THORATEC CORP
Form 10-K
April 02, 2007

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

(Mark one)

þ **ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 30, 2006

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: 000-49798

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:

Title of Each Class	Name of Each Exchange of which Registered
Common Stock, no par value per share	NASDAQ Global Select Market

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

Indicate by a check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

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

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 a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer þ Accelerated filer o Non-accelerated filer o

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

The aggregate market value of the voting stock held by non-affiliates computed by reference to the last sale reported of such stock on June 30, 2006, the last business day of the Registrant s second fiscal quarter, was

$696,996,322.

As of February 24, 2007, the Registrant had 52,977,715 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of Thoratec s definitive proxy statement for its 2007 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

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

CentriMag is a registered trademark of Levitronix LLC.

ITC, A-VOX Systems, AVOXimeter, HEMOCHRON, Hemochron Signature Elite, ProTime, Surgicutt, Tenderlett, Tenderfoot, and IRMA are registered trademarks of International Technidyne Corporation (ITC), our wholly-owned subsidiary.

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PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the documents incorporated by reference in this Annual Report, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements can be identified by the words expects, projects, hopes, believes, intends, should, estimate, will, would, may, anticipates, pl similar words. Actual results, events or performance could differ materially from these forward-looking statements based on a variety of factors, many of which are beyond our control. Therefore, readers are cautioned not to put undue reliance on these statements. Factors that could cause actual results or conditions to differ from those anticipated by these and other forward-looking statements include those more fully described in the Risk Factors section of this Annual Report and in other documents we file with the Securities and Exchange Commission (SEC). These forward-looking statements speak only as of the date hereof. We undertake no obligation to publicly release the results of any revisions to these forward-looking statements that may be made to reflect events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events.

Item 1. *Business*

OVERVIEW

Thoratec Corporation (we, our, us, the Company) is a world leader in therapies to address advanced heart failure (HF) and point-of-care diagnostics and incision applications.

For advanced HF we develop, manufacture and market proprietary medical devices used for circulatory support. Our primary product lines are our ventricular assist devices (VADs): the Paracorporeal Ventricular Assist Device (PVAD), the Implantable Ventricular Assist Device (IVAD), the HeartMate Left Ventricular Assist System (HeartMate XVE), and the HeartMate II Left Ventricular Assist System (HeartMate II). The IVAD, PVAD and the HeartMate XVE are approved by the U.S. Food and Drug Administration (FDA) and CE Mark approved in Europe. The HeartMate II is CE Mark approved in Europe and is in a Phase II pivotal trial in the U.S. We also manufacture a vascular access graft for renal dialysis.

In addition to our circulatory support products, we also develop, manufacture and market point-of-care diagnostic test systems for hospital point-of-care and alternative site point-of-care and incision products.

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

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

The product line within the Cardiovascular segment is:

Circulatory Support Products. Our circulatory support products include the PVAD, IVAD, HeartMate XVE and HeartMate II for short, intermediate and long-term treatment of advanced HF. In addition, in August 2006 we began marketing the CentriMag Blood Pumping System (CentriMag) for acute HF. CentriMag is manufactured by Levitronix LLC (Levitronix) and distributed by us in the U.S. under a distribution agreement with Levitronix. We also manufacture and sell small diameter grafts using our proprietary materials to address the vascular access market for hemodialysis.

The product lines of our ITC segment are:

Point-of-Care Diagnostics. Our point-of-care products include diagnostic test systems that monitor blood coagulation while a patient is being administered certain anticoagulants, as well as monitor blood gas/electrolyte, oxygenation and chemistry status, including total hemoglobin.

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

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

Our VADs have been clinically proven to improve patient survival and quality of life. We currently offer the widest range of products to serve this market, including VADs for short, intermediate and long-term support, as well as devices that are FDA-approved as a bridge-to-transplantation (BTT), for permanent support for patients suffering from late-stage HF who are not eligible for heart transplantation (Destination Therapy or DT) and/or postcardiotomy myocardial recovery. We believe that our long-standing reputation for quality and innovation and our excellent relationships with leading cardiovascular surgeons worldwide position us to capture growth opportunities in the expanding HF market.

We currently market VADs that may be implanted or worn outside the body, can be used for left, right or biventricular support and that are suitable for treatments for different durations for patients of varying sizes and ages. We estimate that doctors have implanted more than 11,000 of our devices, primarily for patients awaiting a heart transplant or those who require permanent support. On November 6, 2002, the FDA approved the HeartMate VE as the first heart assist device for Destination Therapy. On April 7, 2003, the FDA approved the HeartMate XVE, an enhanced version of the HeartMate VE, for Destination Therapy. Thoratec is the only company to offer a VAD approved by the FDA for Destination Therapy and marks the first time a VAD has been approved as a permanent treatment for late-stage HF patients who do not qualify for heart transplants because of age or extenuating health circumstances, and who otherwise have a life expectancy of less than two years. The FDA s decision to approve the HeartMate VAD for Destination Therapy was based on data from a clinical trial called Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive HF, which showed our HeartMate device nearly doubled and tripled survival over the drug therapy group at one and two years, respectively.

