

THORATEC CORP  
Form 10-K  
March 16, 2006

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
Form 10-K**

**(Mark one)**

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

**For the fiscal year ended December 31, 2005**

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from      to      .**

**Commission file number: 1-8145**

**Thoratec Corporation**

*(Exact Name of Registrant as Specified in Its Charter)*

**California**

*(State or Other Jurisdiction of  
Incorporation or Organization)*

**94-2340464**

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

**6035 Stoneridge Drive, Pleasanton, California**

*(Address of Principal Executive Offices)*

**94588**

*(Zip Code)*

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

**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 if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by a check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

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

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

Indicate by a check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one): Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Indicate by a check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12(b)-2) Yes ☐ No ☒

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, 2005, the last business day of the Registrant's second fiscal quarter, as listed on The Nasdaq National Stock Market was \$739,742,359.

As of March 10, 2006, registrant had 52,319,017 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

## Edgar Filing: THORATEC CORP - Form 10-K

Designated portions of Thoratec's definitive proxy statement for its 2006 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

Thoratec, the Thoratec logo, Thoralon, TLC-II, HeartMate and *Vectra* are registered trademarks of Thoratec Corporation, and Heart Hope, HeartMate II 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.

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**PART I**

**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, as amended. These statements can be identified by the words expects, projects, hopes, believes, intends, should, estimate, will, would, may, anticipates, plans, could, or may. Actual results, events or performance 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. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the Risk Factors section of this Annual Report and in other documents we file with the Securities and Exchange Commission. 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.

**Item 1. Business**

**OVERVIEW**

Thoratec Corporation ( we, our, us, the Company ) is a leading manufacturer of circulatory support products for the treatment of heart failure, or HF. We sell Ventricular Assist Devices, or VADs, our primary product, to leading heart transplant centers throughout the world and account for three out of the four VADs approved by the U.S. Food and Drug Administration, or FDA, as a bridge to heart transplant for adults and are commercially marketed. These devices are used for the temporary support of adult patients awaiting a heart transplant and as the only FDA-approved ventricular assist device approved for permanent implant, or Destination Therapy. We also are a leading provider of point-of-care and incision blood diagnostic test systems.

Incorporated in the state of California in 1976, Thoratec Corporation trades on the NASDAQ under the ticker symbol THOR and is headquartered in Pleasanton, California.

Our business is comprised of two operating divisions: Cardiovascular and International Technidyne Corporation, or ITC, a wholly owned subsidiary.

The product line within the Cardiovascular segment is:

*Circulatory Support Products.* Our circulatory support products include VADs for the short, intermediate, and long-term treatment of advanced HF. In addition, we have developed small diameter grafts using our proprietary materials to address the vascular access market. Our grafts are sold in the U.S. and internationally for use in hemodialysis.

The product lines within the ITC segment are:

*Point-of-Care Diagnostics.* Our point-of-care products, or POC, include coagulation diagnostic test systems that monitor a patient in a variety of clinical settings during the administration of certain anticoagulants, and blood gas/electrolyte/chemistry products that monitor patients in a variety of clinical settings.

*Incision.* Our incision products include devices to obtain patients' blood samples for diagnostic testing and screening for platelet function.

Heart failure is a disorder in which the heart loses its ability to pump blood efficiently. This condition may affect the right side, the left side or both sides of the heart, depriving many organs, including the kidneys and liver, of adequate oxygen and nutrients. This damages these organs and reduces their ability to function properly. Approximately 23 million people worldwide suffer from HF, with two million new cases of HF diagnosed each year worldwide. In the U.S., according to the American Heart Association, or AHA, nearly five million patients suffer from HF and an additional 550,000 patients are diagnosed with the condition annually. In contrast to other cardiovascular disorders, many of which have actually declined in the past few decades, the incidence of heart failure ranks as the most rapidly growing cardiovascular disorder in the U.S. Our VADs provide hemodynamic restoration therapy, which supports the performance of the heart and restores blood flow to adequately meet the needs of vital organs.

Our VADs have been clinically proven to improve patient survival and quality of life. We currently offer the widest range of products to serve this market, including VADs for short, intermediate and long-term support, as well as devices that are FDA-

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approved as a bridge-to-transplantation, for Destination Therapy and/or postcardiotomy myocardial recovery. 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 heart failure market.

We currently market VADs that may be implanted or worn outside the body, can be used for left, right or biventricular support and that are suitable for treatments for different durations for patients of varying sizes and ages. We estimate that doctors have implanted more than 10,000 of our devices, primarily for patients awaiting a heart transplant or those who require permanent support. On November 6, 2002, the FDA approved the HeartMate VE as the first heart assist device for Destination Therapy, or permanent support for patients suffering from late-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 VE, for Destination Therapy. Thoratec is the only company to offer a VAD approved by the FDA for Destination Therapy and marks the first time a VAD has been approved as a permanent treatment for late-stage heart failure patients who do not qualify for heart transplants because of 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 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 covering reimbursement for the use of a Left Ventricular Assist System 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, or DRG 103, to raise the average payment for CMS Destination Therapy-certified Centers 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.

Several private payors have also issued positive coverage decisions. The majority of local Blue Cross and Blue Shield plans have created positive medical policy for both bridge-to-transplantation and long-term therapy indications. Since December 2002, the majority of national insurance carriers, including Aetna, Cigna, Humana, United Health Group and UNICARE, have issued positive coverage policies to cover the use of ventricular assist devices for FDA-approved indications, including Destination Therapy.

**OUR MARKETS****CARDIOVASCULAR SEGMENT*****Circulatory Support and Graft Products***

The primary markets for our VAD products serve those patients suffering from late stage HF. Late-stage HF 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. The condition can be caused by artery or valve diseases or a general weakening of the heart muscle itself. Other conditions, such as high blood pressure or diabetes, also can lead to HF.

According to estimates by the AHA, 5 million patients suffer from HF in the U.S. and approximately 550,000 new cases are diagnosed each year. The AHA also estimates that approximately 80% of men and 70% of women HF patients under age 65 will die within eight years of diagnosis. While the number of treatment options for earlier stage HF has increased in recent years, 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 HF through drug therapy, the only curative treatment for the disease is 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 one. The United Network for Organ Sharing reported that there were only 2,096 hearts available for transplant in the U.S. in 2004. At any given time, approximately 4,000 patients are 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 is approximately nine months; many patients have to wait as long as two years. In 2002,

approximately 15% of these patients died while waiting for a donor heart.

In the U.S., there are currently two FDA-approved indications for the long-term use of VADs in patients with HF: as a bridge to heart transplant and as Destination Therapy. We are currently pursuing an additional indication for our Thoratec VAD products: therapeutic recovery of the heart. Beyond the HF markets, VADs are also approved for use during recovery following cardiac surgery. All four indications are summarized below.



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***Bridge-to-Transplantation*** Ventricular assist devices provide additional cardiac support for patients 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 U.S., we estimate that approximately 25% receive a VAD. We believe that the percentage of patients bridged to transplant will continue to increase with surgeons' level of comfort with the technology, particularly for longer-term support cases. There are currently five devices approved in the U.S. as a bridge to-transplant in adults, four of which are Thoratec devices.

***Destination Therapy*** On November 6, 2002, we received approval to market the HeartMate VAD for Destination Therapy patients with late-stage HF 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 U.S. For these late-stage HF patients, drug therapy is currently the only other treatment available. Even with drug therapy, the 12-month mortality rate for these patients is approximately 80%. We believe that the HeartMate provides 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 products such as our HeartMate that deliver substantial longevity and proof of clinical efficacy.

***Therapeutic Recovery*** We believe that for most patients the 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 HF 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 HF could benefit from this indication, based upon our estimate of the percentage of patients with late-stage HF, we believe that the patient population could be substantial. We are pursuing a bridge to myocardial recovery indication to add to our labeling that is approved by the FDA which would allow the Thoratec VAD to be used to treat patients diagnosed with acute cardiac disorders such as fulminate myocarditis. We will continue working with the FDA toward this goal in 2006. We are also formulating a regulatory and clinical strategy for non-U.S. markets.

***Post-cardiotomy Myocardial Recovery Following Cardiac Surgery*** In addition to chronic HF, 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 open-heart procedures. 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 that this patient population could benefit substantially from the use of our FDA approved Thoratec VAD and IVAD products in this market.

***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.

**ITC SEGMENT**

***Point-of-Care Diagnostics Products*** Our point-of-care 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 point-of-care market, into the alternate site point-of-care market including physicians' offices, long-term care facilities, clinics, visiting nurse associations, home healthcare companies, and directly to patients. We believe that the market growth for point-of-care diagnostic products is fueled by convenience, ease of use, the clinical benefits that more frequent monitoring at alternate site point-of-care allows and availability of time sensitive test results where the patient is being treated.

***Incision Products*** Our incision products are used by professionals to obtain a patient's blood sample for diagnostic testing. Our incision products are sold into both the hospital point-of-care and the alternate site point-of-care markets. All products feature permanently retracting blades for a safe, less painful incision.

**OUR STRATEGY**

Our strategy to maintain and expand our leadership position is comprised of the following:

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*Offer a broad range of products.* Our VADs provide hemodynamic restoration therapy for the heart and have been clinically proven to improve patient survival and quality of life. We currently offer the widest range of VADs to cover indications for use ranging from acute to long-term support. We believe that our broad and diverse product offering represents an important competitive advantage because it allows us to address the various preferences of surgeons, the clinical needs of a wide variety of patients, and the economic requirements of third party payors. We intend to further broaden our product line through internal development, acquisition and licensing.

*Focus on and partner with leading heart centers.* We have developed long-standing relationships with leading cardiovascular surgeons and heart centers worldwide. We believe that no other cardiac assist company enjoys the same depth of relationships and access to these customers. These relationships are 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. In 2005, we continued our investment in building these relationships by hiring five heart failure therapy specialists as part of our program to generate referrals to our leading VAD centers, including those in our Heart Hope Program that we began in 2004. These specialists work in partnership with our VAD centers to increase the awareness of hemodynamic restoration therapy and VADs in the cardiology community.

*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 building upon our existing relationships with leading cardiac surgeons, cardiac catheterization labs and hospitals, and using our existing sales channels to gain acceptance and adoption of our products.

*Bridge-to-Transplantation Market.* On July 28, 2003, Thoratec received CE mark certification, providing approval to market the Thoratec Implantable Ventricular Assist Device, or IVAD, within European Union countries. 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 HF patients who are not candidates for heart transplants. While the initial CMS reimbursement approval was limited to 69 centers in 2004, we estimate the market penetration for this indication could eventually be a meaningful portion of the 100,000 patients annually diagnosed with late-stage HF mentioned above, as we introduce new technologies that increase the useful 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 (the unit providing power, monitoring and operational control of a VAD) for home use. The TLC-II was already approved for in-hospital use in the U.S., and had been approved for home therapy in Europe for several years. This approval enables 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.

*Point-of-Care Market.* 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 which combines coagulation and blood gas tests into one platform. In the interim, 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. We also currently sell the ProTime for monitoring anticoagulation therapy to physician offices, nursing homes and other Clinical Laboratory Improvement Act, or CLIA, waived settings (facilities that perform simple types of tests and have lower level training for performing these tests).

*Obtain approval for new products.* We completed a U.S. Phase I clinical trial of 25 patients at 10 study sites for our HeartMate II VAD and began our U.S. Phase II pivotal trial in the first quarter of 2005. The Phase II study includes

both a BTT and DT arm, the first time the FDA has approved a clinical trial with both indications in one protocol. The BTT arm will involve 133 patients in total, with the primary endpoint being the rate of survival to either transplantation or 180 days of support. The DT arm of the study will involve 200 total patients, randomizing the HeartMate II to the company's HeartMate XVE on a 2-1 basis, respectively. The DT arm provides for a two-year composite endpoint, which includes patient survival, rate of neurological events and device reliability. We had more than 180 patients enrolled in the clinical trial as of the end of 2005. The pivotal trial will evaluate the safety and effectiveness of the HeartMate II for use as a bridge to-transplantation and Destination Therapy. The HeartMate II is an implantable Left Ventricular Assist Device System consisting of a miniature rotary blood pump 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.

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*Increase cost effectiveness of the therapies that employ 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 late-stage heart failure patients. We work closely with the 69 CMS-approved centers to develop the Destination Therapy market, which we believe will ultimately improve the cost effectiveness of this solution. We also are expanding our market education and training programs, and continue to make improvements that enhance the performance and cost effectiveness of our products.

*Increase our presence in Cardiovascular and ITC market segments.* In addition to increasing our presence in the heart failure, cardiovascular disease, point-of-care and incision markets through internal growth, we continue to evaluate strategic alliances, joint ventures, acquisitions and related business development opportunities.

**OUR PRODUCTS****Cardiovascular Segment**

Our Cardiovascular segment offers the following 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. The device, which is sold worldwide, is approved to assist left, right and biventricular support and is worn outside of the body. The Thoratec VAD is approved by the FDA for use as a bridge to transplantation and for post-cardiotomy myocardial recovery.

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

The HeartMate XVE Left Ventricular Assist System, or LVAS, is an implantable device for mid to longer-term cardiac support and is the only device approved in the U.S., Europe and Canada for permanent support for those patients ineligible for heart transplantation. This device is designed to assist the pumping function of the left ventricle of the natural heart and feature a unique textured blood-contacting surface that eliminates the need for systemic anticoagulation.

The HeartMate II is an implantable LVAS consisting of a miniature rotary blood pump designed to provide long-term support. Its design is intended to be not only smaller, but also simpler, quieter, and longer lasting than the current generation of ventricular assist device. The HeartMate II is CE Marked and approved for distribution in Europe, but is currently only approved in the U.S. for investigational use.

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

***Circulatory Support and Graft 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 left ventricle to the pump chamber via the cannula, powered by an electric or air driven mechanism that 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 in some devices. 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.



