2003
Deferred tax assets:		
Write-off of acquired technology	$ 913	$ 1,043
Reserves and accruals	2,463	2,265
Depreciation and amortization	842	368
Inventory basis difference	2,627	2,621
Research and development credit carryforwards	3,830	2,324
Net operating loss carryovers	2,107	5,570
Other, net	69	322
Total deferred tax assets	12,851	14,513
Deferred tax liabilities:		
Purchased intangibles	(60,971)	(65,845)
Depreciation and amortization	(1,046)	
Net deferred tax liabilities	$ (49,154)	$ (51,332)

Foreign earnings were considered to be permanently invested in operations outside the United States through 2004, except for those earnings required to be allocated to Subpart F income.

At the end of 2004, we had federal and state net operating loss (NOL) carryforwards of approximately $6.0 million and $2.0 million, respectively. If not utilized, the federal NOL will expire in 2021.

Acquired foreign NOL S, were fully utilized in 2004 and treated as a post acquisition purchase price adjustment.

Table of Contents

At the end of 2004, we had available carryforward research and experimentation tax credits for federal and state income tax purposes of approximately $2.8 million and $1.4 million, respectively. Federal tax credit carryforwards expire from 2007 through 2024. State tax credits carry forward indefinitely.

The federal and state provisions do not reflect the tax savings resulting from reductions associated with our various stock option plans. These savings were $.5 million, $2.1 million and $0.3 million in 2004, 2003 and 2002, respectively.

We are currently under examination by the State of New Jersey for the years 1997 through 2000. Although the ultimate outcome of this examination is unknown, we believe that adequate amounts have been provided for any adjustments that may result from the current examination and that the final outcomes will not have a material adverse affect on company s results of operations.

We have provided adequate amounts for anticipated tax audit adjustments in the U.S., state and other foreign tax jurisdictions based on our estimate of whether, and the extent to which, additional taxes and interest may be due. If events occur which indicate payment of these amounts are unnecessary, the reversal of the liabilities would result in tax benefits being recognized in the period when we determine the liabilities are no longer necessary. If our estimate of tax liabilities proves to be less than the ultimate assessment, a further charge to expense would result.

12. 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.

Business segments (in thousands):

	For the Fiscal Years Ended		
	2004	**2003**	**2002**
Product sales:			
Cardiovascular	$ 103,002	$ 94,382	$ 84,442
ITC	69,339	55,534	46,402
Total product sales	$ 172,341	$ 149,916	$ 130,844
Income (loss) before taxes:			
Cardiovascular(a)	$ 2,129	$ 1,315	$ (3,992)
ITC(a)	9,940	10,542	9,680
Corporate (b)	(6,362)	(5,931)	(5,016)
In-process research and development		(220)	
Impairment of intangible asset		(8,987)	
Litigation, merger, restructuring and other costs (c)	(733)	(2,132)	(1,409)
Total operating loss	4,974	(5,413)	(737)
Other income and (expense):			
Interest expense	(2,460)		(544)
Interest income and other	2,176	1,837	2,175

Total income (loss) before taxes	$ 4,690	$ (3,576)	$ 894
Total assets:			
Cardiovascular	$ 314,636	$ 326,872	$ 352,008
ITC	38,437	31,546	23,464
Corporate (b)	171,342	117,713	92,960
Total assets	$ 524,415	$ 476,131	$ 468,432
Depreciation and amortization:			
Cardiovascular	$ 16,854	$ 18,797	$ 17,150
ITC	1,928	1,222	1,074
Total depreciation and amortization	$ 18,782	$ 20,019	$ 18,224
Capital expenditures:			
Cardiovascular	$ 3,734	$ 4,785	$ 6,321
ITC(d)	2,477	4,634	1,207
Total capital expenditures	$ 6,211	$ 9,419	$ 7,528

(a) Amortization expense of $11.6 million, $12.3 million and $12.4 million for the fiscal years ended 2004, 2003 and 2002 respectively, related to the Cardiovascular segment. The ITC segment had amortization expense of

Table of Contents

$0.2 million, $44,000, and none for the fiscal years ended 2004, 2003 and 2002 respectively.