Our HeartMate II, which is intended for long-term cardiac support for approximately five to ten years, for patients who are in late-stage HF, is currently in a Phase II pivotal trial in the U.S. The HeartMate II is a small, implantable, electrically powered device that weighs about 12 ounces and is approximately 1.7 inches in diameter and 3.2 inches long. In addition to being significantly smaller than the HeartMate XVE, with only one moving part the HeartMate II is simpler and designed to operate more quietly than pulsatile devices. As an axial flow device, the HeartMate II is designed to provide blood flow through the circulatory system on a continual basis and is smaller and easier to implant than pulsatile devices.

In August 2006, we announced a distribution agreement under which we will distribute the CentriMag in the U.S. The initial term of the agreement expires in 2011. This device is 510(k), as further described in the Government Regulations below, approved and cleared by the FDA for patients requiring short-term extracorporeal circulatory support for up to six hours during cardiac surgery.

The Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Decision Memorandum covering reimbursement for the use of a Left Ventricular Assist System for Destination Therapy, effective October 1, 2003. CMS has subsequently adjusted the relative weight and base level of reimbursement it will provide under diagnosis-related group 103 Heart Transplant or Implant of Implantable Heart Assist Systems (DRG 103), to raise the average payment for CMS Destination Therapy-certified Centers to approximately $143,000 in 2006, compared to the average payment of approximately $136,000 in 2005, the same reimbursement given for heart transplants. In many cases, the actual payments to hospitals under DRG 103 could be higher or lower, based on geographical location and other factors.

Several private payors have also issued positive coverage decisions. The majority of local Blue Cross and Blue Shield plans cover procedures for both bridge-to-transplantation and long-term therapy indications. Since

December 2002, the majority of national insurance carriers, including Aetna, Cigna, Humana, United Health Group and UNICARE, have policies covering the use of ventricular assist devices for FDA-approved indications, including DT.

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OUR MARKETS

CARDIOVASCULAR SEGMENT

Circulatory Support and Graft Products

Our VAD products primarily serve patients suffering from late-stage HF. HF is a chronic disease that occurs when degeneration of the heart muscle reduces the pumping power of the heart, causing the heart to become too weak to pump blood at a level sufficient to meet the body s demands. The condition can be caused by arterial and valvular diseases or a cardiomyopathy, which is a disease of the heart muscle itself. Other conditions, such as high blood pressure or diabetes, also can lead to HF.

According to estimates by the AHA, 5 million patients suffer from HF in the U.S. and approximately 550,000 new cases are diagnosed each year. The AHA also estimates that approximately 80% of men and 70% of women HF patients under age 65 will die within eight years of diagnosis. While the number of treatment options for earlier stage HF has increased in recent years, pharmacologic medications remain the most widely used approach for treatment of HF. These drug therapies include ACE inhibitors, anti-coagulants and beta-blockers, which facilitate blood flow, thin the blood or help the heart work in a more efficient manner. Other procedures include angioplasty, biventricular pacing, valve replacement, bypass and left ventricular reduction surgery.

Despite attempts to manage HF through drug therapy, the only curative treatment for late stages of the disease is heart transplantation. Unfortunately, the number of donor hearts available each year can meet the needs of only a small number of patients who could benefit from transplantation. The United Network for Organ Sharing reported that there were approximately 2,000 hearts available for transplant in the U.S. in 2006. At any given time, approximately 3,000 patients are on the U.S. national transplant waiting list, and we believe a comparable number of patients are waiting in Europe. The median wait for a donor heart is approximately nine months; many patients have to wait as long as two years.

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

Bridge-to-Transplantation Ventricular assist devices provide additional cardiac support for patients with late-stage HF waiting for a donor heart. Approximately 25% of the patients on the waiting list for a heart transplant in the U.S. receive a VAD. We believe that the percentage of patients bridged to transplant will continue to increase with surgeons level of comfort with the technology, particularly for longer-term support cases. There are currently four devices approved in the U.S. as a bridge to-transplant in adults that are commercially marketed, three of which are Thoratec devices.