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### *The Thoratec VAD*

The Thoratec VAD has been FDA approved since 1995 and has treated over 2,900 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 18 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 as well as left-sided ventricular assist. The Thoratec VAD is also the only device approved for both bridge-to-transplantation 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 incorporates our proprietary biomaterial, Thoralon, which has excellent tissue and blood compatibility and is resistant against blood clots.

The Thoratec VAD uses our TLC-II driver, which is a small portable driver that increases portability and ambulation options compared to the typical drive console. The TLC-II portable driver was approved in the U.S. in June 2001 for use in off-site excursions and in December 2003 for home discharge use. The TLC-II has been approved for use in Europe since 1998.

### *The Thoratec IVAD*

We received CE Mark certification to market the Thoratec IVAD in Europe in July 2003 and FDA approval for the U.S. market in August 2004. The IVAD was approved in Canada in November 2004. The IVAD is 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 90 lbs to more than 220 lbs. The IVAD is designed as a bridge-to-transplantation and potentially for therapeutic recovery, but is not currently considered for Destination Therapy.

### *The HeartMate XVE LVAS*

The HeartMate VE initially received FDA approval in September 1998. 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 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, other than aspirin, because of the product's incorporation of 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.

### *The HeartMate II*

The HeartMate II is a next generation device intended for long-term cardiac support (5-7 years) for patients who are in late-stage heart failure. The HeartMate II is a small, implantable, electrically powered device that weighs about 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. More than 180 patients have been enrolled in the clinical trials of the HeartMate II device as of the end of 2005. The Investigational Device Exemption (IDE) for the pivotal trial in the U.S. for both bridge-to-transplantation and Destination Therapy indications for use was fully approved by the FDA in May 2005. Approval to apply the CE Mark for commercial distribution in Europe was obtained in November 2005.

### *VAD Products Under Development*

We are also developing the HeartMate III, which is a centrifugal, continuous flow pump that incorporates a magnetically levitated rotor in order to eliminate the potential for bearing-induced wear. The device is designed for implantation of 10 years or more in patients with late-stage HF, 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.



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

The *Vectra* vascular access graft was approved for sale in the U.S. 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.

### ***ITC Segment***

Our ITC segment offers a broad portfolio of point-of-care diagnostic test systems and incision products.

### ***Point-of-Care Diagnostics***

Our ITC point-of-care product lines consist of the following:

Hemochron point-of-care coagulation system;

Immediate Response Mobile Analysis, or IRMA, point-of-care blood gas/electrolyte and chemistry system;

ProTime coagulation monitoring system; and

Hemoglobin Pro system.

### ***Hospital point-of-care***

The Hemochron and IRMA products are primarily sold into the hospital point-of-care segment of the market. 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 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.

### ***Alternate site point-of-care***

The ProTime and Hemoglobin Pro products are sold into the alternate site point-of-care market comprising physicians' offices, long-term care facilities, clinics, visiting nurse associations, and home healthcare companies.

ProTime is used to monitor a patient's coagulation while taking oral anticoagulants such as Coumadin, and can be prescribed to be used by the patient at home or in the physician's office or clinic. The system consists of a small, portable analytical instrument and disposable test cuvettes.

Hemoglobin Pro, or Hgb Pro, is used by professionals, mainly in doctor's offices to test for anemia; it provides quick results from a very small blood sample. The system consists of a small, hand-held test meter and disposable test strips.

Growth in this market is being fueled by convenience and ease of use for 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.

### ***Incision Products***

Our ITC incision product lines consist of the following:

Tenderfoot incision;

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Tenderlett incision; and,

Surgicutt Bleeding Time Devices.

Our incision products are used to obtain a patient's blood sample for diagnostic testing. These products are sold to both the hospital and alternate site point-of-care markets. Our products offer certain advantages and command a premium over the competition, and are sold in the higher end of the market.

Tenderfoot is used by professionals as a heel stick for infant testing, allowing blood to flow more freely to reduce the need to squeeze the foot. The Tenderfoot is our most successful incision product and is available in four incision depths. We market this product based on its high-end features. Long-term, however, we believe that price will increasingly drive purchasing decisions.

Tenderlett is used by professionals as a finger incision device that contains a surgical stainless steel blade that incises to a controlled, standardized depth. The Tenderlett creates a small, shallow incision in the finger and is available in three incision depths.

Surgicutt is used to perform screening tests to determine platelet function. This product is also engineered to perfect the bleeding time test and better control many of the variables that have previously hindered test standardization. The Surgicutt contains a stainless steel blade that incises to a standardized depth and length for more reproducible results. It is sold in three sizes to meet the needs of specific patient populations from infants to adults.

The growth in this segment will require increased patient testing, better patient outcomes reflecting the importance of timely and accurate results for health care professionals and increased decentralization of testing from central laboratories to point-of-care.

Our cardiac assist and vascular graft products represented 62%, 60%, and 63% of our product sales in 2005, 2004, and 2003, respectively. Our point-of-care blood diagnostics test systems and services and incision products amounted to 38%, 40% and 37% of our total product sales in 2005, 2004, and 2003, respectively. For financial information related to our segments for each of the past three years, please see Item 8, Note 11 to our Consolidated Financial Statements.

## **SALES AND MARKETING**

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

Hospitals that perform open heart surgery and heart transplants are the potential customers for our circulatory support products. We estimate that 136 of the approximately 1,000 hospitals in the U.S. that perform open-heart surgery also perform heart transplants. We actively market to heart transplant hospitals and large cardiac surgery centers as well as to the approximately 100 heart transplant hospitals in Europe.

We have recruited and trained a direct sales force that, as of December 31, 2005, comprised 19 experienced cardiovascular sales specialists to sell our circulatory support systems in the U.S., Canada, France, Germany, Spain, United Kingdom, Austria, Switzerland, Netherlands, Portugal and South Africa.

Thoratec's sales effort is complemented by 13 direct clinical specialists and five heart failure therapy specialists. The clinical specialists conduct clinical educational seminars, assist with a new open-heart center's first VAD implant and resolve clinical questions or issues. Our heart failure therapy specialists work with four leading VAD centers to generate referrals and increase awareness in the cardiology community regarding hemodynamic restoration therapy and VADs. We 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 representing the majority of our remaining VAD sales potential. Our sales and marketing tactics include direct mail, education seminars, symposia, equipment purchase and lease programs and journal advertisements, all common in the cardiovascular device market.

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 18 months, due to the expense of the product

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and common hospital capital equipment acquisition procedures. Upon receipt of a purchase order, we usually ship the products within thirty days.

The introduction of a VAD system in a hospital or other medical facility requires that the surgical and clinical support personnel possess certain product expertise. We provide initial training and best practice instruction for these personnel, along with a variety of training materials that accompany the initial delivery of our VAD products, including instructions for use, patient management manuals and assorted videos. We provide clinical support during implants and provide 24-hour access to clinically trained personnel. In addition, our sales force helps customers understand and manage reimbursement from third-party payors.

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

We market the *Vectra* through C.R. Bard Corp. (a competitor of ours) in the U.S., and selected countries in Europe, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan. On December 5, 2005 we modified our distributor agreement to continue exclusive distribution until December 31, 2006.

### ***Point-of-Care Diagnostics***

In 2005, ITC completed the process of establishing a direct sales force in the U.S. to sell our hospital point-of-care coagulation and IRMA products. We currently maintain a direct sales staff of 46 people in the U.S. that sell directly to hospitals and to distributors in the alternate site market. Outside the U.S., ITC has four salespeople selling principally to third party distributors. ITC's product sales prior to 2005, came through our distributor channels, with Quality Assured Services as our largest distributor.

As we have integrated the IRMA product line of blood gas analyzers into our business, an increasing portion of our revenue in the U.S. 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 to provide our customers with the support and service historically provided by our distributors.

### ***Incision Products***

Our incision products are sold by distributors worldwide. Our largest incision distributor in the U.S. market is Cardinal Healthcare, which generated 71% of ITC's annual incision product sales in 2005. In October of 2005, we appointed a second distributor, Surgilance, for our Tenderfoot incision product in the U.S. market. Both Cardinal and Surgilance will distribute the Tenderfoot on a co-exclusive basis in the U.S.

## **COMPETITION**

Competition from medical device companies and medical device divisions of health care and pharmaceutical companies is intense and is expected to increase. Our principal competitors for the VAD system include WorldHeart Corporation, MicroMed Technology, Inc., AbioMed, Inc., and SynCardia Systems, Inc. in the U.S. and Berlin Heart AG in Europe. Principal 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., Radiometer A/S, Abbott Diagnostics, and Instrument Laboratories. Our primary competitor in the skin incision device market is Becton, Dickson and Company. Competitors in the alternate site point-of-care diagnostics market include Roche Diagnostics and HemoSense, Inc.

We believe that key competitive factors include the relative speed with which we can develop products, complete clinical testing, receive regulatory approvals, achieve market acceptance and manufacture and sell commercial quantities of our products.

We estimate that we have a majority of the VAD market domestically and more than 50% internationally. We believe that potential competitors are several years away from completion of clinical trials required before those products will become commercially available and compete with our products in the U.S. In addition, unless our competitors' products result in significantly better outcomes than our products, we believe that absent any compelling reason, cardiac centers will not generally change suppliers.

Large medical device companies dominate the markets in which our ITC business competes and we estimate that we hold anywhere from a 2% to 20% market share, depending on the product. 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:



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New competitors 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.

New drug therapies under development may not require the intense monitoring of a patient's coagulation necessary with the current anti-coagulation drug of choice, Heparin. To try to mitigate this risk, we participate in clinical trials with key pharmaceutical companies to provide the hemostasis monitoring that will ultimately be required for new drug therapies.

## **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, and blood chemistry 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. Aspects of our blood coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision device products are covered by patents directed to tube-and micro-coagulation whole blood analysis, including test methods, reagents and integral (on-board) controls, thick film electrochemical analysis of blood gases, blood electrolytes, and blood chemistry, and low trauma skin incision devices for capillary blood sampling, and methods of manufacturing such devices. The duration remaining of some of our biomaterials patents ranges from four to nine years, on our grafts from two to 15 years and on our blood coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision device products from two 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 nine to 16 years. In August 1998, we obtained a license to incorporate technology developed by Sulzer Electronics Ltd. and Lust Antriebstechnik GmbH into the HeartMate III. HeartMate III is a miniature centrifugal pump featuring a magnetically levitated rotor with a bearingless motor that has been developed by Levitronix GmbH. The license from Sulzer and Lust gives us the exclusive right to use in our HeartMate products technology protected by several U.S. and foreign patents covering implantable bearingless motors for the duration of those patents, subject to our payment of royalties. In December 2000, we were informed by Sulzer Electronics that Sulzer had sold all of 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.

We also hold, or have exclusive rights to, several international patents.

We have developed technical knowledge which, although non-patentable, we consider to be significant in enabling us to compete. It is our policy to enter into confidentiality agreements with each of our employees prohibiting the disclosure of any confidential information or trade secrets. In addition, these agreements provide that any inventions or discoveries by employees relating to our business will be assigned to us and become our sole property.

Despite our patent rights and policies with regard to confidential information, trade secrets and inventions, we may be subject to challenges to the validity of our patents, claims that our products allegedly infringe the patent rights of others and the disclosure of our confidential information or trade secrets. These and other related risks are described more fully under the heading *Our inability to protect our proprietary technologies or an infringement of others patents could harm our competitive positions* in the Risk Factors section of this Annual Report.

At this time, we are not a party to any 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 U.S., the FDA regulates the design, manufacture, distribution and promotion of medical devices pursuant to the Federal Food, Drug, and Cosmetic Act and its 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 Investigational Device Exemption (IDE). An IDE application must contain pre-clinical test data supporting the safety of the product for human investigational use, information on manufacturing processes and procedures, proposed clinical protocols and other information. If the IDE application is accepted, human clinical trials may begin. The trials must be conducted in compliance with FDA regulations and with the approval of one or more institutional review boards. The results obtained from these trials, if satisfactory, are accumulated and submitted to the FDA in support of either a 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, PMA Supplement or 510(k) submission to the FDA to help offset the cost of scientific data review that is required before the 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 U.S.

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 preclinical data, and sometimes 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, during which 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 can 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 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 U.S.

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 be sure that any regulatory agency will grant its approval. Our inability to obtain, or delays in obtaining, such approval would adversely affect our ability to begin 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. This law amends the FDA Act and regulations to provide, among other things, the ability for the FDA to impose user fees for medical device reviews. Our activities require that we make many filings with the FDA that are subject to this



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 be a significant amount per year.

In addition, any products distributed pursuant to the above authorizations are subject to continuing regulation by the FDA. Products must be manufactured in registered establishments and must be manufactured in accordance with Quality System Regulations. 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, for significant risk devices, such as VADs, that require ongoing collection of clinical data during commercialization that must be gathered, analyzed and

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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/or suspension of FDA approval. The export of devices such as ours is also subject to regulation in certain instances.

We are also subject to regulation by various state authorities, which may inspect our facilities and manufacturing processes 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. These regulations relate 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 more than 90 member countries and ISO certification is widely regarded as essential to enter Western European markets. We obtained EN ISO 13485:2003 Certification in February 2006. Since 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 devices, 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 certification is required 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 provide assurance that we will not be required to incur significant costs to comply with environmental laws or regulations in the future.

## **THIRD PARTY REIMBURSEMENT AND COST CONTAINMENT**

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

To date, CMS and a majority of private insurers with whom we have dealt approved reimbursement 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 late-stage HF patients. Sixty-nine centers are now recognized by CMS as Medicare LVAD centers.

