THORATEC CORP
Form 10-K
March 16, 2005

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

(Mark one)

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

For the fiscal year ended January 1, 2005

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

For the transition period from to .

Commission file number: 1-8145

Thoratec Corporation

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the documents incorporated by reference in this Annual Report, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements can be identified by the words expects, projects, hopes, believes, intends , should , estimate , will , would , may , anticipates , plans , could and other similar w could differ materially from these forward-looking statements based on a variety of factors, many of which are beyond our control. Therefore, readers are cautioned not to put undue reliance on these statements. Investors are cautioned that all such statements involve risks and uncertainties, including risks related to the development of new markets such as Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of our products, changes in the mix of our product sales and the related gross margin for such product sales, the results of clinical trials including the HeartMate II, the ability to improve financial performance, regulatory approval processes, the effect of healthcare reimbursement and coverage policies, the effects of seasonality in our product sales, the effects of price competition from any of our competitors and the effects of any merger and acquisition related activities. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the Factors That May Affect Future Results section and in other documents we file with the Securities and Exchange Commission. Actual results, events or performance may differ materially. These forward-looking statements speak only as of the date hereof. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

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

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

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PART I

Item 1. *Business*

OVERVIEW

We are a leading manufacturer of circulatory support products for use by patients with congestive heart failure, or CHF. We are a leading provider of circulatory support products worldwide. We sell Ventricular Assist Devices, or VADs, to virtually every leading heart transplant center in the world; marketing three out of the four VADs approved by the United States Food and Drug Administration, or FDA, as a bridge to heart transplant for adults. We are also a leading provider of point-of-care blood diagnostic test systems.

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

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

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

The major product line of our ITC segment is:

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

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

We currently market VADs that may be implanted or worn outside the body and that are suitable for treatments for different durations for patients of varying sizes and ages. We estimate that doctors have implanted over 9,000 of our devices in patients suffering from heart failure. Our devices are currently used primarily for patients awaiting a heart transplant or Destination Therapy implants. On November 6, 2002, the FDA approved the HeartMate VAD as the first heart assist device for Destination Therapy, or permanent support for patients suffering from end-stage heart failure who are not eligible for heart transplantation. On April 7, 2003, the FDA approved the HeartMate XVE, an enhanced version of the HeartMate VAD, for Destination Therapy. Thoratec is the only company to have a ventricular assist device approved for Destination Therapy in the United States.

Destination Therapy

The FDA approval of the HeartMate VAD for Destination Therapy marks the first time a VAD has been approved as a long-term, permanent treatment for end-stage congestive heart failure patients who do not qualify for heart transplantation due to age or extenuating health circumstances and who otherwise have a life expectancy of less than two years.

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

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

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

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

OUR MARKETS

Circulatory Support Products

The primary markets for our VAD products are those patients suffering from heart failure, and in particular, from CHF. CHF is a chronic disease that occurs when degeneration of the heart muscle reduces the pumping power of the heart, causing the heart to become too weak to pump blood at a level sufficient to meet the body s demands. CHF can be caused by artery or valve diseases or a general weakening of the heart muscle itself. In addition, other conditions, such as high blood pressure or diabetes, can also lead to CHF.

According to the American Heart Association, or the AHA, there are 4.9 million CHF patients in the United States and approximately 550,000 new cases are diagnosed each year. The AHA also estimates that approximately 70% of CHF patients under age 65 will die within eight years of diagnosis. We believe that the number of patients suffering from end-stage CHF who could benefit from some form of cardiac assist could be over 100,000 annually. While the number of treatment options for earlier stage CHF has increased in recent years, the use of medication remains the most widely used approach for treatment of the disease. These drug therapies include ACE inhibitors, anti-coagulants and beta-blockers, which facilitate blood flow, thin the blood or help the heart work in a more efficient manner. Other procedures include angioplasty, biventricular pacing, valve replacement, bypass and left ventricular reduction surgery.

Despite attempts to manage CHF through drug therapy, there is currently only one curative treatment for the disease a heart transplant. Unfortunately, the number of hearts available for transplant each year can meet the needs of only a small number of the patients requiring a heart transplant. The United Network for Organ Sharing reported that there were only 2,085 hearts available for transplant in the United States in 2003. At any given time, there are approximately 4,000 patients on the U.S. national transplant waiting list and we believe a comparable number of patients are waiting in Europe. The median wait for a donor heart by patients on a heart transplant waiting list is approximately nine months, and many patients have to wait as long as two years before receiving one of the few donor hearts available. In 2001, approximately 15% of these patients died while waiting for a donor heart.