Destination Therapy On November 6, 2002, we received approval to market a HeartMate VAD for Destination Therapy patients with late-stage HF who are not candidates for heart transplantation due to other degenerative illnesses or advanced age. The National Institutes for Health estimated that the Destination Therapy application represents a long-term market opportunity of up to 100,000 additional patients annually in the U.S. For these late-stage HF patients, drug therapy is currently the only other treatment available. Even with drug therapy, the 12-month mortality rate for these patients is approximately 80%. We believe that the HeartMate provides a significant survival benefit for this patient population. We believe that the success in transitioning this market from maximum drug therapy to VADs is dependent on the development of products such as our HeartMate products that deliver substantial longevity and proof of clinical efficacy.

Therapeutic Recovery We believe that for most patients recovery of their own heart function, if possible, would be a better alternative than either heart transplantation or permanent implantation of a blood pumping device. We intend to continue pursuing a bridge to myocardial recovery indication to add to our labeling, that if approved by the FDA, would allow the VAD to be used to treat patients diagnosed with acute cardiac disorders such as fulminate myocarditis. Our work towards this end will continue in 2007. In addition, based on recently reported cases of recovery in HF patients in Europe, we believe that our VADs, in combination with other agents such as cell or drug therapies, have the potential to reverse late-stage HF in certain patients. While a combination therapeutic recovery

indication is not yet approved for our devices, we are actively performing research and collaborating with leading medical centers in this area. While it is not certain how many patients with HF could benefit from these recovery indications, based upon our estimate of the percentage of patients with late-stage HF, we believe that the patient population could be substantial.

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Post-Cardiotomy Myocardial Recovery Following Cardiac Surgery In addition to chronic HF, our devices are also used for patients who suffer from acute cardiac failure after undergoing cardiac surgery. Some patients have difficulty being weaned off heart/lung machines after surgery, a complication that arises in open-heart procedures. Many of these patients ultimately die from HF when the heart, weakened by disease and the additional trauma of surgery, fails to maintain adequate blood circulation. We believe that only a small portion of this market is currently being treated with VADs and that this patient population could benefit substantially from the use of our FDA-approved PVAD and IVAD products in this market.

Cardiac Surgery Support In August 2006, we signed a distribution agreement with Levitronix under which we will distribute the CentriMag in the U.S. This agreement allows us to expand more broadly beyond transplant centers and enables us to better address opportunities in short-term patient recovery. The CentriMag device currently has FDA 510(k) approval in the U.S. for use in patients requiring short-term extracorporeal circulatory support during cardiac surgery. Levitronix is currently in discussion with the FDA regarding an Investigational Device Exemption (IDE) to begin a pivotal trial to demonstrate safety and effectiveness of the CentriMag for any cardiac condition resulting in ventricular failure where there is an opportunity for recovery.

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 (*Vectr*a), for patients undergoing renal hemodialysis.

ITC SEGMENT

Point-of-Care Diagnostics Products Our point-of-care blood diagnostic test systems provide fast, accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes. These products are sold into the hospital point-of-care market, into the alternate site point-of-care market including physicians offices, long-term care facilities, clinics, visiting nurse associations, home healthcare companies, and directly to patients. We believe that the market growth for point-of-care diagnostic products is driven by greater convenience and ease of use for the clinician and patient. In addition, there are clinical benefits derived from more frequent monitoring and providing time sensitive information at the patient s bedside.

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

OUR STRATEGY

Our strategy to maintain and expand our leadership position in our markets is comprised of the following market and product development activities:

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

Focus on and partner with leading heart centers. We have developed long-standing relationships with leading cardiovascular surgeons and heart centers worldwide. We believe that no other cardiac assist company enjoys the same depth of relationships and access to these customers. These relationships are an important part of our growth strategy, particularly for the development and introduction of new products and the pursuit of additional indications for our existing products. We continued our investment in building these relationships through a team of Market Development Managers as part of our program to generate referrals to our leading VAD centers, including those in our Heart Hope Program that we began in 2004. These specialists work in partnership with our VAD centers to increase the awareness of hemodynamic restoration therapy and VADs in the cardiology community.

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

adoption of our products.

Destination Therapy Market. In November 2002, we received approval for a HeartMate VAD for Destination Therapy in the treatment of late-stage HF patients who are not candidates for heart transplants. While the initial CMS reimbursement approval was limited to sixty-nine centers in 2004, we estimate the market penetration for this indication could eventually

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comprise of a meaningful portion of the 100,000 patients annually diagnosed with late-stage HF, as we introduce new technologies that increase the useful life of our VAD and improve the outcome of procedures.

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

Acute Market. In August 2006, we entered into a distribution agreement with Levitronix to distribute the CentriMag in the U.S. This agreement allows us to expand more broadly beyond transplant centers and enables us to better address opportunities in short-term patient recovery. The CentriMag device currently has FDA 510(k) approval for use in patients requiring short-term extracorporeal circulatory support during cardiac surgery. Levitronix is currently in discussion with the FDA regarding an IDE to begin a pivotal trial to demonstrate safety and effectiveness of the CentriMag for any cardiac condition resulting in ventricular failure where there is an opportunity for recovery.