Effective October 1, 2004, Medicare reimbursement payment increased for heart assist devices with CMS LVAD centers receiving an average payment of approximately \$90,000 to approximately \$136,000. This change of DRG

category for implantable heart assist devices to DRG 103 from 525 has raised the average payment under DRG 103 by more than 30%. Twenty-six new Healthcare Common Procedure Coding System codes also have been created by CMS to provide reimbursement for outpatient equipment and supplies. Since FDA approval of the HeartMate LVAS for Destination Therapy, several private payors also have issued positive coverage decisions. In December 2002, Blue Cross/Blue Shield Technology Evaluation Center issued a positive decision on the use of

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LVADs for Destination Therapy. The majority of local Blue Cross Blue Shield plans now have created positive medical policy for both bridge-to-transplantation and Destination Therapy indications. Since December 2002, the majority of national private insurance carriers, such as Aetna, Cigna, Humana, United Health Group 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**

Our Cardiovascular segment products are manufactured at our facility in Pleasanton, California. This facility has been inspected, approved and licensed by the FDA and the State of California Department of Health Services, Food and Drug Section for the manufacture of medical devices and has received the International Standards Organization (ISO) 9001 certification. Our manufacturing processes 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 a majority, but not all, of our single-sourced items.

Our ITC segment 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, respectively. 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 ITC segment manufacturing at these facilities is vertically integrated, with only limited reliance on third parties, such as for the manufacture of printed circuit boards and the sterilization and testing of products. 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.

Both segments have typically been able to fill orders from inventory and historically have not had significant order backlogs. At the end of 2004 and during 2005, we experienced backlog due to higher demand. We have expanded capacity during 2005 and plan to continue expansion efforts in 2006 to accommodate the increased demand for both the Cardiovascular and ITC manufacturing locations. Total backlog as of the end of fiscal 2005 and 2004 were approximately \$1.2 million and \$0.6 million for our Cardiovascular segment and \$0.5 million and \$0.7 million for our ITC segment, respectively.

## **RESEARCH AND DEVELOPMENT**

Thoratec's research and development expenses in 2005, 2004 and 2003 totaled \$32.3 million, \$28.7 million, and \$26.1 million, respectively. Research and development costs are largely project driven, and the level of spending depends on the level of project activity planned and subsequently approved and conducted. The primary component of our research and development costs is employee salaries and benefits. Projects related to our Cardiovascular segment typically include clinical trials, such as our HeartMate II pivotal trial, efforts to develop new products, such as the HeartMate II and HeartMate III, and efforts to improve the operation and performance of current products, such as efforts to improve the life of various components of the HeartMate and Thoratec VAD products. ITC research and development projects are typically involved with developing instruments and disposable test cuvettes or cartridges that will be used at the point-of-care. One such system is the Hemochron Signature Elite which was introduced in September of 2005. In addition, ITC devotes research and development efforts to maintain and improve current products based on customer feedback. Research and development costs for both segments also include regulatory and clinical costs associated with our compliance with FDA regulations and clinical trials such as the Phase II HeartMate II pivotal trial.

## **MAJOR CUSTOMERS AND FOREIGN SALES**

We primarily sell our products to large hospitals and distributors. No customer accounted for more than 10% of total product sales in fiscal year 2005.

Sales originating outside the U.S. and U.S. export sales accounted for approximately 23%, 23% and 19% for the years ended 2005, 2004 and 2003, 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.

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### **EMPLOYEES**

As of December 31, 2005, we had a total of 963 employees, consisting of 955 full-time employees and eight part-time employees, 526 of whom worked in manufacturing, 99 in engineering, 127 in quality control and regulatory affairs, 137 in marketing and sales support, 33 in administration and finance and 41 in other support functions, including human resources, management information systems, purchasing and facilities. Of our total employees, 938 are employed in the U.S. and 25 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**

Additional information about Thoratec is available on our website at <http://www.thoratec.com> (although none 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.

#### **Item 1A. Risk Factors**

*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 occur, 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.*

***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 U.S. 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 U.S., we must obtain PMA approval or 510(k) clearance from the FDA. This process is lengthy and uncertain. In the U.S., one must obtain clearance from the FDA of a 510(k) pre-market notification or approval of a more extensive submission known as a PMA application. If the FDA concludes that any of our products do not meet the requirements to obtain clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, then we will 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 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 them, thereby harming our ability to generate sales. The FDA also may limit the claims that we can make about our products. We also may be required to obtain clearance of a 510(k) notification or a PMA Supplement from the FDA before we can market products that have been cleared, that have since been 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.

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Sales of our products outside the U.S. 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. In any event, if we fail to obtain the necessary approvals to sell any of our products in a foreign country, or if any obtained approval is revoked or suspended, we will not be able to sell those products there.

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

***If hospitals do not conduct Destination Therapy procedures using our VADs, market opportunities for our product will be diminished.***

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

The number of Destination Therapy procedures actually performed depends on many factors, many 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 include 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 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 Cardiovascular product sales.

***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 insurance 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.

***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 vendors and receive components from these vendors 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 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

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suppliers or manufacturing our own components or materials. Existing suppliers could also become 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.

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

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

We may encounter difficulties manufacturing products in quantities sufficient to meet demand in the quantities required. 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 those products and indications currently under development, including the HeartMate II VAD. If we have difficulty manufacturing any of our products, our sales may prove lower than would otherwise be the case and our reputation could be harmed.

### ***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 identified quality issue can therefore both harm our business reputation and result in substantial costs and write-offs, which in either case could materially harm our business and financial results.

### ***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 and Point-of-Care blood diagnostics 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.

### ***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 U.S. Patent and Trademark Office may deny or significantly narrow claims made under patent applications and the issued patents, if any, may not provide us with commercial protection. We could incur substantial costs in proceedings before the U.S. Patent and Trademark Office 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.

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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 or will do 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, 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.

***Our future product sales in our Cardiovascular segment will be affected by the number of heart transplants conducted.***

A significant amount of our product sales are 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.

***Our future disposable cuvette test product sales in our ITC segment could be affected by changes in monitoring requirements for medical procedures.***

ITC product sales are generated by medical procedures that require monitoring of coagulation and blood gas parameters done in cardiovascular operating rooms and cardiac catheterization labs. The sales of our disposable test products could decline if there were a significant reduction in those medical procedures.

***Since we depend upon distributors, if we lose a distributor or a distributor fails to perform, our operations may 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 U.S. and selected countries in Europe, the Middle East and 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 December 31, 2005, 22% of ITC's total product sales were through distributors.

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.

***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. In the European market, competitors include SynCardia Systems, Inc., Berlin Heart AG and Abiomed, Inc. We will also compete with other, smaller companies that have similar products in trials. Principal competitors in the vascular graft market include W.L. Gore, Inc., C.R. Bard Corporation, which 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., Radiometer A/S, Abbott Diagnostics, and Instrument Laboratories. Our primary competitor in the skin incision device market is Becton, Dickson and Company. Competitors in the alternate site point-of-care diagnostics market include Roche Diagnostics and HemoSense, Inc.

Some of our competitors, especially those of our ITC segment, have substantially greater financial, technical, distribution, marketing and manufacturing resources, while other competitors have different technologies that may achieve broader customer

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acceptance or better cost structures than our products. Accordingly, our competitors may be able to develop, manufacture and market products more efficiently, at a lower cost and with more market acceptance than we can. In addition, new drugs or other devices may reduce the need for VADs. 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 ITC competes. 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 central laboratories to the hospital and alternate site 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 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 market share.

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

A substantial portion of our total sales occurs outside the U.S. We anticipate that sales outside the U.S. 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 U.S.;

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;

U.S. export licenses may be difficult to obtain;

intellectual property rights may be (and often are) 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 financial results.

***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 currency exchange rates. At present, we use forward foreign currency contracts to hedge the gains and losses created by the re-measurement of non-functional currency denominated assets and liabilities. However, we do not engage in

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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.

### ***Certain lawsuits have been filed against us.***

On August 3, 2004, a Federal securities law putative class action suits entitled *Johnson v. Thoratec Corporation, et al.* was filed in the U.S. District Court for the Northern District of California on behalf of purchasers of our publicly traded securities of the Company between April 28, 2004, and June 29, 2004. Subsequent to the filing of the *Johnson* complaint, additional complaints were filed in the same court alleging substantially similar claims. On November 24, 2004, the Court entered an order consolidating the various putative class action complaints into a single action entitled *In re Thoratec Corp. Securities Litigation* and thereafter entered an order appointing Craig Toby as Lead Plaintiff pursuant to the Private Securities Litigation Reform Act of 1995. On or about January 18, 2005, Lead Plaintiff filed a Consolidated Complaint. The Consolidated Complaint generally alleges violations of the Securities Exchange Act of 1934 by Thoratec, its former Chief Executive Officer, its former Chief Financial Officer, and its Cardiovascular Division President 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 Consolidated Complaint seeks to recover unspecified damages on behalf of all purchasers of the Company's publicly traded securities during the putative class period. On March 4, 2005, defendants moved to dismiss the Consolidated Complaint and that motion currently is pending.

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 class action suit referred to above. This action names the individual members of our Board of Directors, including the former Chief Executive Officer and certain other current and former executive officers, as defendants and alleges that the defendants breached their fiduciary duties and wasted corporate assets, and that certain of the defendants traded in Thoratec securities while in possession of material nonpublic information. Proceedings in *Wong v. Grossman* are currently stayed until at least April 2006.

We believe that the claims asserted in both the Federal securities law putative class action and the state shareholder derivative action are without merit. We have moved to dismiss the Federal action and will file a similar motion in the *Wong* action if necessary. We are unable to predict at this time the 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.

### ***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 to a new center 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.

### ***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. Such uncertainty could delay or prevent adoption of these products 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 Centers for Medicine & Medicaid Services, or

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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 partially or completely reduced, our revenues would be reduced.

***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. 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.

***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 any 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 any other indebtedness we may have incurred. 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 of our common stock 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 Emerging Issues Task Force ( EITF ) 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

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the effect of the 7.3 million shares was anti-dilutive as of the years ended 2005, 2004 and 2003. 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 we had not adopted EITF 04-8, as they were in the fourth quarter of 2005.

***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.***

A substantial portion of our assets is comprised of goodwill and purchased intangible assets, recorded as a result of our merger with TCA completed in September 2001. 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 or recoverability of these intangible assets is impaired. 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 decided 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. In the event of another such charge to net income, the market price of our common stock could be adversely affected.

***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 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, clinical, regulatory, 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.

***The price of our common stock may fluctuate significantly.***

The price of our common stock has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. For example our closing stock price has ranged from \$9.39 to \$22.36 in the 12 months ended December 31, 2005. The price of our common stock could fluctuate significantly for many reasons, including the following:

future announcements concerning us or our competitors;

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

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

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

acquisition or loss of significant customers, distributors or suppliers;

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reaction to Company guidance;

business acquisitions or divestitures;

changes in earnings estimates by analysts;

changes in third party reimbursement practices;

charges, amortization and other financial effects relating to our merger with TCA; 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, fluctuations that frequently have 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 often have 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.

### ***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, 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.

### ***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, any of 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 carrying value.

### ***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 products 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.

### ***We have a history of net losses***

We were founded in 1976 and we have a history of incurring losses from operations. 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

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costs could prevent us from maintaining profitability in future periods.

***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 has substantially increased during the past several years. We expect to continue to increase 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.

***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.

We have a rights plan, commonly known as a poison pill, which would make it difficult for someone to acquire us 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 1B. Unresolved Staff Comments**

None.

### **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 37,000 square feet of office and research facilities in Piscataway, New Jersey, expiring in 2010.

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.

In January 2006, Thoratec purchased a 66,000 square foot building in Pleasanton, California, that will become Thoratec's corporate office building. We expect to complete improvements on approximately 36,000 square feet of this



building in 2006. We plan to occupy this space on or about May 2006. The remaining building square footage is currently leased from us by a third party and we expect to improve and occupy this portion of the building upon the expiration of the third party lease on March 31, 2007.

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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.

The Cardiovascular segment utilizes all of the facilities in California, Massachusetts and in the United Kingdom. The ITC segment utilizes all of the facilities in New Jersey and Minnesota.

**Item 3. Legal Proceedings**

On August 3, 2004, a putative Federal securities law class action suit entitled *Johnson v. Thoratec Corporation, et al.* was filed in the U.S. District Court for the Northern District of California on behalf of purchasers of our publicly traded securities between April 28, 2004 and June 29, 2004. Subsequent to the filing of the *Johnson* complaint, additional complaints were filed in the same court alleging substantially similar claims. On November 24, 2004, the Court entered an order consolidating the various putative class action complaints into a single action entitled *In re Thoratec Corp. Securities Litigation* and thereafter entered an order appointing Craig Toby as Lead Plaintiff pursuant to the Private Securities Litigation Reform Act of 1995. On or about January 18, 2005, Lead Plaintiff filed a Consolidated Complaint. The Consolidated Complaint generally alleges violations of the Securities Exchange Act of 1934 by Thoratec, its former Chief Executive Officer, its former Chief Financial Officer and its Cardiovascular Division President 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 Consolidated Complaint seeks to recover unspecified damages on behalf of all purchasers of the Company's publicly traded securities during the putative class period. On March 4, 2005, defendants moved to dismiss the Consolidated Complaint and that motion currently is pending.

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 class action suit referred to above. This action names the individual members of our Board of Directors, including the former Chief Executive Officer and certain other current and former executive officers as defendants, and alleges that the defendants breached their fiduciary duties and wasted corporate assets, and that certain of the defendants traded in Thoratec securities while in possession of material nonpublic information. Proceedings in *Wong v. Grossman* are currently stayed until at least April 2006.

We believe that the claims asserted in both the Federal securities law putative class action and the state shareholder derivative action are without merit. We have moved to dismiss the Federal action and will file a similar motion in the *Wong* action if necessary. We are unable to predict at this time the 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 December 31, 2005.

**Our Executive Officers**

*Gerhard F. Burbach, President, Chief Executive Officer and Director*, joined our company as President, Chief Executive Officer and a director, in January 2006. Prior to joining us, Mr. Burbach served as the president and chief executive officer of Digirad Corporation, a leading provider of solid-stage imaging products and services to cardiologist offices, hospitals and imaging centers. He continues to serve on the Digirad board of directors. Before that he served for two years as president and chief executive officer of Bacchus Vascular Inc, a developer of interventional cardiovascular devices. Previously, he served for three years as chief executive officer of Philips Nuclear Medicine. Until its acquisition by Philips Electronics, he spent four years at ADAC Laboratories where he became president and general manager of the nuclear medicine division. He also spent six years with the consulting firm of McKinsey & Company, primarily within the firm's healthcare practice.