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

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

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

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

Therapeutic Recovery We believe that, for most patients, recovery of their own heart is a better alternative than either heart transplantation or permanent implantation of a blood pumping device. Based on recently reported cases of recovery in heart failure patients, we believe that our VAD system, in combination with other agents such as cell or drug therapies, has the potential to reverse the complications of late-stage heart failure in certain patients.

While this therapeutic recovery indication is not yet approved for our devices, we are actively investigating the worldwide experience with our VAD systems as a means of therapeutic recovery and the requirements for pursuing regulatory approval for this indication. Although it is not certain how many patients with CHF could benefit from this indication, based upon our estimate of the percentage of patients with late-stage CHF, we believe that the patient population could be substantial. We are continuing with our strategy to add this indication to our labeling. It will require FDA approval and we will continue working with the FDA towards this goal in 2005. We are also formulating a regulatory and clinical strategy for non-U.S. markets.

Recovery Following Cardiac Surgery In addition to CHF, our devices are also used for patients who suffer from acute cardiac failure and undergo cardiac surgery. Following cardiac surgery, some patients have difficulty being weaned off heart/lung machines, a complication that arises in approximately one percent of the more than 900,000 open-heart procedures performed each year. Many of these patients ultimately die from heart failure when the heart, weakened by disease and the additional trauma of surgery, fails to maintain adequate blood circulation. We believe that only a small portion of this market is currently being treated with VADs and this patient population could benefit substantially from further awareness and use of our VADs in this market.

Point-of-Care Diagnostics Products

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

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

Vascular Graft Products

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

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OUR STRATEGY

Our key strategies to maintain and expand our leadership position are to:

Offer a broad range of products. We believe that our broad and diverse product offering is an important competitive advantage because it allows us to address the various preferences of surgeons and the clinical needs of a wide variety of patients, as well as the economic needs and concerns of third party payers. An important part of our strategy is to further broaden our product line to meet customer needs by improving and developing new products internally or acquiring or licensing new products.

Increase Cost Effectiveness of our Products. While a recent study indicates that the cost of implanting a VAD for Destination Therapy is comparable with that of a heart, liver or other major organ transplant, cost remains a significant concern for our customers. In October 2003, CMS issued a favorable National Coverage decision for the use of left ventricular assist systems that are approved by the FDA for treating Destination Therapy in end-stage heart failure patients. We work very closely with the approximately 69 centers approved by CMS in developing the Destination Therapy market, which we believe will ultimately improve the cost effectiveness of Destination Therapy. Additionally, we are expanding our market education and training programs and we continue to implement improvements that enhance the performance and cost effectiveness of our products.

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

Bridge-to-Transplant Market. On July 28, 2003, Thoratec received CE mark certification, providing approval to market the Thoratec Implantable Ventricular Assist Device, or IVAD, in countries in the European Union. In August 2004, we received FDA approval in the U.S. to market the IVAD for use in bridge-to-transplantation and post-cardiotomy recovery patients who are unable to be weaned from cardiopulmonary bypass. This makes the IVAD the only currently approved implantable cardiac assist device that can provide left, right or biventricular support.

Destination Therapy Market. In November 2002, we received approval for the HeartMate VAD for Destination Therapy in the treatment of late-stage CHF patients who are not candidates for heart transplants. While the initial CMS reimbursement approval was limited to approximately 69 centers in 2004, we estimate the market penetration for this indication could eventually be a meaningful portion of the 100,000 patients annually mentioned above, as we introduce new technologies that increase the life of our VAD and improve the outcome of procedures.

Home Discharge for our TLC-II portable driver. On December 1, 2003, the FDA approved the TLC-II portable driver for home use. The TLC-II was already approved for in-hospital use in the United States, and has been approved for home therapy in Europe for several years. This approval will enable patients supported by the device to be discharged from the hospital to their home while awaiting heart transplantation or recovery of their existing heart. The TLC-II driver is the first portable driver approved for home discharge to support biventricular patients.

Obtain approval for new indications or uses of our products.

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

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

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

Focus on and partner with leading heart centers. We have developed extremely strong, long-standing relationships with leading cardiovascular surgeons and heart centers worldwide. We believe that no other cardiac assist company enjoys the same depth of relationship and access to these customers. Maintaining and expanding these relationships is an important part of our growth strategy, particularly for the development and introduction of new products and the pursuit of additional indications for our existing products. Our Heart Hope program, designed to partner with some CMS approved Destination Therapy centers, to build the market for this new indication, and, in the process, address important issues such as reimbursement, clinical outcomes, and the building of a strong referral program for Destination Therapy patients was launched in 2004. Heart Hope is a collaboration between Thoratec and leading heart centers to advance clinical, educational and economic outcomes associated with the treatment of end-stage heart failure. Underlying the Heart Hope initiative is an educational program designed to increase acceptance of Destination Therapy among heart failure cardiologists, generate physician referrals and broaden patient awareness of this new therapy. An important element of this effort is the program s use of marketing materials such as newsletters, direct mail pieces, education symposia, web presence, print and radio advertising and public relations materials.