Point-of-Care Market. On October 3, 2006, we acquired A-VOX Systems, Inc., (Avox) a point-of-care company that develops and manufactures portable, bedside CO-oximetry systems to assist clinicians in assessing a patient s oxygenation status. These systems are used in hospitals in the cardiac catherization lab, the intensive care unit (ICU), the neonatal intensive care unit (NICU) and the emergency department. Our strategy is to sell these systems along with our Hemochron and IRMA point-of-care products and our data management system that connects all of these systems together.

Obtain approval for new products. We began our U.S. Phase II clinical trial for our HeartMate II in the first quarter of 2005 following a successful Phase I trial that allowed enrollment of 133 BTT patients, with 26 centers participating. In May 2006, and again in November 2006, the FDA approved an IDE supplement that allowed enrollment of an additional 90 patients each, for a combined total of 180 additional patients, in the BTT arm under a Continued Access Protocol (CAP). In October 2006, we filed the first two modules of the Pre-Market Approval (PMA) application seeking BTT approval for the HeartMate II that addressed all of the supporting engineering and preclinical studies, as well as manufacturing and quality systems. In December 2006, we completed the PMA submission for the BTT arm of the clinical trial. The PMA filing is based on data from 133 BTT patients representing more than 57 years of cumulative support; days of support ranged from 1-568 days.

In addition, we have a separate arm of the trial seeking approval for DT. Enrollment in this arm is continuing and, as of December 30, 2006, 140 randomized patients have been enrolled in the DT arm. The trial calls for 200 total patients randomized to Thoratec s HeartMate XVE on a 2-1 basis.

Increase cost effectiveness of the therapies that employ our products. While a recent study indicates that the cost of implanting a VAD for Destination Therapy is comparable with that of a heart, liver or other major organ transplant, cost remains a significant concern for our customers. In October 2003, CMS issued a favorable National Coverage decision for the use of left ventricular assist systems that are approved by the FDA for treating Destination Therapy in late-stage HF patients. We work closely with the sixty-nine CMS-approved centers to develop the Destination Therapy market, which we believe will ultimately improve the cost effectiveness of this therapy. We also are expanding our market education and training programs, and continue to make improvements that enhance the performance and cost effectiveness of our products.

OUR PRODUCTS

Cardiovascular Segment

Our Cardiovascular segment offers the following broad product portfolio of implantable and external circulatory support product devices:

The PVAD is an external device for short to mid-term cardiac support. The device, which is sold worldwide, is approved to assist left, right and biventricular support and is worn outside of the body. The PVAD is approved by the FDA for use as a bridge to transplantation and for post-cardiotomy myocardial recovery.

The IVAD is the only implantable blood pump approved for both bridge-to-transplantation and post-cardiotomy myocardial recovery that can be used for left, right, or biventricular support. The IVAD

utilizes the same internal working components as the PVAD, but has an outer housing made of a titanium alloy that makes it more suitable for implantation.

The HeartMate XVE, is an implantable device for mid to longer-term cardiac support and is the only device approved in the U.S., Europe and Canada for permanent support for those patients ineligible for heart transplantation. This device is designed

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to assist the pumping function of the heart s left ventricle and features a unique, textured blood-contacting surface that eliminates the need for systemic anticoagulation.

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

CentriMag is an external device for short-term circulatory support consisting of a single-use blood pump, a motor and a device console. This device is 510(k) approved by the FDA for patients requiring short-term extra corporeal circulatory support during cardiac surgery.

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

Circulatory Support and Graft Products

Ventricular assist devices perform some or most of the pumping function of the heart in patients with severe HF. In most cases, a cannula connects the left ventricle of the heart to a blood pump. Blood flows from the left ventricle to the pump chamber via the cannula, powered by an electric or air driven mechanism that drives the blood through another cannula into the aorta. From the aorta, the blood then circulates throughout the body. Mechanical or tissue valves enable unidirectional flow in some devices. Currently, the power source remains outside the body for all FDA-approved VADs.

Certain VADs are implanted internally, while others are placed outside the body. Some external devices are placed immediately adjacent to the body (paracorporeal), while other external VADs are positioned at a distance from the body (extracorporeal).

The Paracorporeal Ventricular Assist Device

The PVAD is a paracorporeal device that is less invasive than implantable VADs since only the cannula is implanted. The paracorporeal nature of the PVAD 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 PVAD. It is designed for intermediate duration use of a few weeks to several months, although this device has supported numerous patients for six to 18 months. Offering left, right or biventricular support, the PVAD and the IVAD, described below, are the only biventricular support systems approved for use as a bridge-to-transplant. This characteristic is significant since approximately 50% of bridge-to-transplant patients treated with the PVAD require right as well as left-sided ventricular assist. The PVAD is also the only device approved for both bridge-to-transplantation and recovery following cardiac surgery. We are working with the FDA to gain approval for a therapeutic recovery indication for the PVAD. The PVAD incorporates our proprietary biomaterial, Thoralon, which has excellent tissue and blood compatibility and is resistant to blood clots.