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

(c) In 2004, relates to expenses not specifically identified to any particular business segment. In 2003 and 2002, this amount related solely to the Cardiovascular segment.

(d) ITC capital expenditures in 2003 include $2.5 million of property, plant and equipment acquired through our acquisition of the IRMA product line.

Geographic Areas (in thousands):

	For the Fiscal Years Ended		
	2004	**2003**	**2002**
Product Sales:			
Domestic	$ 133,081	$ 121,831	$ 106,983
International	39,260	28,085	23,861
Total	$ 172,341	$ 149,916	$ 130,844

13. Retirement Savings Plan

Substantially all of our full-time employees are eligible to participate in a 401(k) retirement 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 2004, 2003 and 2002, our matching contribution 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 2004, 2003 and 2002, we made contributions to the Retirement Plan of approximately $0.9 million, $0.8 million and $0.8 million, respectively.

In 2004, we established a non-qualified, unfunded compensation plan for certain management employees and our Board of Directors. Amounts deferred and contributed under the deferred compensation plan (DCP) are credited or charged with the performance of investment options offered under the plan and elected by the participants. The liability for compensation deferred under this plan was $0.3 million and none at January 1, 2005 and January 3, 2004, respectively and is included in Long-term deferred tax liability and Other . We manage the risk of changes in the fair value of the liability for deferred compensation by electing to match our liability under the plan with an investment vehicle that offsets a substantial portion of the company s exposure. The cash value of the investment vehicle, which includes funding for future deferrals, was $1.0 million and $0.4 million at January 1, 2005 and January 3, 2004, respectively and is included in Other Assets .

14. Litigation, Merger, Restructuring and Other Costs

Litigation, merger, restructuring and other costs are comprised of (in thousands):

	For the Fiscal Years Ended		
	2004	**2003**	**2002**
Litigation	$ 733	$ 2,256	$

Merger			356
Restructuring and other		(124)	1,053
Total	$ 733	$ 2,132	$ 1,409

Litigation

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

In June of 2004, MicroMed Technology, Inc., a competitor, sued us in Texas. MicroMed sought injunctive relief against us in connection with our HeartMate II Phase I clinical trial on the grounds that we had provided the HeartMate II VAD to clinical sites without charge and that doing so was a violation of Texas anti-trust law. In

Table of Contents

addition to injunctive relief, the plaintiff is seeking unspecified damages and fees, including those arising from potential sales of its VAD products which plaintiff alleges it lost due to our HeartMate II clinical trial. We have successfully defended ourselves against MicroMed s requests for injunctive relief, believe MicroMed s claims are without merit, and will continue to vigorously defend any and all of the claims made by MicroMed in this action.

Commencing on or about August 3, 2004, several putative securities law class action suits were filed in the United States District Court for the Northern District of California on behalf of purchasers of the publicly traded securities of the Company between April 28, 2004 and June 29, 2004. These suits were consolidated in a consolidated complaint filed on or about January 18, 2005. The complaint generally alleges violations of the Securities Exchange Act of 1934 by us, our Chief Executive Officer, our former Chief Financial Officer and the President of our cardiovascular division based upon, among other things, alleged false statements about the Company s expected sales and the market for HeartMate as a Destination Therapy treatment. The complaint seeks to recover unspecified damages on behalf of all purchasers of our publicly traded securities during the class period.

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

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

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

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

Merger Costs

Merger costs recorded during 2002 consisted principally of employee severance, pre-merger employee retention costs, and outside consulting, accounting and legal expenses associated with the TCA merger.

Restructuring Costs and Other

We completed consolidation of our VAD manufacturing operations in the second quarter of 2003. Total costs related to this consolidation were $1.5 million. Following is a summary of restructuring cost activity relating to the consolidation for 2003 (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

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.

15. Earnings (Loss) Per Share

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.