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

OUR PRODUCTS

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

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

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

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

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

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

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

Circulatory Support Products

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

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

Certain VADs are implanted internally, while others are placed outside the body. Some external devices are placed immediately adjacent to the body (paracorporeal), while other external VADs are positioned at a distance from the body (extracorporeal). We estimate that between 20% and 35% of assist patients require biventricular support and therefore require a second pump for the right ventricle.

The Thoratec VAD

The Thoratec VAD has been FDA approved since 1995 and has treated over 2,500 patients worldwide. The Thoratec VAD is a paracorporeal device that is less invasive than implantable VADs since only the cannula must be implanted. The paracorporeal nature of the Thoratec VAD has several positive consequences including relatively shorter and less invasive implantation times (approximately two hours) and the ability to use the device in smaller patients.

A pneumatic power source drives the Thoratec VAD. It is designed for intermediate duration use of a few weeks to several months, though this device has supported numerous patients for six to eighteen months. Offering left, right or biventricular support, the Thoratec VAD is the only biventricular support system approved for use as a bridge to transplant. This characteristic is significant since approximately 50% of bridge to transplant patients treated with the Thoratec VAD require right-sided ventricular assist. The Thoratec VAD is also the only device approved for both bridge to transplant and recovery following cardiac surgery. We are working with the FDA to gain approval for a therapeutic recovery indication for the Thoratec VAD. The Thoratec VAD is made with our proprietary biomaterial, Thoralon, which may reduce clotting.

While it is possible for most patients with paracorporeal VADs to walk or otherwise move about, the large size of the typical drive console renders movement difficult. In order to improve patient mobility, we developed the TLC-II, a small portable driver, which increases portability and ambulation options. The portable driver was approved in the United States in June 2001 for use in off-site excursions and was approved December 1, 2003 for home discharge use. The TLC-II has been approved for use in Europe since 1998.

The HeartMate VAD

The HeartMate VE initially received FDA approval in September 1998 and the enhanced version of the product, called the HeartMate XVE, received FDA approval in December 2001 for bridge to transplantation. In April 2003, the HeartMate XVE version received FDA approval for Destination Therapy. The HeartMate XVE is designed for use for a duration from several months to up to two or three years. The HeartMate XVE offers only left ventricular support.

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

Implantable VAD

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

biventricular support. The IVAD maintains the same blood flow path, valves and blood pump as the paracorporeal (Thoratec VAD) device and is better suited for longer-term support compared to the Thoratec VAD. The outer covering of the IVAD is made of a titanium alloy, which facilitates implantation. The device weighs less than one pound and can be implanted in patients ranging in weight from 40 kg to over 100 kg. The small blood pump is implanted in the body. The IVAD is designed as a bridge to transplant and possibly for therapeutic recovery, but is not currently considered for Destination Therapy.

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HeartMate II

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

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

HeartMate III

We are also developing our third generation device, the HeartMate III, which is a centrifugal, continuous flow pump that employs a magnetically levitated rotor that eliminates wear from touching parts. The device is designed for long-term implantation (10 years or more) in patients with end-stage heart failure, including Destination Therapy, bridge-to-transplantation and therapeutic recovery. The product design is being finalized and pre-clinical studies are being performed to ready the device for clinical evaluation.

Vascular Graft Products

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

Point-of-Care Diagnostics

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

Hemochron POC coagulation system;

Immediate Response Mobile Analysis (IRMA) POC blood gas/electrolyte and chemistry system;

ProTime coagulation monitoring system;

Hemoglobin Pro system; and

Tenderfoot, Tenderlett and Surgicutt incision products.

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

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

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

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

The ProTime and Hemoglobin Pro products are sold into the Alternate Site POC market comprising physicians offices, long-term care facilities, clinics, visiting nurse associations, and home healthcare companies. Historically, this segment has represented about 20% of the ITC s total annual product sales.

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

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

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

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

In late 2003, we acquired the IRMA product line of blood gas/electrolyte and chemistry tests from Diametrics Medical, Inc. This has significantly increased our test menu offering, and also provides us with the opportunity to develop the next generation system, combining the coagulation and blood gas tests into one platform, which we anticipate will take 3-5 years to complete. In the interim period, the idms data management and connectivity system, acquired as part of the IRMA acquisition, will allow the stand-alone Hemochron and IRMA systems to interface with a hospital s laboratory or hospital information system. This project was completed in the fourth quarter of 2004.