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

The Implantable Ventricular Assist Device

We received CE Mark certification to market the Thoratec IVAD in Europe in July 2003 and FDA approval for the U.S. market in August 2004. The IVAD was approved in Canada in November 2004. The IVAD is currently the only 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 PVAD device and is better suited for longer-term support compared to the PVAD. The outer covering of the IVAD is made of a titanium alloy, which facilitates implantation. The device weighs less than one pound and can be implanted in patients ranging in weight from 90 lbs to more than 220 lbs. The IVAD is designed as a bridge-to-transplantation and potentially for therapeutic recovery.

The HeartMate XVE

The HeartMate VE initially received FDA approval in September 1998. The enhanced version of the product, called the HeartMate XVE, received FDA approval in December 2001 for bridge-to-transplantation. In April 2003, the

HeartMate XVE received FDA

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approval for Destination Therapy. The HeartMate XVE is designed for use for a duration from several months to up to three years. The HeartMate XVE offers only left ventricular support. Patients with a HeartMate XVE do not require anti-coagulation drugs, other then aspirin, because of the product s incorporation of proprietary textured surfaces and tissue valves. As a result, we believe this device has the lowest rate of stroke incidence for patients using ventricular support. The implantable nature of this device enables patient mobility and home discharge.

The HeartMate II

The HeartMate II is designed to improve survival and quality of life and to provide five to ten years of circulatory support for a broad range of advanced heart failure patients. The HeartMate II is a small, implantable, electrically powered device that weighs about 12 ounces and is approximately 1.7 inches in diameter and 3.2 inches in length. 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. The HeartMate II is designed to provide blood flow through the circulatory system on a continual basis. More than 600 patients worldwide have been implanted with the HeartMate II as of the end of 2006. The IDE for the pivotal trial in the U.S. for both bridge-to-transplantation and Destination Therapy indications for use was fully approved by the FDA in May 2005. The device received CE Mark approval in November 2005, allowing for its commercial sale in Europe.

The CentriMag

The CentriMag, manufactured by Levitronix, is approved to provide mechanical circulatory support for up to 6 hours for patients suffering from severe, acute potentially reversible cardiac failure and is based on Levitronix s magnetically levitated bearingless motor technology. We entered into a distribution agreement with Levitronix in August 2006, with an initial term effective through December 2011, to distribute the CentriMag in the U.S. Levitronix expects to complete shortly three pilot trials in the U.S. to demonstrate safety in patients suffering from cardiogenic shock, experienced after cardiac surgery or acute myocardial infarction (AMI), and for patients requiring short-term right ventricular support. The CentriMag is 510(k) approved by the FDA for use in patients requiring short-term extracorporeal circulatory support during cardiac surgery and Levitronix has CE Mark approval in Europe to market the product to provide support for up to 14 days. Levitronix is currently in discussion with the FDA regarding an IDE to begin a pivotal trial to demonstrate safety and effectiveness of the CentriMag for any cardiac condition resulting in ventricular failure where there is an opportunity for recovery. These include but are not limited to AMI, post-cardiotomy cardiogenic shock, acute myocarditis, intractable ventricular arrhythmias, failed transplant and postpartum cardiomyopathy.

VAD Products Under Development

Our HeartMate III is a magnetically levitated centrifugal continuous flow pump. The original design goal for the device was 10 years or more of durability in patients with late-stage HF, including DT, BTT and therapeutic recovery. During the fourth quarter of 2006, we evaluated various options to enhance the clinical utility of HeartMate III, and during 2007, will be redefining its attributes to focus on unmet clinical needs.

Vascular Graft Products

The *Vectra* vascular access graft was approved for sale in the U.S. in December 2000 and in Europe in January 1998. It is designed for use as a shunt between an artery and a vein, primarily to provide access to the bloodstream for renal hemodialysis patients requiring frequent needle punctures during treatment.

ITC Segment

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

Point-of-Care Diagnostics

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

Hemochron point-of-care coagulation system;

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

Avox point-of-care CO-oximetry systems;

ProTime coagulation monitoring system; and

Hemoglobin Pro system.

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Hospital point-of-care

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

Hemochron is used to monitor a patient s coagulation while being administered anticoagulants in various settings, including in the cardiovascular operating room to monitor the drug Heparin and in an anticoagulation clinic to monitor the drug warfarin. 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. The system consists of a small, portable analytical instrument and disposable test cartridges.