*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 held

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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.

*Cynthia L. Lucchese, Senior Vice President and Chief Financial Officer*, joined our company in September 2005 as Senior Vice President and Chief Financial Officer. Prior to joining us, Ms. Lucchese spent 10 years working for Guidant Corporation, most recently as Vice President and Treasurer. She also served as Vice President, Finance & Administration, Guidant Sales Corporation and Vice President, Controller and Chief Accounting Officer. Prior to that, she spent eight years working for Eli Lilly & Company in a variety of financial roles. She also spent three years working in public accounting for Ernst & Young LLP.

*David A. Lehman, Vice President, General Counsel and Secretary*, joined our company as Vice President and General Counsel in May 2003. Mr. Lehman was appointed as Secretary in December 2004. Prior to joining us, Mr. Lehman served as Vice President and General Counsel of Brigade Corporation, a provider of business process outsourcing services, from June 2000 to May 2003. From November 1997 to June 2000, Mr. Lehman was Assistant General Counsel at Bio-Rad Laboratories, Inc., a diagnostic and life science products company. Prior to November 1997, Mr. Lehman was in the legal department of Mitsubishi International Corporation, in New York and Tokyo for more than seven years. Mr. Lehman started his career as an associate attorney at the law firm of Hall, Dickler, Kent, Friedman and Wood.

*Beth A. Taylor, Vice President, Administration*, joined our company as Director of Human Resources in November 1999 and was promoted to Vice President of Human Resources in February 2001. In October 2005, Ms. Taylor was promoted to Vice President, Administration. Prior to joining us, Ms. Taylor served as Director of Human Resources for CCI/Triad, a supplier of information technology solutions to the automotive aftermarket, hardware retailers and the lumber industry, from March 1998 to November 1999. Prior to March 1998, Ms. Taylor held various other human resource positions such as Corporate Employee Development Manager with Valent U.S.A. Corporation, and Director of Human Resources with ADP.

**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 10, 2006, there were 52,319,017 shares of our common stock outstanding with approximately 720 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.

	<b>High</b>	<b>Low</b>
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
Fiscal Year 2005		
First Quarter	\$ 12.49	\$ 9.39
Second Quarter	15.60	11.45
Third Quarter	17.82	15.20

Fourth Quarter	\$22.36	\$16.38
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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 a total of \$130 million of shares of the company's common stock, were announced on February 11, 2004 as a \$25 million program, on May 12, 2004 as a \$60 million program, on July

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29, 2004 as a \$25 million program, and on February 6, 2006 as an additional \$20 million program. These programs do not have an expiration date. Through December 2005, we repurchased 8.5 million shares of our common stock for \$104.9 million under these combined programs.

**Item 6. Selected Consolidated Financial Data**

The selected consolidated financial data presented below for the five fiscal years ended December 31, 2005 are 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. We have reclassified our long-term deferred tax assets against our long-term deferred tax liabilities in the financial statements previously filed with the SEC in order to conform to the current year's presentation of a single net long-term deferred tax balance.

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 merger. For accounting purposes, 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 2001 ended on December 29, 2001, fiscal 2002 ended December 28, 2002, fiscal 2003 ended January 3, 2004, fiscal 2004 ended January 1, 2005 and fiscal 2005 ended December 31, 2005. Fiscal 2006 will end on December 30, 2006.

	Fiscal Year				
	2005	2004	2003	2002	2001
	(In thousands, except per share data)				
<b>Statement of Operations:</b>					
Product sales	\$201,712	\$172,341	\$149,916	\$130,844	\$113,384
Gross profit	123,340	100,222	88,748	75,720	60,544
Amortization of goodwill and purchased intangible assets	11,204	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	95	733	2,132	1,409	7,134
Net income (loss)	13,198	3,564	(2,182)	511	(87,866)
Basic earnings (loss) per share	\$ 0.27	\$ 0.07	\$ (0.04)	\$ 0.01	\$ (1.68)
Diluted earnings (loss) per share	\$ 0.26	\$ 0.07	\$ (0.04)	\$ 0.01	\$ (1.68)
<b>Balance Sheet Data:</b>					
Cash and cash equivalents and short term available-for-sale investments	\$210,936	\$145,859	\$ 62,020	\$ 45,483	\$ 91,726
Working capital	269,293	206,250	116,430	107,972	135,924
Total assets	573,918	518,034	471,335	463,188	520,928
Subordinated convertible debentures	143,750	143,750			54,838
Long-term deferred tax liability and other	50,430	56,670	62,327	69,210	71,707
Total shareholders' equity	\$348,147	\$292,108	\$386,236	\$374,340	\$373,343

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

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, as amended. These statements can be identified by the words expects, projects, hopes, believes, intends, should, estimate, will, would, may, anticipates, plans, could

Actual results, events or performance 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. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the Risk Factors section of this Annual Report and in other documents we file with the Securities and Exchange Commission. These forward-looking

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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.

*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 heart failure, or HF. Our Ventricular Assist Devices, or VADs, are used primarily by HF patients to perform some or all of the pumping function of the heart. 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 HF market. Through our wholly-owned subsidiary, ITC, we design, develop, manufacture and market point-of-care diagnostic test systems and incision products that provide for fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes.

### **Our Business Model**

Our business is comprised of two segments: Cardiovascular and ITC.

The product line of our Cardiovascular segment is:

*Circulatory Support Products.* Our circulatory support products include VADs for the short, intermediate and long-term treatment of advanced heart failure. In addition, we have developed small diameter grafts using our proprietary materials to address the vascular access market. Our grafts are used for hemodialysis.

The product lines of our ITC segment are:

*Point-of-Care Diagnostics.* Our point-of-care products include coagulation diagnostic test systems that monitor a patient while being administered certain anticoagulants, blood gas/electrolyte and chemistry status, or anemia.

*Incision.* Our incision products include devices used to obtain a patient's blood sample for diagnostic testing and screening for platelet function.

### **Cardiovascular segment**

We offer the following broad product portfolio of implantable and external circulatory support 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 left, right and biventricle support and is worn outside of the body. The Thoratec VAD is approved for use in bridge-to-transplantation, or BTT and for post-cardiotomy myocardial recovery.

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

The HeartMate XVE Left Ventricular Assist System, or LVAS, is an implantable device for mid to long-term cardiac support and the only device approved in the U.S., Europe and Canada for permanent support for those patients ineligible for heart transplantation. The HeartMate XVE is also approved for use in BTT.

The HeartMate II, which is currently in clinical trials for BTT and Destination Therapy, is an implantable device consisting of a miniature rotary blood pump designed to provide long-term cardiac support. Its design is intended to be not only smaller, but also simpler, quieter, and longer lasting than the current generation of ventricular assist devices.

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



The primary markets for our VAD products are those patients suffering from heart failure and, in particular, from late-stage HF. HF is a chronic disease that occurs when degeneration of the heart muscle reduces the pumping power of the heart, causing the heart

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to become too weak to pump blood at a level adequate to meet the body's demands. HF can be caused by artery or valve diseases or a general weakening of the heart muscle itself. Other conditions, such as high blood pressure or diabetes, can also lead to HF.

In the United States, we currently have two FDA-approved indications for the use of VADs in patients with HF: as a bridge to heart transplant and as Destination Therapy. We are currently pursuing an additional indication for our Thoratec VAD products: therapeutic recovery of the heart. Beyond the HF markets, VADs are also approved for use during recovery following cardiac surgery.

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 nearly 10,000 of our devices in patients suffering from heart failure. Our devices are currently used primarily for patients awaiting a heart transplant or as Destination Therapy implants. On November 6, 2002, the United States Food and Drug Administration, or FDA, approved the HeartMate VAD as the first heart assist device for Destination Therapy. 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. 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.

### **ITC Segment**

The major product lines of point-of-care, or POC, diagnostic test systems and incision device products are:

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

The IRMA POC blood gas/electrolyte and chemistry system, which 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 coagulation monitoring system, which is used to monitor patients' coagulation while they are taking oral anticoagulants such as Coumadin, and can be prescribed for use by patients 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.

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

Tenderfoot, Tenderlett and Surgicutt incision products, which are used by professionals to obtain a patient's blood sample for diagnostic testing. The Tenderfoot is a heel stick used for infant testing, the Tenderlett is used for finger incisions and the Surgicutt is used to perform screening tests to determine platelet function. All products feature permanently retracting blades for safe, virtually pain-free incision.

The Hemochron and IRMA products are primarily sold into the hospital POC segment of the market. The ProTime and Hemoglobin Pro products are sold into the alternate site (non-hospital) POC market comprising physicians offices, long-term care facilities, clinics, visiting nurse associations, and home healthcare companies.

Our incision products are sold to both the hospital POC and the alternate site POC markets. Our most successful incision product is the Tenderfoot. Although we market this product based on its high-end features, we believe that

customers are increasingly making purchasing decisions on these types of products based on price. We have seen a gradual erosion of market share in the current year.

**Acquisitions**

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****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 of, 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.

***Make-Whole Premium***

Under the terms of our senior subordinated convertible notes issued in 2004, if we experience a change in control or a termination of trading of our common stock, each note holder may require us to purchase all or a portion of their notes at a price equal to the issue price plus any original issue discount. In addition, if the consideration for the change in control is all cash, the company will pay a make-whole premium to the note holders. This premium is considered an embedded derivative under SFAS 133 and has been bifurcated from the convertible notes and recorded at its estimated fair value, \$0.2 million and none at December 31, 2005 and January 1, 2005, respectively.

There are significant variables and assumptions used in valuing the make-whole provision including, but not limited to, the company's stock price, volatility of the company's stock, the probability of acquisition and the probability of the type of consideration used by a potential acquirer. If any of these variables move significantly or if management's assumptions prove incorrect, our financial statements could be materially and adversely affected.

***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. Other distributors have certain rights of return upon termination of their distribution agreement. A reserve for sales returns is recorded for these customers applying reasonable estimates of product returns based upon historical experience. No other direct sales customers or distributors have return rights or price protection.

We recognize sales of certain Cardiovascular segment products to first-time customers when we have 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. Training is not considered essential to the functionality of the products. The amount of revenue under these arrangements allocated to training is based upon fair market value of the training, which is typically performed on behalf of the Company 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 majority of our products are covered by up to a two-year limited manufacturer's warranty from the date of shipment or 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.

In determining when to recognize revenue, management makes decisions on such matters as the fair values of the product and training elements when sold together, customer credit worthiness and warranty reserves. If these decisions prove incorrect, the carrying value of these assets and liabilities on our condensed consolidated balance sheets could be significantly different and it could have a material adverse effect on our results of operations for any fiscal period.

***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. When the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

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.



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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.

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

***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.

In accordance with SFAS No. 142, Goodwill and Other Intangible Assets, we no longer amortize 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 2005, we determined that neither goodwill nor intangible assets were impaired.

**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:

	<b>Fiscal Year</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Product sales	100%	100%	100%
Cost of product sales	39	42	41
Gross profit	61	58	59
Operating expenses:			
Selling, general & administrative	30	31	30
Research and development	16	17	17
Amortization of purchased intangible assets	6	7	8
Impairment of intangible asset			6
Litigation, restructuring and other costs			1
Total operating expenses	52	55	62
Income (loss) from operations	9	3	(4)
Other income and (expense):			
Interest expense	(2)	(1)	
Interest income and other	2	1	1
Income (loss) before taxes	9	3	(3)
Income tax expense (benefit)	2	1	(1)
Net income (loss)	7%	2%	(2)%

**Fiscal Years 2005 and 2004**

***Product Sales***

Product sales in 2005 were \$201.7 million compared to \$172.3 million in 2004. The Cardiovascular segment increased sales by \$22.2 million and the ITC segment increased sales by \$7.2 million. Product sales increases are due to an increase in volume unless otherwise noted. The primary components of the total \$29.4 million increase in product sales were the following:

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VAD product sales increased \$16.7 million. The increase came from higher sales of our HeartMate II and IVAD products, partially offset by a reduction in sales of our PVAD and XVE product lines.

Other ancillary revenue (drivers, cannulae, service, rentals and spares) increased \$2.6 million, including increases in driver rental revenue and cannulae sales associated with the IVAD product line.

Graft product sales increased by \$2.9 million, principally due to the recognition of a payment related to the modification of our distribution agreement with C.R. Bard Corporation in December 2004 as well as a higher average selling price.

Point-of-care diagnostic product sales increased \$8.5 million, due primarily to increases in our sales of Protime, IRMA, and Hemochron products partially offset by a modest decrease in sales of our Hgb Pro products year over year.

Incision product sales were down \$1.3 million year over year.

Sales originating outside of the United States and U.S. export sales accounted for approximately 23% of our total product sales in 2005 and 2004.

***Gross Profit***

Gross profit as a percentage of product sales for 2005 and 2004 was 61% and 58%, respectively. The 3% increase in gross profit was due to the proportionate sales of ITC versus Cardiovascular products in conjunction with the following:

The Cardiovascular segment increased gross profit by 4% due to increased sales of higher margin VAD products, coupled with a decrease in manufacturing costs; and

The ITC segment increased gross profit by 1%, due to higher margin sales in the point-of-care product line and reduced manufacturing costs.

***Selling, General and Administrative***

Selling, general and administrative expenses in 2005 were \$61.8 million, or 30% of product sales, compared to \$54.1 million, or 31% of product sales, in 2004. The \$7.7 million increase in spending was primarily attributable to the following:

Increased personnel costs of \$3.7 million associated with CEO transition, CFO recruitment, and other bonus and retention programs not specifically identified to any particular business segment.

Increased personnel costs associated with higher product sales and overall headcount increases in the Cardiovascular segment of \$2.5 million partially offset by a \$0.3 million decrease in personnel costs for the ITC segment.