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

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

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

SALES AND MARKETING

Circulatory Support Products

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

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

We have recruited and trained a direct sales force that, as of January 1, 2005, comprised 21 experienced cardiovascular sales specialists to sell our circulatory support systems in the United States, Canada, France, Germany, Spain, United Kingdom, Austria, Switzerland, Netherlands, Portugal and South Africa.

The sales effort is complemented by 16 direct clinical specialists, who conduct clinical educational seminars, assist with a new open-heart center s first VAD implant and resolve clinical questions or issues. We also partner with universities, experienced clinicians and opinion leaders to assist with expanding clinical educational needs. The sales team focuses on cardiac surgeons that perform heart transplantation, perfusionists and the transplant nursing staff.

In addition to our direct selling efforts, we have a network of international distributors who cover those markets that represent the majority of the remaining VAD potential. We employ sales and marketing tactics commonly found within the cardiovascular device market such as direct mail, clinical education seminars, symposia, equipment purchase and lease programs and journal advertisement.

Hospitals or other medical institutions that acquire a VAD system generally purchase VAD pumps, related disposables and training materials, and purchase or rent two of the associated pump drivers (to ensure that a backup driver is available). The time from the initial contact with the cardiac surgeon until purchase is generally between nine and eighteen months, due to the expense of the product and common hospital capital equipment acquisition procedures. Upon receipt of a purchase order, we usually ship the products within thirty days. We do not typically carry a backlog of orders pending shipment.

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

Vascular Graft Products

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

Point-of-Care Diagnostics

ITC currently maintains a direct sales staff of 46 in the United States, who sell to hospitals as well as to third party dealers and distributors. Outside the United States, ITC has four salespeople selling principally to third party distributors. Substantially all of ITC s product sales have historically come through our distributor channels with Cardinal Healthcare as our largest distributor generating 21% of ITC s annual product sales in 2004.

As we have integrated the IRMA product line of blood gas analyzers into our business, an increasing portion of our revenue in the United States market has been generated by direct sales rather than through distributors. This shift has required expanding the sales, technical service, customer service and shipping headcount at ITC in order to provide

our customers with the support and service that they historically obtained from our distributors.

COMPETITION

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

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

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

develop products;

complete clinical testing;

receive regulatory approvals; and

manufacture and sell commercial quantities of products.

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

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

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

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

PATENTS AND PROPRIETARY RIGHTS

We seek to patent certain aspects of our technology. We hold, or have exclusive rights to, several U.S. and foreign patents. Except for the patents mentioned below and one patent pertaining to the TLC-II, the Thoratec VAD system is not protected by any other patents. We do not believe that this lack of patent protection will have a material adverse effect on our ability to sell our VAD system because of the lengthy regulatory period required to obtain approval of a VAD. Several patents cover aspects of our HeartMate line of products.

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

Several patents cover aspects of our proprietary biomaterials technology, some of which were sold to TH Goldschmidt AG, a German chemical manufacturer, in 1989, but as to which we have retained worldwide, royalty-free, exclusive rights for most medical applications. The patent license from Goldschmidt will remain in effect for the duration of the patents sold to Goldschmidt and includes medical uses that we expect are necessary for our business as now conducted or as proposed to be conducted in the future. For example, the medical applications include blood pumps, artificial hearts and cardiac assist devices of all kinds, cardiovascular products, including heart valves and prosthetic blood vessels and cannulae and blood tubing of all kinds. Aspects of our blood

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coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision device products are covered by patents directed to tube-and micro-coagulation whole blood analysis, including test methods, reagents and integral (on-board) controls, thick film electrochemical analysis of blood gases, blood electrolytes, and blood chemistry, and low trauma skin incision devices for capillary blood sampling, and methods of manufacturing such devices. The duration remaining of some of our biomaterials patents ranges from 5 to 10 years, on our grafts up to 16 years and on our blood coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision device products from 2 to 16 years. During the term of our patents, we have the right to prevent third parties from manufacturing, marketing or distributing products that infringe upon our patents.