Avox CO-oximeters are used to assess a patient s oxygenation status and are commonly used in the cardiac catherization lab, the ICU, the NICU and the emergency department. The system consists of a small, battery-operated instrument and disposable test cuvettes.

Alternate site point-of-care

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

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

Hemoglobin Pro (Hgb Pro), is used by professionals, mainly in doctors offices, to test for anemia. It provides quick results from a very small blood sample. The system consists of a small, hand-held test meter and disposable test strips.

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

Incision Products

Our incision products are used to obtain a patient s blood sample for diagnostic testing. These products are sold to both the hospital and alternate site point of care markets. Our products offer certain advantages and command a premium over the competition and are sold in the higher end of the market. We sell the Tenderfoot to obtain a heel stick blood sample from an infant, the Tenderlett to obtain a blood sample from a finger and Surgicutt to perform screening tests to determine platelet function. Our growth in this segment is limited due to lower priced products competing for the same customers.

Product Segments

Our cardiac assist and vascular graft products and services represented 62%, 62% and 60% of our product sales in 2006, 2005, and 2004, respectively. Our point-of-care blood diagnostics test systems and services and incision products represented 38%, 38% and 40% of our total product sales in 2006, 2005, and 2004, respectively. For financial information related to our segments for each of the past three years, please see Item 8, Note 15 to our Consolidated Financial Statements.

SALES AND MARKETING

Circulatory Support Products

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

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We have recruited and trained a direct sales force that, as of December 30, 2006, comprised of 20 experienced cardiovascular sales specialists who sell our circulatory support systems in the U.S., Canada, France, Germany, Spain, United Kingdom, Austria, Switzerland, Netherlands, Portugal and South Africa.

Thoratec s sales effort is complemented by nineteen direct clinical specialists and ten Market Development Managers. The clinical specialists conduct clinical educational seminars, assist with a new open-heart center s first VAD implant and resolve clinical questions or issues. Our Market Development Managers work with our leading VAD centers to generate referrals and increase awareness in the cardiology community regarding hemodynamic restoration therapy and VADs. We partner with universities, experienced clinicians and opinion leaders to assist with expanding clinical educational needs. Our sales team focuses on cardiac surgeons that perform heart transplantation, perfusionists and the transplant nursing staff.

In addition to our direct selling efforts, we have a network of international distributors who cover those markets representing the majority of our remaining VAD sales potential. Our sales and marketing tactics include direct mail, education seminars, symposia, equipment purchase and lease programs and journal advertisements, all common in the cardiovascular device market.

Hospitals and 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 product within thirty days to meet the surgeons requirements.

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

Vascular Graft Products

We market the *Vectra* through C.R. Bard Corporation (a competitor of ours) in the U.S., and selected countries in Europe, the Middle East and Northern Africa and through Goodman Co. Ltd. in Japan. In December 22, 2006, we modified our distributor agreement to continue exclusive distribution by C.R. Bard Corporation of this product until December 31, 2007.

Point-of-Care Diagnostics

In 2005, ITC completed the process of establishing a direct sales force in the U.S. to sell our hospital point-of-care coagulation and IRMA products. The Avox products have been added to the direct sales force s responsibilities as a result of our acquisition of Avox in October 2006. We currently maintain a direct sales staff of approximately 30 people in the U.S. that sell directly to hospitals. In the alternate site market segment, we have 16 sales people that sell through national and regional distributors, such as Cardinal Health, Inc., Quality Assured Services, Inc., Physician Sales and Service, Inc. and Caligor, A Henry Schein Company. Outside the U.S., ITC has four salespeople selling principally to third party distributors.

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

Incision Products

Our incision products are sold worldwide by distributors. In 2006, our largest incision distributor in the U.S. market is Cardinal Healthcare. In September 2006, we added Fisher Scientific as a distributor of Tenderfoot in the U.S.

COMPETITION

Competition from medical device companies and medical device divisions of health care and pharmaceutical companies is intense and is expected to increase. In our cardiovascular division, we are expecting new VAD competitors, Ventracor Limited and Heartware Limited to begin new clinical trials in the U.S. in 2007. Our incumbent competitors include AbioMed, Inc., Jarvik Heart, Inc., SynCardia

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Systems, Inc., and WorldHeart Corporation in the U.S. and Europe and Berlin Heart AG and MicroMed Technology, Inc. in Europe. In the vascular graft market, our principal competitors include Boston Scientific Corporation, C.R. Bard Corporation and W.L. Gore, Inc. Principal competitors in the hospital coagulation and blood gas monitoring equipment market include the Cardiac Surgery Division of Medtronic, Inc., the Diagnostic Division of Abbott Laboratories, Instrumentation Laboratory Company and Radiometer A/S. Our primary competitor in the skin incision device market is Becton Dickson and Company. Competitors in the alternate site point-of-care diagnostics market include HemoSense, Inc. and Roche Diagnostics.