Higher spending on marketing and related activities primarily associated with Destination Therapy and costs associated with training efforts in the Cardiovascular segment totaling \$1.2 million, in addition to a \$0.8 million increase in spending by the ITC segment related to increased Group Purchasing Organization and consulting fees partially offset by a decrease of \$0.2 million related to travel and supplies.

***Research and Development***

Research and development expenses in 2005 were \$32.3 million, or 16% of product sales, compared to \$28.7 million, or 17% of product sales, in 2004. Of the \$3.6 million increase, our Cardiovascular and ITC segments incurred \$3.3 million and \$0.3 million, in additional expenses, respectively, year over year. 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 and clinical trials such as the Phase II HeartMate II pivotal trial.



***Amortization of Purchased Intangible Assets***

Amortization of purchased intangible assets in 2005 was \$11.2 million compared to \$11.7 million in 2004. The \$0.5 million decrease is the result of changes in certain asset lives in January 2005 as a result of our 2004 SFAS No. 144 impairment test.

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***Litigation, Restructuring and Other Costs***

Litigation, restructuring and other charges in 2005 were \$0.1 million compared to \$0.7 million in 2004. The expense in both years is primarily comprised of costs associated with a Federal securities law putative class action, and a shareholder derivative action entitled *Wong v. Grossman*, that were filed in the third quarter of 2004.

***Interest Expense***

Interest expense in 2005 was \$4.1 million compared to \$2.5 million in 2004. The expenses include \$3.5 million and \$2.1 million in interest payments and \$0.6 million and \$0.4 million in amortization of the debt issuance costs, related to our convertible notes for 2005 and 2004, respectively.

***Interest Income and Other***

Interest income and other in 2005 was \$4.2 million compared to \$2.2 million in 2004. This increase was primarily due to higher interest income earned on our portfolio based on increased average cash balances and higher interest rates in 2005 compared with 2004.

***Income Taxes***

Our effective tax rate was 26.9% in 2005 compared to 24.0% in 2004. The increase in our effective tax rate on a comparative basis was due primarily to a combination of a significant increase in current profitability and increased nondeductible executive compensation, offset in part by increased interest income from tax favorable investments and increased research and development credits.

**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 \$9.0 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.

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 in the second quarter of 2004; partially offset by

\$1.7 million in lower graft product sales.

***Gross Profit***

Gross profit as a percentage of product 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.

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### ***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 174 employees 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. Of the \$2.6 million increase, our Cardiovascular and ITC segments incurred \$0.8 million and \$1.8 million, in additional expenses, respectively, year over year. 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 and clinical trials.

### ***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 in 2004 coupled with the \$9.0 million write-off of the Aria assets at the end of 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.

### ***Litigation, Restructuring and Other Costs***

Litigation, 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 outstanding 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 2004, increased interest income from tax favorable investments and increased research and development credits, which were offset in part by increased expenditures for non-deductible expenses.

**Table of Contents****Liquidity and Capital Resources**

At December 31, 2005, we had working capital of \$269.3 million compared with \$206.3 million at January 1, 2005. Cash and cash equivalents and short-term available-for-sale investments at December 31, 2005 were \$210.9 million compared to \$145.9 million at January 1, 2005. The increase is due primarily to cash generated from operations and proceeds from stock option exercises, offset in part by net purchases of property, plant and equipment and purchases of investment securities.

Cash provided by operating activities for the year ended December 31, 2005 was \$36.7 million. This amount included net income of \$13.2 million and non-cash adjustments to net income of \$23.4 million primarily made up of \$18.9 million for depreciation and amortization, \$7.3 million related to tax benefits on stock options, \$1.9 million related to amortization of deferred compensation expenses principally related to CEO transition costs, and \$1.2 million for unrealized costs related to investments and interest and other, partially offset by a \$5.9 million change in the deferred tax liability. Additionally, \$6.8 million was provided by accounts payable and other liabilities, driven by increased accruals for income taxes and compensation related costs, partially offset by an increase in cash used for inventory of \$3.8 million and an increase in accounts receivable of \$2.9 million due primarily to increased sales at the end of the year.

Investing activities used \$51.1 million, with \$43.1 million net purchases of investment securities and \$8.0 million to acquire property, plant and equipment, net of \$1.3 million in transfers of product inventory of drivers and demonstration equipment into fixed assets. The purchases of property, plant and equipment consisted of equipment purchases of \$9.4 million, of which \$5.7 million relates to the Cardiovascular segment and \$3.7 million relates to the ITC segment.

Cash provided by financing activities for year ended December 31, 2005 was \$34.4 million, including \$37.9 million from proceeds related to stock option exercises and purchases under our Employee Stock Purchase Plan partially offset by \$2.2 million paid to repurchase 0.2 million shares of stock under our stock repurchase programs in the first quarter of 2005 and \$1.3 million related to restricted stock forfeiture.

In March 2005, we agreed to purchase a new enterprise resource planning software system, or ERP system, for our ITC segment. The cost of the purchased software licenses, hardware, implementation costs and consulting for the ERP system for the year ended December 31, 2005 was \$1.2 million, with \$1.1 million capitalized.

In September 2005, we agreed to purchase a 67,000-square foot office building in Pleasanton, California for approximately \$13.4 million, subject to certain adjustments and other expenses at closing. During the third quarter of 2005 we paid a deposit of \$1.0 million. The remaining amount due, \$12.4 million, was paid at the close of escrow, which occurred in January 2006 and was paid for with existing cash.

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.

**Off Balance Sheet Arrangements**

*Letter of Credit* In the third quarter of 2004 we obtained an Irrevocable Standby Letter of Credit for \$460,000 as part of our workers compensation insurance program. The Letter of Credit is not collateralized. The Letter of Credit expires on June 30, 2006 and is scheduled to automatically renew each year on June 30th.

**Contractual Obligations**

As of December 31, 2005, we had the following contractual obligations (in millions):

	<b>Total</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>Thereafter</b>
Long-Term Debt Obligations (a)	\$ 265.8	\$ 3.4	\$ 3.4	\$ 3.4	\$ 3.4	\$ 3.4	\$ 248.8
Real Estate Purchase Obligation	12.4	12.4					
Operating Lease Obligations	19.4	2.9	2.9	2.5	2.2	2.2	6.7
Purchase Obligations	18.2	2.8	2.2	2.2	1.8	1.9	7.3

Total	\$ 315.8	\$ 21.5	8.5	8.1	7.4	7.5	262.8
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Our operating lease obligations of \$19.4 million were comprised of our various leased facilities and office equipment. Our purchase obligations of \$18.2 million were comprised of supply agreements in effect at December 31, 2005. The real estate obligation relates to the balance due at December 31, 2005 for the purchase of a 67,000-square foot office building in Pleasanton, California, which closed in January 2006.

(a) Includes interest of \$18.3 million and original issue discount of \$103.7 million. See note 7 to our audited consolidated financial statements in this Annual Report for data related to long-term debt.

***Accounting Pronouncements***

In December 2004, the Financial Accounting Standards Board ( FASB ) issued statement 123(R) Share-Based Payment, an amendment of FASB statements Nos. 123 and 95. 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. In April 2005, the Securities and Exchange Commission adopted a rule amendment that delayed the compliance dates for SFAS 123(R), and as such, we have adopted this statement on January 1, 2006.

We have elected to adopt the modified prospective application transition approach for implementing the provisions of SFAS 123(R). Under this method, stock compensation expense will be included in our financial statements as of January 1, 2006, on a prospective basis, without any restatement of prior period expense. In addition, we will continue to use the Black-Scholes model for the valuation of our stock-based awards consistent with our previously reported pro forma results under the original SFAS 123. The option life and forfeiture assumptions that we use under SFAS 123(R) will change as underlying stock option data is refined. The valuation assumptions, given stock option data refinements, may differ in material respects from those disclosed in the pro forma results under the original SFAS 123 disclosed previously in footnote #1 to the consolidated financial statements.

The effects of the adoption of SFAS 123(R) will result in significant, although non-cash, stock-based compensation expense which we estimate to be \$13.5 to \$14.5 million for our 2006 fiscal year.

In November 2005, the Financial Accounting Standards Board ( FASB ) issues FASB Staff Position (FSP) 115-1/124-1, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments. This FSP provides additional guidance on when an investment in a debt or equity security should be considered impaired and when that impairment is deemed other-than-temporary, even if a decision to sell has not been made. The FSP also requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. Companies are required to apply the guidance in this FSP to reporting periods beginning after December 15, 2005. We adopted this FSP in 2005.

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

Our investment portfolio is made up of marketable investments in money market funds, auction rate securities, U.S. Treasury securities and debt instruments of government agencies, 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 some of the investments in U.S. Treasuries that are held as restricted investments as collateral for future interest payments related to our convertible debt, which mature within three years from the original 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 its 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



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(primarily assets and liabilities on our U.K. subsidiary's consolidated balance sheet that are not denominated in U.K. Pounds Sterling) 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 in 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 December 31, 2005, we had forward foreign currency contracts in Euros with a notional value of \$4.4 million, and at January 1, 2005, we had forward foreign currency contracts in Pounds Sterling and Euros with a notional value at \$6.9 million. These contracts had an average exchange rate of Euros to U.S. dollars of 0.8358 as of December 31, 2005. The impact of foreign currency revaluation, net of forward foreign currency contracts, was a gain of \$0.1 million for the year ended December 31, 2005 and a loss of \$0.2 million for the year ended January 1, 2005.



**Item 8. Financial Statements and Supplementary Data**  
**THORATEC CORPORATION AND SUBSIDIARIES**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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**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 December 31, 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, and our overall control environment. 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 December 31, 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 a 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.

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**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 December 31, 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 December 31, 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 December 31, 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 schedule as of and for the year ended December 31, 2005 of the Company and our report dated March 15, 2006 expressed an unqualified opinion on those financial statements and financial statement schedule.

DELOITTE & TOUCHE LLP

San Francisco, California

March 15, 2006

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**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 December 31, 2005 and January 1, 2005, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for the years ended December 31, 2005, January 1, 2005 and January 3, 2004. Our audits also included the financial statement schedule listed in the Index to this Annual Report of Form 10-K at Part VI Item 15 (a) 2. These financial statements and the financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule 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 December 31, 2005 and January 1, 2005, and the results of their operations and their cash flows for the years ended December 31, 2005, January 1, 2005, and January 3, 2004, in conformity with accounting principles generally accepted in the U.S. of America. Also, in our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

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 December 31, 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 15, 2006 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.

DELOITTE & TOUCHE LLP

San Francisco, California

March 15, 2006

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

	For the Fiscal Year Ended	
	2005	2004
	(In thousands)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 35,109	\$ 16,017
Short-term available-for-sale investments	175,827	129,842
Restricted short-term investments	3,330	3,362
Receivables, net of allowances of \$634 in 2005 and \$708 in 2004	35,904	33,051
Inventories	41,671	39,141
Deferred tax asset	5,461	6,470
Prepaid expenses and other assets	3,582	3,873
Total current assets	300,884	231,756
Property, plant and equipment, net	28,906	27,584
Restricted long-term investments	1,610	4,845
Goodwill	94,097	94,097
Purchased intangible assets, net	141,938	153,141
Other assets	6,483	6,611
Total Assets	\$ 573,918	\$ 518,034
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 8,421	\$ 7,699
Accrued compensation	15,707	9,507
Accrued liabilities for legal, audit and warranty	1,602	1,610
Accrued income taxes	3,659	2,299
Other accrued liabilities	2,202	4,391
Total current liabilities	31,591	25,506
Senior subordinated convertible notes	143,750	143,750
Long-term deferred tax liability and other	50,430	56,670
Total Liabilities	225,771	200,420
Shareholders' equity:		
Common shares: authorized 100,000; issued and outstanding 51,737 in 2005 and 48,375 in 2004	407,531	364,775
Deferred compensation	(184)	(1,586)
Accumulated deficit	(58,801)	(71,514)
Accumulated other comprehensive income (loss):		
Unrealized gain (loss) on investments	(258)	(325)
Cumulative translation adjustments	(141)	758

Total accumulated other comprehensive income (loss)	(399)	433
Total Shareholders' Equity	348,147	292,108
Total Liabilities and Shareholders' Equity	\$ 573,918	\$ 518,034

See notes to consolidated financial statements.

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**THORATEC CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>For the Fiscal Years Ended</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>(In thousands, except per share data)</b>		
Product sales	\$ 201,712	\$ 172,341	\$ 149,916
Cost of product sales	78,372	72,119	61,168
Gross profit	123,340	100,222	88,748
Operating expenses:			
Selling, general and administrative	61,804	54,134	44,437
Research and development	32,331	28,657	26,052
Amortization of purchased intangible assets	11,204	11,724	12,333
Impairment of intangible asset			8,987
In-process research and development			220
Litigation, restructuring and other costs	95	733	2,132
Total operating expenses	105,434	95,248	94,161
Income (loss) from operations	17,906	4,974	(5,413)
Other income and (expense):			
Interest expense	(4,090)	(2,460)	
Interest income and other	4,237	2,176	1,837
Income (loss) before taxes	18,053	4,690	(3,576)
Income tax expense (benefit)	4,855	1,126	(1,394)
Net income (loss)	\$ 13,198	\$ 3,564	\$ (2,182)
Net income (loss) per share			
Basic	\$ 0.27	\$ 0.07	\$ (0.04)
Diluted	\$ 0.26	\$ 0.07	\$ (0.04)
Shares used to compute earnings (loss) per share:			
Basic	49,359	52,187	55,583
Diluted	51,008	53,160	55,583

See notes to consolidated financial statements.

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**THORATEC CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**

	<b>For the Fiscal Years Ended</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
		<b>(In thousands)</b>	
Net income (loss)	\$ 13,198	\$ 3,564	\$ (2,182)
Other net comprehensive income (loss):			
Unrealized gain (loss) on available-for-sale investments (net of taxes of \$(75), \$(130), and \$(54) in 2005, 2004, and 2003, respectively)	67	(376)	(79)
Foreign currency translation adjustments (net of taxes of \$(256) in 2005 and \$0 in 2004 and 2003, respectively)	(899)	394	273
Comprehensive income (loss)	\$ 12,366	\$ 3,582	\$ (1,988)

See notes to consolidated financial statements.