Table of Contents

Options to purchase 6.2 million, 3.3 million and 4.2 million shares of common stock were not included in the computation of diluted earnings and losses per share for 2004, 2003 and 2002, respectively, as their inclusion would be antidilutive. In addition, the computation of diluted earnings per share for 2004 excludes the effect of assuming the conversion of our convertible notes, which are convertible at $19.72 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):

	2004	2003	2002
Net income (loss)	$ 3,564	$ (2,182)	$ 511
Weighted average number of common shares-Basic	52,187	55,583	56,184
Dilutive effect of stock-based compensation plans	973		578
Weighted average number of common shares-Diluted	53,160	55,583	56,762
Basic and diluted earnings (loss) per common share	$ 0.07	$ (0.04)	$ 0.01

16. Quarterly Results of Operations (Unaudited)

The following is a summary of our unaudited quarterly results of operations for fiscal years 2004 and 2003:

	First	Second	Third	Fourth
	(In thousands, except per share data)			
Fiscal Year 2004 Product sales	$ 42,792	$ 40,603	$ 40,661	$ 48,285
Gross profit	25,071	24,289	23,015	27,847
Net income (loss)	1,294	207	(398)	2,461
Basic and diluted earnings (loss) per share	$ 0.02	$ 0.00	$ (0.01)	$ 0.05
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)

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.

Table of Contents

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

None.

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

Attached as exhibits to this Form 10-K are certifications of our Chief Executive Officer and principal financial officer, which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended. This Controls and Procedures section includes information concerning the controls and controls evaluation referred to in the certifications. Item 8 of this Form 10-K sets forth the report of Deloitte & Touche LLP, our independent registered public accounting firm, regarding its audit of our internal control over financial reporting and of management s assessment of internal control over financial reporting. This section should be read in conjunction with the certifications and the Deloitte & Touche LLP report for a more complete understanding of the topics presented .

Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of January 1, 2005. The evaluation of our disclosure controls and procedures included a review of our processes and implementation and the effect on the information generated for use in this Annual Report on Form 10-K. In the course of this evaluation, we sought to identify any significant deficiencies or material weaknesses in our disclosure controls and procedures, to determine whether we had identified any acts of fraud involving personnel who have a significant role in our disclosure controls and procedures, and to confirm that any necessary corrective action, including process improvements, was taken. This type of evaluation is done quarterly so that our conclusions concerning the effectiveness of these controls can be reported in our periodic reports filed with the SEC. The overall goals of these evaluation activities are to monitor our disclosure controls and procedures and to make modifications as necessary. We intend to maintain these disclosure controls and procedures, modifying them as circumstances warrant.

Based on that evaluation, our management, including the Chief Executive Officer and principal financial officer, concluded that as of January 1, 2005 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.

Changes to Internal Controls

Prior to year end 2004, as part of the implementation of the Section 404 of the Sarbanes Oxley Act, the Company instituted internal controls which were designed to and did detect the situation which resulted in the restatement of the pro forma stock compensation fair value disclosures for the years ended January 3, 2004 and December 28, 2002. Management concluded that the control deficiency which resulted in the restatement was not indicative of a material weakness in internal controls as of January 1, 2005. There have been no other changes in our internal controls over financial reporting during the fiscal year ended January 1, 2005 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive Officer and the principal financial officer, does not expect that 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. As these inherent limitations are known features of the financial reporting process it is possible to design into the process safeguards to reduce, though not eliminate, these risks. 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

Table of Contents

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.

Item 9B. Other Information

None.

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 herein 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 2005 annual meeting of stockholders.

Item 11. *Executive Compensation*

The information required by Item 11 is incorporated herein 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 2005 annual meeting of stockholders.

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

The information required by Item 12 is incorporated herein 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 2005 annual meeting of stockholders.

Item 13. *Certain Relationships and Related Transactions*

The information required by Item 13 is incorporated herein 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 2005 annual meeting of stockholders.