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

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

Large medical device companies dominate the markets in which our ITC business competes. We estimate that we hold anywhere from approximately 5% to 60% market share, depending on the product. We expect that our growth in this market will be generated by gaining market share and from a shift of testing from central laboratories to the hospital and alternate site point-of-care. However, this market segment is very competitive, and includes the following potential drivers:

New competitors might enter the market with broader test menus. To address this risk, in late 2003 we acquired the IRMA product line of blood gas/electrolyte and chemistry tests, and in the fourth quarter of 2006, we acquired Avox, which has significantly increased our test menu offering, and also offers us the opportunity to develop the next generation system that combines blood gas, electrolyte and oxygenation testing in one machine.

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

PATENTS AND PROPRIETARY RIGHTS

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

Several patents cover aspects of our proprietary biomaterials technology. Aspects of our blood coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision device products are covered by patents directed to tube-and micro-coagulation whole blood analysis, including test methods, reagents and integral (on-board) controls, thick film electrochemical analysis of blood gases, blood electrolytes, and blood chemistry, and low trauma skin incision devices for capillary blood sampling, and methods of manufacturing such devices. The duration remaining of some of our biomaterials patents ranges from three to eight years, on our grafts from one to fourteen years and on our blood coagulation, blood gas, blood electrolytes, blood chemistry, and skin incision products from two to 16 years. During the term of our patents, we have the right to prevent third parties from manufacturing, marketing or distributing products that infringe upon our patents. ITC acquired a patent for cuvette technology from Avox, the remaining duration of which is approximately 6 years.

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 eight to 15 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 was originally developed by Sulzer and Lust. 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 it had sold all of its business in the bearingless motor and magnetic bearing fields to Levitronix GMBH and had assigned its portion of the agreements between Sulzer and us to Levitronix. We believe that the license remains in full force and effect.

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

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

Despite our patent rights and policies with regard to confidential information, trade secrets and inventions, we may be subject to challenges to the validity of our patents, claims that our products allegedly infringe the patent rights of others and the disclosure of our confidential information or trade secrets. These and other related risks are described more fully under the heading *Our inability to protect our proprietary technologies or an infringement of others patents could harm our competitive positions* in the Risk Factors section of this Annual Report on Form 10-K.

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

GOVERNMENT REGULATIONS

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

U.S. Regulations

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

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

Under the FDA s requirements, if a manufacturer can establish that a newly developed device is substantially equivalent to a legally marketed predicate device, the manufacturer may seek marketing clearance from the FDA to market the device by filing with the FDA 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 should be subjected to a more rigorous review, the FDA will require that the manufacturer submit a PMA application that must be approved by the FDA prior to marketing the device in the U.S.

Both a 510(k) and a PMA, if approved, may include significant limitations on the indicated uses for which a product may be marketed. FDA enforcement policy prohibits the promotion of approved medical devices for

unapproved uses. In addition, product approvals can be withdrawn for failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial marketing.

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On October 26, 2002, the FDA signed into law The Medical Device User Fee and Modernization Act of 2002. This law amends the FDA Act and regulations to provide, among other things, the ability of the FDA to impose user fees for medical device reviews. Our activities require that we make many filings with the FDA that are subject to this fee structure. Although the precise amount of fees that we will incur each year will be dependent upon the specific quantity and nature of our filings, these fees could be a significant amount per year.

In addition, any products distributed pursuant to the above authorizations are subject to continuing regulation by the FDA. Products must be manufactured in registered establishments and must be manufactured in accordance with Quality System Regulations. Adverse events must be reported to the FDA. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The FDA often requires post market surveillance (PMS), 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/or suspension of FDA approval. The export of devices such as ours is also subject to regulation in certain instances.

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

International Regulations

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

In order to be positioned for access to European and other international markets, we sought and obtained certification under the International Standards Organization (ISO) 13485 standards. ISO 13485 is a set of integrated requirements, which when implemented form the foundation and framework for an effective quality management system. These standards were developed and published by the ISO, a worldwide federation of national bodies, founded in Geneva, Switzerland in 1947. ISO has more than 90 member countries and ISO certification is widely regarded as essential to enter Western European markets. We obtained EN ISO 13485:2003 Certification in February 2006. Since 1998, all companies are required to obtain CE Marks for medical devices sold or distributed in the European Union. The CE Mark is an international symbol of quality. With it, medical devices can be distributed within the European Union. A prerequisite for obtaining authority to CE Mark products is to achieve full quality system certification in accordance with ISO 13485 and European Directives, such as the Medical Device Directive (MDD), In-Vitro Device Directive (IVDD) and the Active Implantable Medical Device Directive (AIMD). These are quality standards that cover design, production, installation and servicing of medical devices manufactured by us. We have the ISO 13485 and appropriate MDD, IVDD or AIMD certification and authority to CE Mark all our devices in commercial distribution, including our skin incision devices, blood coagulation testing devices, *Vectra* graft and VAD systems such as the PVAD, IVAD and HeartMate Systems. We are also certified to be in compliance with the requirements of the Canadian Medical Device Regulations at all Thoratec manufacturing sites, which certification is required to sell medical devices in Canada.