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**THORATEC CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**

	Common	Stock	Retained Earnings (Accumulated Deficit)	Deferred Compensation	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
	Shares	\$				
	(In thousands)					
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
Tax benefit related to employees' and directors' stock plans		2,148				2,148
Amortization of deferred compensation				1,105		1,105
Other comprehensive income:						
Unrealized loss on available-for-sale investments (net of taxes of \$(54))					(79)	(79)
Foreign currency translation adjustment					273	273
Net Loss			(2,182)			(2,182)
 BALANCE, 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
	(8,255)	(62,200)	(40,484)			(102,684)

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Repurchase of common stock							
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
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Exercise of common stock options for cash	3,509	36,671					36,671
Issuance of common shares under Employee Stock Purchase Plan	143	1,219					1,219
Tax benefit related to employees and directors stock plans		7,346					7,346
Repurchase of common stock	(233)	(1,753)	(485)				(2,238)
Restricted Stock Forfeiture	(57)	(1,259)					(1,259)
Amortization of deferred compensation		357		1,402			1,759
Expense of deferred compensation		175					175
Other comprehensive income:							
Unrealized loss on available-for-sale investments (net of taxes of \$(75))						67	67
Foreign currency translation adjustment (net of taxes of \$(256))						(899)	(899)
Net Income			13,198				13,198

BALANCE, DECEMBER 31, 2005	51,737	\$ 407,531	\$ (58,801)	\$ (184)	\$ (399)	\$ 348,147
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**THORATEC CORPORATION AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	For the Fiscal Years Ended		
	2005	2004 (In thousands)	2003
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 13,198	\$ 3,564	\$ (2,182)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	18,888	18,782	18,785
Investment premium amortization	374	948	18
Unrealized loss on available-for-sale investments		130	54
Impairment of intangible asset			8,987
In-process research and development			220
Non-cash interest and other expenses	588	778	32
Tax benefit related to stock options	7,346	485	2,148
Amortization of deferred compensation	1,934	715	1,105
Loss on disposal of asset	242	122	55
Change in net deferred tax liability	(5,862)	(2,178)	(4,756)
Changes in assets and liabilities:			
Receivables	(2,853)	(5,082)	565
Inventories	(3,813)	(3,116)	3,525
Prepaid expenses and other assets	(257)	(30)	(1,043)
Accounts payable and other liabilities	6,806	3,372	3,004
Other	73	(255)	
Net cash provided by operating activities	36,664	18,235	30,517
<b>Cash flows from investing activities:</b>			
Purchases of available-for-sale investments	(181,500)	(197,015)	(33,897)
Sales of available-for-sale investments	94,016	119,782	1,200
Maturities of available-for-sale and restricted investments	44,385	21,620	15,891
Capitalized transaction costs			(395)
Purchases of property, plant and equipment, net	(7,967)	(5,812)	(6,785)
Acquisition of product line			(5,200)
Net cash used in investing activities	(51,066)	(61,425)	(29,186)
<b>Cash flows from financing activities:</b>			
Net proceeds from issuance of convertible notes		139,454	
Proceeds from stock option exercises, net	36,671	2,432	9,494
Proceeds from stock issued under employee stock purchase plan	1,219	1,341	1,107
Restricted Stock Forfeiture	(1,259)		
Repurchase of common stock	(2,238)	(102,684)	

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Net cash provided by financing activities	34,393	40,543	10,601
Effect of exchange rate changes on cash and cash equivalents	(899)	394	194
Net increase (decrease) in cash and cash equivalents	19,092	(2,253)	12,126
Cash and cash equivalents at beginning of period	16,017	18,270	6,144
Cash and cash equivalents at end of period	\$ 35,109	\$ 16,017	\$ 18,270
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for taxes	\$ 3,176	\$ 1,114	\$ 889
Cash paid for interest	\$ 3,485	\$ 1,631	\$
<b>Supplemental disclosure of Non-cash investing and financing activities:</b>			
Transfers of equipment from inventory to property, plant and equipment	\$ 1,283	\$ 392	\$ 142
Cancellation of restricted stock	\$	\$ (328)	\$

See notes to consolidated financial statements.

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**THORATEC CORPORATION AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Operations and Significant Accounting Policies**

*Operations* Thoratec Corporation, 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 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 and incision products. We conduct business both domestically and internationally. In February 2001, we merged with Thermo Cardiosystems, Inc., or TCA. Prior to the merger with TCA (the Merger), TCA was a subsidiary of Thermo Electron Corporation, or TCI. In September 2003, ITC acquired the Immediate Response Mobile Analysis, or IRMA, point-of-care blood analysis system product line from Diametrics Medical, Inc., or 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 January 3, 2004, (2003) and January 1, 2005 (2004) included 53 weeks and the fiscal year ended December 31, 2005 (2005) included 52 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 total product sales in fiscal year 2005, 2004 or 2003. No distributor customer accounted for 10% or more of total accounts receivable as of the year end of 2005. One distributor customer accounted for 11% of total accounts receivable as of the end of 2004. No other customer had an accounts receivable balance greater than 10% of total accounts receivable at the end of 2005 or 2004.

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 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; physician acceptance of our current or future products; our reliance on specialized suppliers; 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 ability to identify and correct quality issues in a timely manner and at a reasonable cost; new product development and introduction, including FDA approval and market receptiveness; our ability to develop and introduce new products; the ability to protect our proprietary technologies or an infringement of others' patents; the number of heart transplants conducted; any reduction in the number of medical procedures requiring certain types of blood monitoring; our dependence upon distributors and any changes made to our method of distribution; competition from other 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; foreign currency fluctuations; certain lawsuits that have been filed against us; the long and variable sales and deployment cycle of our ventricular assist device

( VAD ) products; the ability of third party payors to cover and provide appropriate levels of reimbursement for our products; our convertible notes, their repayment and potential related dilution from conversion; the ability to realize the full value of our intangible assets; claims relating to the handling, storage or disposal of hazardous chemicals and biomaterials; the ability to attract and retain talented employees; stock price volatility due to general economic conditions or future issuances and sales of our

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stock; product liability or other claims; the integration of any current and future acquisitions of companies or technologies; the occurrence of natural catastrophic disasters; and the ability to achieve and maintain profitability.

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

*Investments* Investments classified as short-term available-for-sale are reported at fair value based upon quoted market prices and consist primarily of auction rate securities, corporate and municipal bonds, and U.S. government obligations. All investments mature within two years or less from the date of purchase. Investments with maturities beyond one year may be classified as short-term, if they are available and intended for use in current operations, based on their highly liquid nature or due to the frequency with which the interest rate is reset such as with auction rate securities.

Investments classified as restricted are securities held in U.S. Treasuries as collateral for future interest payments related to our convertible debt and are reported at fair value based upon quoted market prices. 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.

For all investments, temporary differences between cost and fair value are presented as a separate component of accumulated other comprehensive income. We have determined that the investments had no impairments that were other than temporary. The specific identification method is used to determine realized gains and losses on investments.

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

*Property, Plant and Equipment* Property, plant and equipment is 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. Depreciation 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. In 2005, our ITC segment capitalized costs for a new enterprise resource planning software system ( ERP System ) of \$1.2 million. No depreciation expense related to this ERP System has been recorded as the project had not been placed into service as of December 31, 2005. 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, we periodically evaluate the carrying value of long-lived assets to be held and used including intangible assets, when events or circumstances warrant such a review. The carrying value of a long-lived asset to be held and used is considered impaired when the anticipated separately identifiable undiscounted cash flows from such an asset are less than the carrying value of the asset. In that event, a loss is recognized based on the amount by which the carrying value exceeds the fair value of the long-lived asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved.

*Purchased Intangible Assets and Goodwill* In accordance with SFAS No. 142, Goodwill and Other Intangible Assets, we do not amortize 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 2005, we determined that neither goodwill nor intangible assets were impaired.



*Fair Value of Financial Instruments* Financial instruments include cash and cash equivalents, short-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 available-for-sale and restricted 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.

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*Sick Leave Accruals* Costs are accrued in connection with sick leave benefits by our ITC segment. These are estimated amounts that have been earned and the Company believes will be paid out to employees in a future period.

*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 statements of operations.

*Foreign Currency Translation* 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's consolidated balance sheet that are not denominated in UK Pounds Sterling) at the period-end exchange rates result in foreign currency gains and losses, which 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 re-measurement 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 Sterling). 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 December 31, 2005, the company had forward foreign currency contracts to exchange Euros for U.S. dollars with both a notional value and a fair value of \$4.4 million. Net foreign currency exchange gain was \$0.1 million in 2005, a loss of \$0.2 million in 2004, and negligible in 2003.

*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, \$25.0 million in July 2004 and \$20.0 million in February 2006. Through December 2005, we repurchased 8.5 million shares of our common stock for \$104.9 million under these 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. Other distributors have certain rights of return upon termination of their distribution agreement. A reserve for sales returns is recorded for these customers applying reasonable estimates of product returns based upon significant historical experience in accordance with SFAS No. 48, Revenue Recognition when Right of Return Exists. No other direct sales customers or distributors have return rights or price protection.

Sales of certain Cardiovascular 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. Training is not essential to the functionality of the products. The amount of revenue under these arrangements allocated to training is based upon fair market value of the training, which is typically performed on behalf of the Company by third party providers. The amount of product sales allocated to the Cardiovascular segment products is done on a fair value basis. Under this approach, 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.

On December 5, 2005 we modified our distributor agreement with C.R. BARD Corporation to continue the exclusive distribution of our *Vectra* product line until December 31, 2006. We received a payment of \$1.8 million in 2004, from C.R. BARD Corporation, of which \$1.7 million was recognized in 2005. The remaining amount 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 2005, 2004, and 2003 are \$7.2 million, \$5.8 million, and \$4.7 million, respectively, of income earned from the rental of these medical devices.

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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 2005, 2004 and 2003 is summarized in the following table (in thousands):

	<b>Balance Beginning of Year</b>	<b>Charges to Costs and Expenses</b>	<b>Warranty Expenditures</b>	<b>Balance End of Year</b>
Fiscal year ended 2005	\$618	\$772	\$ (317)	\$1,073
Fiscal year ended 2004	\$829	\$173	\$ (384)	\$ 618
Fiscal year ended 2003	\$695	\$193	\$ (59)	\$ 829

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

	<b>For Fiscal Year Ended</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net income (loss):			
As reported	\$ 13,198	\$ 3,564	\$ (2,182)
Add: Stock-based compensation expense included in reported net income, net of related tax effects	1,412	793	693
Deduct: Total stock-based compensation expense determined under fair value based method for all awards, net of related tax effects	(6,793)	(12,524)	(7,363)
Pro forma net income (loss)	\$ 7,817	\$ (8,167)	\$ (8,852)
Basic and Diluted earnings (loss) per share:			
As reported			
Basic	\$ 0.27	\$ 0.07	\$ (0.04)
Diluted	\$ 0.26	\$ 0.07	\$ (0.04)
Pro forma income (loss)			
Basic	\$ 0.16	\$ (0.16)	\$ (0.16)
Diluted	\$ 0.15	\$ (0.16)	\$ (0.16)

The decrease in stock-based compensation expense under the fair value based method, net of tax effects, in 2005 was primarily due to a decrease in the number of options granted in 2005, partially offset by an increase in the effective tax rates and an increase in the amortization of restricted stock due to acceleration of vesting related to the CEO transition.

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:

<b>Stock Option Plans For Fiscal Year Ended</b>			
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Risk-free interest rate	4.20%	4.36%	3.69%
Expected volatility	45%	62%	67%
	3.74	3.36	
Expected option life	years	years	3.88 years
Dividends	None	None	None

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	<b>Employee Stock Purchase Plan For Fiscal Year Ended</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Risk-free interest rate	3.09%	1.32%	1.16%
Expected volatility	48%	61%	67%
	0.50	0.50	
Expected option life	years	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 for the full year.

**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 Financial Accounting Standards Board ( FASB ) issued statement 123(R) Share-Based Payment, an amendment of FASB statements Nos. 123 and 95. 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. In April 2005, the Securities and Exchange Commission adopted a rule amendment that delayed the compliance dates for SFAS 123(R), and as such, we have adopted this statement on January 1, 2006.

We have elected to adopt the modified prospective application transition approach for implementing the provisions of SFAS 123(R). Under this method, stock compensation expense will be included in our financial statements as of January 1, 2006, on a prospective basis, without any restatement of prior period expense. In addition, we will continue to use the Black-Scholes model for the valuation of our stock-based awards consistent with our previously reported pro forma results under the original SFAS 123. The option life and forfeiture assumptions that we use under SFAS 123(R) will change as underlying stock option data is refined. The valuation assumptions, given stock option data refinements, may differ in material respects from those disclosed in the pro forma results under the original SFAS 123 disclosed previously in footnote #1 to the consolidated financial statements.

The effects of the adoption of SFAS 123(R) will result in significant, although non-cash, stock-based compensation expense which we estimate to be \$13.5 to \$14.5 million for our 2006 fiscal year.

In November 2005, the Financial Accounting Standards Board ( FASB ) issues FASB Staff Position (FSP) 115-1/124-1, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments. This FSP provides additional guidance on when an investment in a debt or equity security should be considered impaired and when that impairment is deemed other-than-temporary, even if a decision to sell has not been made. The FSP also requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. Companies are required to apply the guidance in this FSP to reporting periods beginning after December 15, 2005. We adopted this FSP in 2005.

**Presentation** We have reclassified the long-term deferred tax asset balance to the long-term deferred tax liability on the 2004 Consolidated Balance Sheet in order to conform to the 2005 presentation of a single net long-term deferred tax balance.

**2. 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 or due to the frequency with which the interest rate is reset and because such marketable securities represent the investment of cash that is available for current operations. We include any unrealized gains and losses on short-term investments, net of tax, in shareholders equity as a component of other comprehensive income.