Item 14. *Principal Accountant Fees and Services*

The information required by Item 14 is incorporated herein 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 2005 annual meeting of stockholders.

Table of Contents

PART IV

Item 15. ***Exhibit and Financial Statement Schedules***

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

1. Financial Statements and Reports of Independent Registered Public Accounting Firm.

   Reference is made to the Index to Financial Statements under Item 8 of Part II of this Annual Report on Form 10-K, 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 1, 2005, January 3, 2004 and December 28, 2002.

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

3. Exhibits

   Reference is made to the Exhibit Index on page 75 of this Annual Report, where these documents are included.

Table of Contents

THORATEC CORPORATION AND SUBSIDIARIES

SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS AND RESERVES
For Each of the Three Fiscal Years for the Period Ended January 1, 2005

	Balance Beginning of Year	Additions (charges to expense)	Deductions	Balance End of Year
		(In thousands)		
Year Ended January 1, 2005:				
Allowance for doubtful accounts	$ 486	$ 417	$ (195)(1)	$ 708
Accrued product warranty	$ 829	$ 173	$ (384)(2)	$ 618
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

(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 February 25, 2005. (2)
4.1	Rights Agreement between Thoratec Corporation and Computershare Trust Company, Inc. as Rights Agent dated as of May 2, 2002.(3)
4.2	Indenture, dated as of May 24, 2004, by and between Thoratec Corporation and U.S. Bank, National Association, as Trustee. (4)
4.3	Form of Senior Subordinated Convertible Note due 2034. (5)
4.4	Pledge Agreement, dated as of May 24, 2004, between Thoratec Corporation and U.S. Bank, National Association, and Pledge Agreement Supplement, dated as of June 7, 2004. (4)
4.5	Control Agreement, dated as of May 24, 2004, between Thoratec Corporation and U.S. Bank, National Association, and Control Agreement Amendment, dated as of June 7, 2004.(4)
4.6	Registration Rights Agreement, dated May 24, 2004, by and among Thoratec Corporation and Merrill Lynch Pierce Fenner & Smith Incorporated as Initial Purchaser of the Senior Subordinated Convertible Notes due 2034. (4)
10.1	Thoratec s 1984 Incentive Stock Option Plan, as amended.(6)
10.2	Intellectual Property Cross-license Agreement between Thermedics and the Thoratec Cardiosystems dated August 19, 1988.(7)
10.3	Form of Indemnification Agreement between Thoratec Cardiosystems and its officers and directors.(7)
10.4	Thoratec s 1993 Stock Option Plan.(8)
10.5	Agreement dated May 26, 1993, between The Polymer Technology Group Incorporated and the Thoratec Cardiosystems.(9)
10.6	Thoratec s 1996 Stock Option Plan.(10)
10.7	Thoratec s 1996 Nonemployee Directors Stock Option Plan, as amended. (11)
10.8	Lease Agreement dated July 25, 1996, between Main Street Associates and Thoratec, as amended.(12)
10.9	First Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(13)
10.10	Second Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(14)

10.11	Thoratec s 1997 Stock Option Plan, as amended.(15)
10.12	Amended and Restated Directors Stock Option Plan of Thoratec Cardiosystems.(16)
10.13	Amended and Restated Nonqualified Stock Option Plan of Thoratec Cardiosystems.(16)
10.14	Agreement and Plan of Merger by and among Thoratec, Lightning Acquisition Corporation, Thermo Cardiosystems Inc, and Thermo Electron Corporation dated October 3, 2000.(17)
10.15	Registration Rights Agreement by and between Thoratec and Thermo Electron dated October 3, 2000.(17)
10.16	Shareholder Agreement by and between Thoratec and Thermo Electron dated October 3, 2000.(17)
10.17	Lease agreement dated August 16, 1995, between International Technidyne Corporation and BHBMC, as amended.(18)
10.18	Employment Agreement by and between Thoratec and D. Keith Grossman, amended as of December 6, 2001.(18)
10.19	Thoratec s 2002 Employee Stock Purchase Plan.(19)
10.20	Form of Separation Benefits Agreement between Thoratec and its executive officers.
10.21	Thoratec s Deferred Compensation Plan effective as of January 1, 2004. (11)
10.22	Grantor Trust Agreement between Thoratec and Wachovia Bank, National Association effective as of November 21, 2003.(11)