In addition, we hold several patents on the HeartMate II axial blood flow pump and transcutaneous energy transmission technology, the remaining duration of which ranges from 10 to 17 years. In August 1998, we obtained a license to incorporate technology developed by Sulzer Electronics Ltd. and Lust Antriebstechnik GmbH into the HeartMate III. HeartMate III is a miniature centrifugal pump featuring a magnetically levitated rotor with a bearingless motor that has been developed by Levitronix GmbH. The license from Sulzer and Lust gives us the exclusive right to use in our HeartMate products technology protected by several U.S. and foreign patents covering implantable bearingless motors for the duration of those patents, subject to our payment of royalties. In December 2000, we were informed by Sulzer Electronics that Sulzer had sold all of its business in the bearingless motor and magnetic bearing fields to Levitronix and had assigned its portion of the agreements between Sulzer and us to Levitronix. We believe that the license remains in full force and effect.

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

We hold, or have exclusive rights to, several international patents, including several biomaterial patents licensed from Goldschmidt referred to above.

We have developed technical knowledge which, although non-patentable, we consider to be significant in enabling us to compete. However, the proprietary nature of such knowledge may be difficult to protect. It is our policy to enter into confidentiality agreements with each of our employees prohibiting such employee from disclosing any confidential information or trade secrets. In addition, these agreements provide that any inventions or discoveries relating to our business by these individuals will be assigned to us and become our sole property. However, we cannot guarantee that every person who obtains access to our confidential information or trade secrets will have signed such an agreement, or that every person who has signed such an agreement will abide by it. If they do not, or if our confidential information or trade secrets are otherwise disclosed, there is no guarantee that any legal remedies will prevent the harmful disclosure or use of our confidential information or trade secrets.

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

our business.

For example, in October 2003, a patent infringement claim was filed against the Company by Bodycote Materials Testing Canada, Inc and David C. MacGregor, M.D. related to materials used in the HeartMate LVAS. On February 3, 2004 we settled the claim and recorded a charge of $2.3 million in the fourth quarter of 2003 and $133,000 in the first six months of 2004 for the settlement and related legal costs.

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

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GOVERNMENT REGULATIONS

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

U.S. Regulations

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

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

Under the FDA s requirements, if a manufacturer can establish that a newly developed device is substantially equivalent to a legally marketed predicate device, the manufacturer may seek marketing clearance from the FDA to market the device by filing a 510(k) premarket notification with the FDA. This is the process that is used to gain FDA market clearance for most of ITC s products. The 510(k) premarket notification must be supported by data establishing the claim of substantial equivalence to the satisfaction of the FDA. The process of obtaining a 510(k) clearance typically can take several months to a year or longer. If substantial equivalence cannot be established, or if the FDA determines that the device requires a more rigorous review, the FDA will require that the manufacturer submit a PMA application that must be approved by the FDA prior to marketing the device in the United States.

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

The approval process for each of our products is expensive and time consuming and we cannot assure that any regulatory agency will grant its approval. Our inability to obtain, or delays in obtaining, such approval would adversely affect our ability to commence marketing our products. We cannot assure you that we will have sufficient resources to complete the required testing and regulatory review processes. Furthermore, we are unable to predict the extent of adverse governmental regulations, which might arise from future U.S. or foreign legislative or administrative action. On October 26, 2002, the FDA signed into law The Medical Device User Fee and Modernization Act of 2002 (MDUFMA). This law amends the FDA Act and Regulations to provide, among other things, the ability for the FDA to impose user fees for medical device reviews. Our activities require that we make

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many filings with the FDA that will now be subject to this new fee structure. Although the precise amount of fees that we will incur each year will be dependent upon the specific quantity and nature of our filings, these fees could amount to hundreds of thousands of dollars per year.

In addition, any products distributed pursuant to the above authorizations are subject to thorough and continuing regulation by the FDA. Products must be manufactured in registered establishments and must be manufactured in accordance with Quality System Regulations and adverse events must be reported to the FDA. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The FDA often requires post market surveillance, or PMS, requirements for significant risk devices, such as VADs, that require ongoing collection of clinical data during commercialization that must be gathered, analyzed and submitted to the FDA periodically for up to several years. These PMS data collection requirements are often burdensome and expensive and have an effect on the PMA approval status. The failure to comply with the FDA s regulations can result in enforcement action, including seizure, injunction, prosecution, civil penalties, recall and suspension of FDA approval. The export of devices is also subject to regulation in certain instances.

We are also subject to regulation by various state authorities, which may inspect us and enforce state regulations. Failure to comply with applicable state regulations may result in seizures, injunctions or other types of enforcement actions.