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.

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Individual securities with a fair value below the cost basis at December 31, 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 and the Company does not intend to liquidate these securities while their fair value is less than cost. The purchase value of securities temporarily impaired for less than 12 months were \$25.9 million, for 12 months or more were \$43.5 million and with no impairment \$140.9 million as of the fiscal year end 2005.

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 2005 and 2004 by major security type are as follows (in thousands):

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized Losses</b>	<b>Fair Value</b>
As of Fiscal Year End 2005:				
Short-term investments:				
Municipal bonds and auction rate securities	\$ 167,694	\$	\$ (323)	\$ 167,371
U.S. government obligations	8,500		(45)	8,456
Restricted investments in U.S. Government obligations	3,363		(33)	3,330
	179,557		(401)	179,157
Long-term investments:				
Restricted Investments in U.S. Government obligations	1,639		(29)	1,610
	\$ 181,196	\$	\$ (430)	\$ 180,767
As of Fiscal Year End 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

The contractual maturities of available-for-sale investments and restricted investments as of December 31 2005 and January 1, 2005, regardless of the consolidated balance sheet classifications, are as follows (in thousands):

	<b>Amortized Cost</b>	<b>Fair Value</b>
As of Fiscal Year End 2005:		
Due within one year	\$ 117,768	\$ 117,759



Due after one year through two years	60,121	59,753
Due after two years through three years	3,307	3,255
	\$ 181,196	\$ 180,767

## As of Fiscal Year End 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

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 2005 and 2004 there were no significant gains or losses recorded.

**3. Inventories**

Inventories consisted of the following (in thousands):

	<b>As of Fiscal Year</b>	
	<b>2005</b>	<b>2004</b>
Finished goods	\$ 19,952	\$ 18,562
Work-in-process	6,303	4,582
Raw materials	15,416	15,997
Total	\$ 41,671	\$ 39,141

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The change in the carrying amount of goodwill, which is only attributable to our Cardiovascular business segment, for fiscal years 2005 and 2004, was as follows (in thousands):

	<b>As of Fiscal Year</b>	
	<b>2005</b>	<b>2004</b>
Balance at the beginning of year	\$ 94,097	\$ 96,065
Adjustment to reflect realization of acquired deferred tax asset		(1,153)
Reversal of accrual for securities registration costs		(815)
Balance as of December 31, 2005	\$ 94,097	\$ 94,097

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 was expected to begin utilizing a portion of this NOL benefit, a portion of the original valuation allowance had 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 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 (Thoralon, our patent protected bio-material that is present in most products) and developed technology (patent technology, other than core technology, acquired in our merger with TCA), which are included in purchased intangible assets on the consolidated balance sheets, are as follows (in thousands):

	<b>Fiscal Year 2005</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Patents and Trademarks	\$ 37,815	\$ (17,692)	\$ 20,123
Core Technology	37,485	(8,762)	28,723
Developed Technology	122,782	(29,750)	93,032
Non-compete Agreement	90	(30)	60
Total Purchased Intangible Assets	\$ 198,172	\$ (56,234)	\$ 141,938

	<b>Fiscal Year 2004</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Patents and Trademarks	\$ 37,815	\$ (14,051)	\$ 23,764
Core Technology	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
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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 in 2003 to write off purchased intangible assets related to the Aria graft, which were recorded as a result of the merger.

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Amortization expense related to identifiable intangible assets for fiscal 2005, 2004, and 2003 was \$11.2 million, \$11.7 million and \$12.3 million, respectively. Amortization expense is expected to be approximately \$11.7 million for each of the next five years. Patents and trademarks have useful lives of eight to twenty years, core and developed technology assets have useful lives ranging from nine to twenty-four years and the useful life of the non-compete agreement is approximately six years.

**5. Property, Plant and Equipment**

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

	<b>As of Fiscal Year</b>	
	<b>2005</b>	<b>2004</b>
Land	\$ 341	\$ 341
Building	2,445	2,445
Building lease	2,285	2,285
Equipment	44,067	38,728
Rental equipment	7,334	6,810
Leasehold improvements	11,526	11,061
Total	67,998	61,670
Accumulated depreciation and amortization	(39,092)	(34,086)
	\$ 28,906	\$ 27,584

Depreciation expense in 2005, 2004, and 2003 was \$7.7 million, \$7.1 million and \$5.7 million, respectively. The estimated lives of some computer equipment were adjusted from five years to three years and the estimated lives of certain sales and marketing equipment were adjusted from three years to two years in 2005. These changes are not material to our consolidated financial statements.

**6. 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 2005 are noted below (in thousands):

**Fiscal year:**

2006	\$ 2,944
2007	2,917
2008	2,528
2009	2,221
2010	2,190
Thereafter	6,664
Total	\$ 19,464

Rent expense for all operating leases was \$2.5 million in 2005, \$2.5 million in 2004 and \$2.1 million in 2003.

*Commitments*

We had various purchase order commitments, which were comprised of supply agreements, totaling approximately \$18.2 million and \$19.8 million as of the end of fiscal years 2005 and 2004, respectively.

*Contingencies*

We are involved in various litigation matters (See Note 13).

**7. 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

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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 on our consolidated balance sheets as restricted short-term and long-term investments. Additional net proceeds were used to repurchase 4.2 million shares of our outstanding common stock for \$60 million. The remaining net proceeds have been and 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 \$3.3 million, net of \$1.0 million in amortization, are included in Other assets on the consolidated balance sheet as of December 31, 2005. 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.

	<b>Fiscal Year 2004 (in millions)</b>
<b>Long Term Debt Offering Proceeds:</b>	
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 have been and are 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 than 120% of the accreted conversion price per share of our common stock. Holders may surrender their convertible notes for conversion on or before 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. However, in such event, if on the day before any conversion the closing sale price of our common stock is greater than the accreted conversion price (i.e., the issue price of the note plus accrued original issue discount divided by the conversion rate) but less than or equal to 120% of the accreted conversion price, instead of shares of our common stock based on the conversion rate, holders will receive cash or common stock, or a combination of each 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 December 31, 2005 no notes had 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 of our common stock 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. This premium is considered an embedded derivative under SFAS 133 and has been bifurcated from the convertible notes and recorded at its estimated fair value, \$0.2 million and none at December 31, 2005 and January 1, 2005, respectively. There are significant variables and assumptions used in valuing the make-whole provision including, but not limited to, the company's stock price, volatility of the company's stock, the probability of acquisition and the probability of the type of consideration used by a potential acquirer.

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 for our failure to comply with our registration obligations regarding the convertible notes.

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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 December 31, 2005, based on market quotes, was \$172.0 million.

**8. Common and Preferred Stock**

We have authorized 100 million shares of no par common stock, and 2.5 million shares of no par 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 December 31, 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 shares vote on an as-converted basis. At December 31, 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 at any time 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.

**9. 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 of restricted stock were granted to a consultant in December 2004. This award is re-valued each period at the current market rate and is accrued ratably over the restriction lapse period of three years.



In August 2005 Mr. Grossman, our CEO, announced his resignation and entered into an agreement which amended his employment contract and provides that he would remain employed by the Company for up to three months following the appointment of the Replacement CEO in order to assist in the transition (the "Transition Period"). We expect that Mr. Grossman will remain a member of the Company's Board of Directors and, for the nine months following the end of the Transition Period, Mr. Grossman will provide consulting services to the Company pursuant to a Consulting Services Agreement dated August 15, 2005. Pursuant to the terms of the amended employment agreement with Mr. Grossman, his restricted common stock was accelerated over the transition period, generating an additional \$0.9 million in expense in 2005. As of the end of fiscal 2005, 125,000 shares had vested.

**Table of Contents***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 have been no grants under any of TCA's plans since the merger. 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 shares 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 they were 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 2005 or 2004.

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 2005 and 2004 no options were granted at fair market value under Part One of the 1996 SOP. Part Two related to the former Chief Executive Officer, Mr. Grossman, and permitted us to grant non-qualified options to the former 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 options granted in each year ended 2005 and 2004, 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 2005 and 2004, 0.6 million and 3.1 million options, respectively, were granted at fair market value under this plan. During 2005 and 2004, no shares and 25,000 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 December 31, 2005. Options may be granted by the Board of Directors at the fair market value on the date of grant and generally become fully exercisable within five years of grant and expire between five and ten years from the date of grant. At the end of 2005, options to purchase 2.2 million common shares remain available for grant under all the plans.

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

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
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

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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
Granted (\$5.45 weighted average fair value per share)	609		14.65
Cancelled and expired	(931)		13.77
Exercised	(3,509)		10.44
Outstanding at fiscal year end 2005 (3,574 exercisable at \$12.64 weighted average price per share)	6,445	\$	12.80

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Options outstanding as of the end of 2005 are summarized as follows:

Exercise Price Range	Number Outstanding	Options Outstanding		Exercise Price	Number Outstanding	Options Exercisable Weighted Average Exercise Price
		Weighted Average Remaining Contractual Life (In Years)	Weighted Average			
\$4.37 - \$6.00	233,394	4.99	\$ 5.74		174,839	\$ 5.72
6.01 - 9.00	526,726	5.83	8.27		307,114	8.05
9.01 - 12.00	1,195,775	6.06	10.13		857,638	9.95
12.01 - 15.00	2,710,328	7.84	12.99		1,153,635	13.06
15.01 - 18.00	1,617,451	6.68	16.00		963,649	15.97
18.01 - 33.05	161,792	5.82	22.33		117,412	23.11
	6,445,466	6.90	12.80		3,574,287	12.64

***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 2005. 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 143,000 shares of common stock were issued in 2005 for \$1.2 million. Approximately 147,000 shares of common stock were issued in 2004 for \$1.3 million. As of the end of fiscal year 2005, approximately 87,000 shares are available for issuance under this plan.

**10. Taxes on Income**

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

	For Fiscal Year Ended		
	2005	2004	2003
Current:			
Federal	\$ 2,647	\$ 401	\$ 232
State	1,687	529	873
Foreign	980	1,126	13
	5,314	2,056	1,118
Deferred:			
Federal	1,631	(112)	(2,175)
State	(2,090)	(818)	(764)
Foreign			427
	(459)	(930)	(2,512)

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Total income tax provision (benefit)	\$ 4,855	\$ 1,126	\$ (1,394)
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The domestic and foreign components of income (loss) before income taxes are as follows (in thousands):

	<b>For the Fiscal Years ended</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Domestic	\$ 14,857	\$ 1,470	\$ (5,123)
Foreign	3,196	3,220	1,547
Income (loss) before income taxes	\$ 18,053	\$ 4,690	\$ (3,576)

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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):

	<b>For Fiscal Year</b>					
	<b>2005</b>		<b>Ended</b>		<b>2003</b>	
			<b>2004</b>			
U.S. federal statutory income tax expense (benefit)	\$ 6,318	35.0%	\$ 1,641	35.0%	\$ (1,251)	35.0%
State income tax expense (benefit), net of federal tax expense (benefit)	(421)	(2.3)	(5)	(.1)	(126)	3.5
Non-deductible expenses	596	3.2	547	11.5	398	(11.0)
Research and development and other credit carryforwards	(432)	(2.3)	(798)	(16.9)	(343)	9.5
Foreign earnings permanently reinvested					(72)	2.0
Tax advantaged investment income	(1,204)	(6.7)	(259)	(5.5)		
	\$ 4,855	26.9%	\$ 1,126	24.0%	\$ (1,394)	39.0%

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):

	<b>As of Fiscal Year</b>	
	<b>2005</b>	<b>2004</b>
Deferred tax assets:		
Write-off of acquired technology	\$ 775	\$ 913
Reserves and accruals	2,540	2,463
Depreciation and amortization		842
Inventory basis difference	2,394	2,627
Research and development and other credit carryforwards	7,351	3,830
Net operating loss carryovers	901	2,107
Other, net	30	69
Total deferred tax assets	13,991	12,851
Deferred tax liabilities:		
Purchased intangibles	(55,985)	(60,971)
Depreciation and amortization	(1,264)	(1,046)
Other, net	(46)	12
Net deferred tax liabilities	\$ (43,304)	\$ (49,154)

Foreign earnings were considered to be permanently invested in operations outside the United States through 2005, except for those earnings required to be allocated to Subpart F income.

At the end of 2005, we had federal net operating loss ( NOL ) carryforwards of approximately \$2.6 million. If not utilized, the federal NOL will begin expiration in 2021.

At the end of 2005, we had available carryforward research and experimentation tax credits for federal and state income tax purposes of approximately \$2.7 million and \$2.4 million, respectively. Federal tax credit carryforwards

expire from 2010 through 2025. State tax credit carryover 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 \$7.5 million, \$0.5 million and \$2.1 million in 2005, 2004 and 2003, 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.

**Table of Contents****11. Enterprise and Related Geographic Information**

We organize and manage our business by functional operating entities. Our functional entities operate in two segments: Cardiovascular and 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 and incision devices.