Table of Contents

Exhibit Number	Exhibit
10.24	Commercial Lease between International Technidyne Corporation and Roseville Properties Management Company dated September 26, 2003. (11)
10.25	Lease Agreement between International Technidyne Corporation and NJ Mortgage Association dated February 21, 2003. (20)
10.26	Separation Agreement and Release between M. Wayne Boylston and Thoratec, entered into on December 17, 2004. (21)
10.27	Consulting Services Agreement between M. Wayne Boylston and Thoratec, entered into on December 17, 2004. (21)
10.28	Amended and Restated Thoratec Corporation Restricted Stock Grant Agreement between M. Wayne Boylston and Thoratec, entered into on December 17, 2004. (21)
10.29	Description of the Executive Disability Income Protection Program.
21	Subsidiaries of Thoratec.(18)
23.1	Consent of Independent Registered Public Accounting Firm Deloitte & Touche LLP.
24	Power of Attorney Reference is made to page 79 hereof.
31.1	Section 302 Certification of Chief Executive Officer
31.2	Section 302 Certification of principal financial officer
32.1	Section 906 Certification of Chief Executive Officer
32.2	Section 906 Certification of principal 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-K filed with the SEC on March 3, 2005.

(3) 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.

(4) Filed as an Exhibit to Thoratec s Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 2004 filed with the SEC on August 12, 2004, and incorporated herein by reference.

(5) Included as an exhibit to Exhibit 4.2.

(6) 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.

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

(8) Filed as an Exhibit to Thoratec s Annual Report on Form 10-K for the fiscal year ended January 1, 1994 filed with the SEC on March 22, 1994, and incorporated herein by reference.

(9) 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.

(10) 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.

(11) Filed as an Exhibit to Thoratec s Annual Report on Form 10-K for the fiscal year ended January 3, 2004 filed with the SEC on March 17, 2004 and incorporated herein by reference.

Table of Contents

(12) 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.

(13) 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.

(14) 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.

(15) 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.

(16) Filed as an Exhibit to Thoratec Cardiosystems Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 1999 filed with the SEC on August 5, 1999, and incorporated herein by reference.

(17) 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.

(18) 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.

(19) 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.

(20) Filed as an Exhibit to Thoratec s Quarterly Report on Form 10-Q for the fiscal quarter ended March 29, 2003 filed with the SEC on May 13, 2003, and incorporated herein by reference.

(21) Filed as an Exhibit to Thoratec s Form 8-K filed with the SEC on December 20, 2004.

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 16th day of March 2005.

THORATEC CORPORATION

By: /s/ D. KEITH GROSSMAN

D. Keith Grossman
Chief Executive Officer

Date: March 16, 2005

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each person whose signature appears below constitutes and appoints D. Keith Grossman and David Lehman, 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 virtue 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 16, 2005
/s/ JEFFREY M. McCORMICK Jeffrey M. McCormick	Corporate Controller, (principal financial and accounting officer)	March 16, 2005
/s/ J. DONALD HILL J. Donald Hill	Director and Chairman of the Board of Directors	March 16, 2005
/s/ HOWARD E. CHASE Howard E. Chase	Director	March 16, 2005
/s/ J. DANIEL COLE J. Daniel Cole	Director	March 16, 2005

/s/ NEIL F. DIMICK Neil F. Dimick	Director	March 16, 2005
/s/ WILLIAM M. HITCHCOCK William M. Hitchcock	Director	March 16, 2005
/s/ GEORGE W. HOLBROOK, JR. George W. Holbrook, Jr.	Director	March 16, 2005
/s/ DANIEL M. MULVENA Daniel M. Mulvena	Director	March 16, 2005