International Regulations

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

In order to be positioned for access to European and other international markets, we sought and obtained certification under the ISO 13485 Series of Standards. ISO 13485 is a set of integrated requirements, which when implemented, form the foundation and framework for an effective quality management system. These standards were developed and published by the ISO, a worldwide federation of national bodies, founded in Geneva, Switzerland in 1947. ISO has over 90 member countries and ISO certification is widely regarded as essential to enter Western European markets. We obtained EN ISO 13485:2000 Certification in March 2003. Commencing in mid-1998, all companies are required to obtain CE Marks for medical devices sold or distributed in the European Union. The CE Mark is an international symbol of quality. With it, medical devices can be distributed within the European Union. A prerequisite for obtaining authority to CE Mark products is to achieve full quality system certification in accordance with ISO 13485 and European Directives, such as the Medical Device Directive (MDD), In-Vitro Device Directive (IVDD) and the Active Implantable Medical Device Directive (AIMD). These are quality standards that cover design, production, installation and servicing of medical devices manufactured by us. We have the ISO 13485 and appropriate MDD, IVDD or AIMD certification and authority to CE Mark all our devices in commercial distribution including our skin incision, blood coagulation testing devices, *Vectra* graft and VAD systems such as the Thoratec VAD, IVAD and HeartMate Systems. We are also certified to be in compliance with the requirements of the Canadian Medical Device Regulations (CMDRs) at all Thoratec manufacturing sites, which is required effective January 1, 2003, to sell medical devices in Canada.

Other Regulations

We are also subject to various federal, state and local laws and regulations relating to such matters as safe working conditions, laboratory and manufacturing practices and the use, handling and disposal of hazardous or potentially

hazardous substances used in connection with our research and development work. Specifically, the manufacture of our biomaterials is subject to compliance with federal environmental regulations and by various state and local agencies. Although we believe we are in compliance with these laws and regulations in all material respects, we cannot assure that we will not be required to incur significant costs to comply with environmental laws or regulations in the future.

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THIRD PARTY REIMBURSEMENT AND COST CONTAINMENT

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

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

The change of DRG category for implantable heart assist devices from DRG 525 to 103 has raised the average payment under DRG 103 by more than 30% from approximately $90,000 to approximately $136,000. Since FDA approval of the HeartMate LVAS for Destination Therapy, several private payors have issued positive coverage decisions as well. In December 2002, Blue Cross/Blue Shield (BC/BS) Technology Evaluation Center issued a positive decision on the use of LVADs for Destination Therapy. Since December 2002, the majority of national insurance carriers, such as Aetna, Cigna, Humana, United Healthcare and UNICARE, have issued positive coverage policies to cover the use of ventricular assist devices for FDA-approved indications, including Destination Therapy.

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

MANUFACTURING

We manufacture our cardiovascular products at our facility in Pleasanton, California. This facility has been inspected, approved and licensed by the FDA and the State of California Department of Health Services, Food and Drug Section for the manufacture of medical devices and has received the International Standards Organization (ISO) 9001 certification. Our manufacturing processes consist of the assembly of standard and custom component parts, and the testing of completed products. We rely on single sources of supply for several components of our VADs. We are aware of alternative suppliers for all single-sourced items.

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

We typically are able to fill orders from inventory and do not have significant order backlogs. At the end of 2003 and during 2004, we experienced higher than normal backlog for disposable test cuvettes due to higher demand. We have expanded capacity during 2004 to accommodate the increased demand. Total backlog as of the end of fiscal 2004 and 2003 were approximately $1.3 million and $1.6 million, respectively.

RESEARCH AND DEVELOPMENT

Thoratec s research and development expenses in 2004, 2003 and 2002 were $28.7 million, $26.1 million, and $25.3 million, respectively. Research and development costs are largely project driven, and the level of spending depends on the level of project activity planned and subsequently approved and conducted. The primary component of our research and development costs is employee salaries and benefits. Projects typically include efforts to develop new products, such as the HeartMate II and HeartMate III, efforts to improve the operation and performance of current products, such as efforts to improve the life of various components of the HeartMate and the Thoratec

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

MAJOR CUSTOMERS AND FOREIGN SALES

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

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

EMPLOYEES

As of January 1, 2005, we had a total of 914 employees, consisting of 905 full-time employees and 9 part-time employees, 421 of whom worked in manufacturing, 130 in engineering, 102 in quality control and regulatory affairs, 138 in marketing and sales support, 38 in administration and finance and 85 in other support functions, including human resources, management information systems, purchasing and facilities. Out of our total employees, 894 are employed in the United States and 20 are employed in the United Kingdom and other European countries. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

ADDITIONAL INFORMATION

You can find additional information about Thoratec on our website at http://www.thoratec.com (although non of this information is, or should be deemed to be, incorporated by reference into this Annual Report on Form 10-K). We make filings of our periodic reports to the Securities and Exchange Commission (SEC), including annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as amendments to those reports, available free of charge on our website as soon as reasonably practicable following electronic filing of those reports with the SEC.