**Business segments (in thousands):**

	<b>For the Fiscal Year Ended</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Product sales:			
Cardiovascular	\$ 125,181	\$ 103,002	\$ 94,382
ITC	76,531	69,339	55,534
Total product sales	\$ 201,712	\$ 172,341	\$ 149,916
Income (loss) before taxes:			
Cardiovascular(a)	\$ 15,103	\$ 2,129	\$ 1,315
ITC(a)	13,657	9,940	10,542
Corporate (b)	(10,759)	(6,362)	(5,931)
In-process research and development			(220)
Impairment of intangible asset			(8,987)
Litigation, restructuring and other costs (c)	(95)	(733)	(2,132)
Total operating income (loss)	17,906	4,974	(5,413)
Other income and (expense):			
Interest expense	(4,090)	(2,460)	
Interest income and other	4,237	2,176	1,837
Total income (loss) before taxes	\$ 18,053	\$ 4,690	\$ (3,576)
Total assets:			
Cardiovascular	\$ 307,043	\$ 314,636	\$ 326,872
ITC	41,701	38,437	31,546
Corporate (b)	233,002	171,342	117,713
Total assets	\$ 581,746	\$ 524,415	\$ 476,131
Depreciation and amortization:			
Cardiovascular	\$ 16,728	\$ 16,854	\$ 18,797
ITC	2,160	1,928	1,222
Total depreciation and amortization	\$ 18,888	\$ 18,782	\$ 20,019
Capital expenditures:			
Cardiovascular	\$ 5,692	\$ 3,734	\$ 4,785
ITC(d)	3,724	2,477	4,634
Total capital expenditures	\$ 9,416	\$ 6,211	\$ 9,419



- (a) Amortization expense of \$11.0 million, \$11.6 million and \$12.3 million for the fiscal years ended 2005, 2004 and 2003 respectively, related to the Cardiovascular segment. The ITC segment had amortization expense of \$0.2 million for the fiscal years ended 2005 and 2004 respectively and \$44,000 for the fiscal year ended 2003.
- (b) Represents primarily general and administrative items not specifically identified to any particular business segment.
- (c) In 2005 and 2004, relates to expenses not specifically identified to any particular business segment. In 2003, 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.

**Table of Contents****Geographic Areas (in thousands):**

	<b>For the Fiscal Year Ended</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Product Sales:			
Domestic	\$ 154,711	\$ 133,081	\$ 121,831
International	47,001	39,260	28,085
Total	\$ 201,712	\$ 172,341	\$ 149,916

**12. 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 2005, 2004 and 2003, 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 2005, 2004 and 2003, we made contributions to the Retirement Plan of approximately \$0.9 million, \$0.9 million and \$0.8 million, respectively.

In 2004, we established a non-qualified, unfunded deferred 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 \$0.8 million and \$0.3 million at December 31, 2005 and January 1, 2005, 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 \$1.5 million and \$1.0 million at December 31, 2005 and January 1, 2004, respectively, and is included in Other Assets.

**13. Litigation, Restructuring and Other Costs**

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

	<b>For the Fiscal Years Ended</b>		
	<b>2005</b>	<b>2004</b>	<b>2003</b>
Litigation	\$ 95	\$ 733	\$ 2,256
Restructuring and other			(124)
Total	\$ 95	\$ 733	\$ 2,132

***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.

On August 3, 2004, a putative Federal securities law class action entitled *Johnson v. Thoratec Corporation, et al.* was filed in the U.S. District Court for the Northern District of California on behalf of purchasers of our publicly traded securities between April 28, 2004 and June 29, 2004. Subsequent to the filing of the *Johnson* complaint, additional complaints were filed in the same court alleging substantially similar claims. On November 24, 2004, the Court entered an order consolidating the various putative class action complaints into a single action entitled *In re Thoratec Corp. Securities Litigation* and thereafter entered an order appointing Craig Toby as Lead Plaintiff pursuant to the Private Securities Litigation Reform Act of 1995. On or about January 18, 2005, Lead Plaintiff filed a

Consolidated Complaint. The Consolidated Complaint generally alleges violations of the Securities Exchange Act of 1934 by Thoratec, its former Chief Executive Officer, its former Chief Financial Officer and its Cardiovascular Division President 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 Consolidated Complaint seeks to recover unspecified damages on behalf of all purchasers of the Company's publicly traded securities during the putative class period. On March 4, 2005, defendants moved to dismiss the Consolidated Complaint and that motion currently is pending.

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 class action suit referred to above. This

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action names the individual members of our Board of Directors, including the former Chief Executive Officer and certain other former and current executive officers of the Company, as defendants, and alleges that the defendants breached their fiduciary duties and wasted corporate assets, and that certain of the defendants traded in Thoratec securities while in possession of material nonpublic information. Proceedings in *Wong v. Grossman* are currently stayed until at least April 2006.

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 moved to dismiss the Federal action and will file a similar motion in the *Wong* action if necessary.

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 potential 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.

***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. There was \$118,000 reversed in 2003 related to the restructuring.

In the fourth quarter of 2002, we terminated a European distribution agreement. In the first quarter of 2003 expenses related to the termination were paid, the actual amount paid was \$6,000 less than the amount accrued and the amount reversed in the second quarter of 2003.

**14. 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. Options to purchase 2.0 million, 6.2 million and 3.3 million shares of common stock were not included in the computation of diluted earnings and losses per share for 2005, 2004 and 2003, respectively, as their inclusion would be antidilutive. In addition, the computation of diluted earnings per share for 2005 and 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 for the full year.

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

	<b>2005</b>	<b>2004</b>	<b>2003</b>
Net income (loss)	\$ 13,198	\$ 3,564	\$ (2,182)
Weighted average number of common shares-Basic	49,359	52,187	55,583
Dilutive effect of stock-based compensation plans	1,649	973	
Weighted average number of common shares-Diluted	51,008	53,160	55,583
Net income (loss) per share			
Basic	\$ 0.27	\$ 0.07	\$ (0.04)
Diluted	\$ 0.26	\$ 0.07	\$ (0.04)

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

The following is a summary of our unaudited quarterly results of operations for fiscal years 2005 and 2004:

	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>
		<b>(In thousands, except per share data)</b>		
Fiscal Year 2005 Product sales	\$50,488	\$47,588	\$48,841	\$54,795
Gross profit	30,440	29,201	30,231	33,468

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Net income (loss)	3,135	2,421	3,102	4,540
Net income (loss) per share				
Basic	\$ 0.07	\$ 0.05	\$ 0.06	\$ 0.09
Diluted(a)	\$ 0.06	\$ 0.05	\$ 0.06	\$ 0.08
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
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(a) The total of Net Income (loss) per share, diluted, for the quarters is not equal to the full year due to the inclusion of the 7.3 million shares available upon conversion of our convertible notes as they were dilutive for the fourth quarter of 2005 but not for the full year.

### **16. Subsequent Events**

In September 2005, we agreed to purchase a 67,000-square foot office building in Pleasanton, California, subject to certain adjustments and expenses at closing. The purchase was completed on January 6, 2006 for \$13.4 million, which includes all costs incurred and adjustments made, using the Company's current cash balances.

In February 2006, the Board of Directors authorized a stock repurchase program under which up to \$20 million of our common stock could be acquired in the open market or in privately negotiated transactions.

### **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 Chief Financial Officer, which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the Exchange Act). 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 management's report on internal control over financial reporting as of December 31, 2005, and 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 as of December 31, 2005. This section should be read in conjunction with management's report on internal control over financial reporting as of December 31, 2005 and the report of Deloitte & Touche LLP 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 Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, as of December 31, 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 Chief Financial Officer, concluded that as of December 31, 2005 the Company's disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, were effective.

### ***Changes to Internal Controls***

As part of the implementation of section 404 of the Sarbanes Oxley Act of 2002, the Company instituted internal controls that were designed to detect errors. There have been no changes in our internal controls over financial reporting during the quarter ended December 31, 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 Chief Financial Officer, does not expect that internal controls will

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prevent all error and all fraud. A control system, no matter how well designed 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. While our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, there can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. While our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2005, the design of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

**Item 9B. Other Information**

None.

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

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 2006 annual meeting of shareholders.

**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 2006 annual meeting of shareholders.

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

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 and Executive Compensation Plan Information in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2006 annual meeting of shareholders.

**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 2006 annual meeting of shareholders.

**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 2006 annual meeting of shareholders.



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**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 December 31, 2005, January 1, 2005, and January 3, 2004.

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 68 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 December 31, 2005**

	<b>Balance Beginning of Year</b>	<b>Additions (charges to expense)</b>	<b>Deductions</b>	<b>Balance End of Year</b>
	<b>(In thousands)</b>			
Year Ended December 31, 2005:				
Allowance for doubtful accounts	\$ 708	\$ 96	\$ (170)(1)	\$ 634
Accrued product warranty	\$ 618	\$ 772	\$ (317)(2)	\$ 1,073
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

(1) Accounts  
written off, net  
of recoveries.

(2) Warranty  
expenditures  
incurred.

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**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit</b>
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	Intellectual Property Cross-license Agreement between Thermedics and the Thoratec Cardiosystems dated August 19, 1988.(6)
10.2	Form of Indemnification Agreement between Thoratec Cardiosystems and its officers and directors.(6)
10.3	Thoratec's 1993 Stock Option Plan.(7)
10.4	Agreement dated May 26, 1993, between The Polymer Technology Group. Incorporated and the Thoratec Cardiosystems.(8)
10.5	Thoratec's 1996 Stock Option Plan.(9)
10.6	Thoratec's 1996 Nonemployee Directors Stock Option Plan, as amended. (10)
10.7	Lease Agreement dated July 25, 1996, between Main Street Associates and Thoratec, as amended.(11)
10.8	First Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(12)
10.9	Second Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(13)

10.10	Thoratec's 1997 Stock Option Plan, as amended.(14)
10.11	Amended and Restated Directors Stock Option Plan of Thoratec Cardiosystems.(15)
10.12	Amended and Restated Nonqualified Stock Option Plan of Thoratec Cardiosystems.(15)
10.13	Agreement and Plan of Merger by and among Thoratec, Lightning Acquisition Corporation, Thermo Cardiosystems Inc, and Thermo Electron Corporation dated October 3, 2000.(16)
10.14	Registration Rights Agreement by and between Thoratec and Thermo Electron dated October 3, 2000.(16)
10.15	Shareholder Agreement by and between Thoratec and Thermo Electron dated October 3, 2000.(16)
10.16	Lease agreement dated August 16, 1995, between International Technidyne Corporation and BHBMC, as amended.(17)

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<b>Exhibit Number</b>	<b>Exhibit</b>
10.17	Amended and Restated Employment Agreement by and between Thoratec and D. Keith Grossman, dated August 15, 2005.(18)*
10.18	Thoratec s 2002 Employee Stock Purchase Plan.(19)
10.19	Thoratec s Deferred Compensation Plan effective as of January 1, 2004. (10)
10.20	Grantor Trust Agreement between Thoratec and Wachovia Bank, National Association effective as of November 21, 2003.(10)
10.21	Commercial Lease between International Technidyne Corporation and Roseville Properties Management Company dated September 26, 2003. (10)
10.22	Lease Agreement between International Technidyne Corporation and NJ Mortgage Association dated February 21, 2003. (21)
10.23	Description of the Executive Disability Income Protection Program.(20)
10.24	Consulting Agreement by and between Thoratec and D. Keith Grossman, dated August 15, 2005.(18)*
10.25	Employment Agreement by and between Thoratec and Jeffrey Nelson, dated August 15, 2005.(18)*
10.26	Employment Agreement by and between Thoratec and Lawrence Cohen, dated August 15, 2005.(18)*
10.27	Purchase and Sale Agreement and Escrow Instructions dated September 2, 2005, by and between Thoratec and Aegis I, LLC.(22)
10.28	Offer letter Agreement by and between Thoratec and Cynthia Lucchese dated August 1, 2005.*
10.29	Employment Agreement by and between Thoratec and Gerhard F. Burbach dated January 13, 2006.(23)*
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 Chief Financial Officer
32.1	Section 906 Certification of Chief Executive Officer

32.2 Section 906 Certification of Chief Financial Officer

- (1) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended December 28, 2002 filed with the SEC on March 20, 2003 and incorporated herein by reference.
- (2) Filed as an Exhibit to Thoratec's Form 8-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.

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- (6) Filed as an Exhibit to Thoratec Cardiosystems Registration Statement on Form S-1 (Registration No. 33-25144) and incorporated herein by reference.
- (7) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended January 1, 1994 filed with the SEC on March 22, 1994, and incorporated herein by reference.
- (8) Filed as an Exhibit to Thoratec Cardiosystems Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 1993 and incorporated herein by reference.
- (9) Filed as an Exhibit to Thoratec's Registration Statement on Form S-8 filed with the SEC on September 12, 1996,



(Registration  
No. 333-11883)  
and incorporated  
herein by  
reference.

(10) Filed as an  
Exhibit to  
Thoratec's 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.

(11) 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.

(12) 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.

(13) 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.

(14) 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.

(15) 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.

(16) 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.

(17) 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.

(18) Filed as an  
Exhibit to  
Thoratec's Form  
8-K filed with the  
SEC on  
August 19, 2005.

(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 Annual  
Report on Form  
10-K for the fiscal  
year ended  
January 1, 2005  
filed with the SEC  
on March 16,  
2005 and  
incorporated  
herein by  
reference.

(21) 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.

(22) Filed as an  
Exhibit to  
Thoratec's Form  
8-K filed with the  
SEC on  
September 8,  
2005

(23) Filed as an  
Exhibit to  
Thoratec's Form  
8-K filed with the  
SEC on  
January 18, 2006

\* Indicates a  
management  
contract or  
compensatory  
plan.

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**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 15th day of March 2006.

THORATEC CORPORATION

By: /s/ Gerhard F. Burbach  
Gerhard F. Burbach  
*President and Chief Executive Officer*

Date: March 15, 2006

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS that each person whose signature appears below constitutes and appoints Gerhard F. Burbach 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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Gerhard F. Burbach Gerhard F. Burbach	Chief Executive Officer, President and Director	March 15, 2006
/s/ Cynthia L. Lucchese Cynthia L. Lucchese	Senior Vice President and, Chief Financial Officer	March 15, 2006
/s/ J. Donald Hill J. Donald Hill	Director and Chairman of the Board of Directors	March 15, 2006
/s/ Howard E. Chase Howard E. Chase	Director	March 15, 2006
/s/ J. Daniel Cole J. Daniel Cole	Director	March 15, 2006
/s/ Neil F. Dimick		

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Neil F. Dimick	Director	March 15, 2006
/s/ D. Keith Grossman		
D. Keith Grossman	Director	March 15, 2006
/s/ William M. Hitchcock		
William M. Hitchcock	Director	March 15, 2006
/s/ George W. Holbrook, Jr.		
George W. Holbrook, Jr.	Director	March 15, 2006
/s/ Daniel M. Mulvena		
Daniel M. Mulvena	Director	March 15, 2006

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