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FACTORS THAT MAY AFFECT FUTURE RESULTS

Our business faces many risks. These risks include those related to the development of new products and markets including Destination Therapy, the growth of existing markets for our products, customer and physician acceptance of our products, changes in the mix of our product sales, and the related gross margin for such product sales, the results of clinical trials, including those for the HeartMate II, the ability to improve financial performance, regulatory approval processes, the effect of healthcare reimbursement and coverage policies, our product sales, the effects of price competition from any of our competitors and the effects of any merger and acquisition related activities. The risks described below are what we believe to be the material risks facing our company. However, the risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risk factors actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline significantly. Investors should consider the following risks, as well as the other information included in this Annual Report on Form 10-K, and other documents we file from time to time with the SEC, such as our quarterly reports on Form 10-Q, our current reports on Form 8-K and any public announcements we make from time to time.

We have a history of net losses.

We were founded in 1976 and we have a history of incurring losses from operations. As of January 1, 2005, our accumulated deficit was approximately $71.5 million. We anticipate that our expenses will increase as a result of increased pre-clinical and clinical testing, research and development and selling, general and administrative expenses. We could also incur significant additional costs in connection with our business development activities and the development and marketing of new products and indicated uses for our existing products as well as litigation and equity based compensation costs. Such costs could prevent us from achieving or maintaining profitability in future periods.

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

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

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

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

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

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

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

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

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

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

Certain lawsuits have been filed against us

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

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

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

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

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

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

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with respect to these actions.

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

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

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

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

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

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

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

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

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

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

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

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costs and related reimbursements of long-term hospitalization.

The different outcomes of these and other factors, and their timing, will have a significant impact on our future operating results. Sales of our VADs for Destination Therapy have proved slower than we had originally anticipated, and we are unable to predict when, if ever, these sales will generate significant revenue for us.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

develop products;

complete clinical testing;

receive regulatory approvals; and

manufacture and sell commercial quantities of products.

Large medical device companies dominate the markets in which our ITC business competes and we estimate our products hold anywhere from 2% to 20% market share. We expect that any growth in this market will come from expanding our market share at the expense of other companies, and from testing being shifted away from the central laboratory to the point-of-care. However, this market segment is very competitive, and includes the following potential drivers:

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

New competitors that might enter the market with broader test menus.

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

The price of our common stock may fluctuate significantly.

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

future announcements concerning us or our competitors;

timing and reaction to the publication of clinical trial results;

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

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future;

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

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

acquisition or loss of significant customers, distributors or suppliers;

business acquisitions or divestitures;

changes in earnings estimates by analysts;

changes in third party reimbursement practices;

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

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

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

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

We may encounter problems manufacturing our products.

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

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

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

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

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

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

This transition to a direct sales model necessitated expanding the sales, technical service, customer service and shipping headcount at ITC in order to provide our customers with the support and service that they historically obtained from our distributors, resulting in an increase in our sales and general and administrative costs. We expect the transition process to conclude in early 2005 when the last distributor will have been converted and the United States hospital point-of-care market will be served exclusively by ITC on a direct basis. This transition and its execution involve significant risks, including:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

foreign customers may have longer payment cycles;

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

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

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

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

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

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

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

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

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

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

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

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign exchange rates. At present, we use forward foreign currency contracts to hedge the gains and losses created by the remeasurement of non-functional currency denominated assets

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and liabilities. However, we do not engage in hedge exposures that will arise from future sales. As a result, sales occurring in the future that are denominated in foreign currencies may be translated into U.S. dollars at a less favorable rate than our current exchange rate environment resulting in reduced revenues and earnings.

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

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

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

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

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

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

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

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

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

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

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

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

Item 2. ***Properties***

We are headquartered in Pleasanton, California, where we lease approximately 72,000 square feet of office, manufacturing and research facilities and 4,000 square feet of warehouse space. Our leases for these facilities expire through 2012. Additionally, we lease the following facilities:

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

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

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

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

Approximately 3,000 square feet of office facilities in the United Kingdom expiring in 2008.

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

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

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

Item 3. ***Litigation***

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

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

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

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

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

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

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

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

No matters were submitted to a vote of security holders during the quarter ended January 1, 2005.

Our Executive Officers

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

Lawrence Cohen, President of ITC, joined our company in May 2001 as President of ITC. Prior to joining ITC, Mr. Cohen served as CEO of HemoSense, Inc., a developer of medical diagnostic products, from August 1998 to April 2001. From October 1989 to March 1998, Mr. Cohen held the positions of Vice President Marketing and Sales, Vice President International and Worldwide Executive Vice President at Ortho-Clinical Diagnostics, a Johnson & Johnson company. From 1980 to 1989, Mr. Cohen also held executive management positions at Instrumentation Laboratory and Beckman Coulter Corporation. He is a past president of the Biomedical Marketing Association and was on the Board of Trustees of the National Blood Foundation from 1998 to 2004.

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

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PART II

Item 5. ***Market for Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Our common stock is traded on the NASDAQ National Market under the symbol THOR. The following table sets forth, for the periods indicated, the high and low closing sales price per share of our common stock, as reported by the NASDAQ National Market. As of March 14, 2005, there were 48,198,480 shares of our common stock outstanding with approximately 775 holders of record, including multiple beneficial holders at depositories, banks, and brokerages listed as a single holder in the street name of each respective depository, bank, or broker.

	High	Low
Fiscal Year 2003		
First Quarter	$ 12.21	$ 7.63
Second Quarter	14.44	11.45
Third Quarter	19.23	13.74
Fourth Quarter	$ 16.99	$ 12.35
Fiscal Year 2004		
First Quarter	$ 15.95	$ 11.75
Second Quarter	14.99	10.49
Third Quarter	11.01	9.40
Fourth Quarter	$ 10.88	$ 8.46

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

Issuer Purchases of Equity Securities

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

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

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

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

The selected consolidated financial data presented below for the five fiscal years ended January 1, 2005 is derived from our audited financial statements. The data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations below and our audited consolidated financial statements and notes thereto appearing elsewhere in this Annual Report, the consolidated financial statements of TCA filed with the SEC on Form 8-K/A on March 30, 2001 and on Form 10-K on March 17, 2000. Certain reclassifications have been made to the financial statements previously filed with the SEC to conform to current practice.

In the merger of Thoratec with TCA that was completed on February 14, 2001, we issued new shares of our common stock to the shareholders of TCA in exchange for all the outstanding common stock of TCA at an exchange ratio of 0.835 shares of Thoratec stock for each share of TCA. The merger was accounted for as a reverse acquisition because former shareholders of TCA owned a majority of our outstanding stock subsequent to the

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merger. For accounting purposes, TCA is deemed to have acquired Thoratec and therefore for fiscal year 2000 all financial information presented herein represents the results of operations of TCA. Our 2001 consolidated financial information presented herein includes the financial results of TCA for the full fiscal year and Thoratec s financial results for the post-merger period from February 14, 2001 through December 29, 2001. The weighted average number of common shares previously reported by TCA has been adjusted for all periods presented to reflect the exchange ratio of 0.835 to 1.

Our fiscal year ends on the Saturday closest to December 31. Accordingly, our fiscal year will periodically contain more or less than 365 days. For example, fiscal 2000 ended on December 30, 2000, fiscal 2001 ended on December 29, 2001, fiscal 2002 ended December 28, 2002, fiscal 2003 ended January 3, 2004 and fiscal 2004 ended January 1, 2005.

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

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

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

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

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

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

Overview

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

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

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

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

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

The major product line of our ITC segment is:

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

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

Our Business Model

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

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

Acquisitions and Strategic Investments

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

On September 30, 2003, we completed an asset purchase of the Immediate Response Mobile Analysis, or IRMA, point-of-care blood analysis system product line from Diametrics Medical, Inc. We paid approximately $5.2 million in cash and assumed trade payables. The purchase price was allocated based on the fair value of assets acquired as determined by an independent valuation firm. There was no goodwill recorded with the transaction. As a result of the acquisition, $220,000 relating to in-process research and development was expensed in the fourth quarter of 2003.

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Restructuring Plan

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

Critical Accounting Policies and Estimates

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

Evaluation of Purchased Intangibles and Goodwill for Impairment

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

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

Revenue Recognition

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

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

of revenue under these arrangements allocated to training is based upon fair market value of the training, which is performed principally by third party providers. The amount of product sales allocated to the Cardiovascular segment products is done on a fair value basis. Under this basis, the total value of the arrangement is allocated to the training and the Cardiovascular segment products based on the relative fair market value of the training and products. The amount of product sales allocated to training is recorded as deferred revenue and is recognized when the training is completed. As of the end of fiscal 2004, all products that had been delivered and recorded as product sales were delivered to customers for which training had been

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

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

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

Reserves

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

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

Results of Operations

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

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

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

Fiscal Years 2004 and 2003

Product Sales

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

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

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

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

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

$1.7 million in lower graft revenue.

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

Gross Profit

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

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

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

Selling, General and Administrative

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

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

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

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

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

Research and Development

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

Amortization of Purchased Intangible