Other Regulations

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

THIRD PARTY REIMBURSEMENT AND COST CONTAINMENT

Our products are purchased primarily by customers, such as hospitals who 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.

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To date, CMS and a majority of private insurers with whom we have dealt approved reimbursement for our VADs and our diagnostic and vascular graft products. Effective October 1, 2003, CMS issued a National Coverage Decision Memorandum for the use of the HeartMate XVE for treating Destination Therapy in late-stage HF patients. Sixty-nine centers are now recognized by CMS as Medicare DT centers.

Effective October 1, 2006, Medicare reimbursement payment increased for heart assist devices with CMS LVAD centers receiving an average payment of approximately $143,000 in 2006 as compared to approximately $136,000 in 2005. Twenty-six new Healthcare Common Procedure Coding System codes also have been created by CMS to provide reimbursement for outpatient equipment and supplies. Since FDA approval of the HeartMate XVE for Destination Therapy, several private payors also have issued positive coverage decisions. In December 2002, Blue Cross/Blue Shield Technology Evaluation Center agreed to cover the use of VADs for Destination Therapy. The majority of local Blue Cross and Blue Shield plans cover procedures for both bridge-to-transplantation and long-term therapy indications. Since December 2002, the majority of national insurance carriers, including Aetna, Cigna, Humana, United Health Group and UNICARE, have policies covering the use of ventricular assist devices for FDA-approved indications, including DT.

MANUFACTURING

Our Cardiovascular segment products are manufactured at our facility in Pleasanton, California. This facility has been inspected, approved and licensed by the FDA and the State of California Department of Health Services, Food and Drug Section for the manufacture of medical devices and has received the ISO 13485:2300 Quality Systems certification. Our manufacturing processes consist of the assembling standard and custom component parts, and the testing of completed products. We rely on single sources of supply for several components of our VADs. We are aware of alternative suppliers for a majority, but not all, of our single-sourced items. The CentriMag is manufactured by Levitronix.

Our ITC segment blood coagulation testing and skin incision devices are manufactured in Edison, New Jersey, with the exception of the ProTime instrument and the hemoglobin monitor, which are manufactured through single source third party contract manufacturers in China and Germany, respectively. Our blood gas analyzer devices are manufactured in Roseville, Minnesota. The New Jersey and Minnesota facilities have been inspected, approved and licensed by the FDA and applicable state regulators. In addition, these facilities maintain ISO 9001, ISO 13485 and Canadian (CMDCAS) ISO certifications.

A significant amount of our ITC segment manufacturing at these facilities is vertically integrated, with only limited reliance on third parties, such as for the manufacture of printed circuit boards and the sterilization and testing of products. We rely on single sources of supply for some components manufactured at our New Jersey and Minnesota facilities, and use safety stocks where there might be risk in qualifying a second supplier in a timely manner.

Avox CO-oximetry instruments and disposable cuvettes are currently manufactured at the Avox facility in San Antonio, Texas. ITC expects to relocate Avox manufacturing to ITC s existing facilities in New Jersey during 2007. The Avox products rely on third parties for materials and electronic components, some of which have only one supplier. We use safety stocks where there might be a risk in qualifying a second supplier in a timely manner.

Both Cardiovascular and ITC have typically been able to fill orders from inventory and historically have not had significant order backlogs. We expanded manufacturing capacity for both Cardiovascular and ITC during 2006 and 2005 to accommodate the increased demand for our products and this has reduced our backlog significantly. Total backlog as of the end of fiscal 2006 and 2005 was none and approximately $1.2 million for our Cardiovascular segment and $0.2 million and $0.5 million for our ITC segment, respectively.

RESEARCH AND DEVELOPMENT

Thoratec s research and development expenses in 2006, 2005 and 2004 totaled $39.8 million, $32.3 million and $28.7 million, respectively. Research and development costs are largely project driven, and the level of spending depends on the level of project activity planned and subsequently approved and conducted. The primary component of our research and development costs is employee salaries and benefits. Projects related to our Cardiovascular segment typically include clinical trials, such as our HeartMate II pivotal trial, efforts to develop new products, such as the HeartMate II and HeartMate III, and efforts to improve the operation and performance of current products, such as efforts to improving the life of various components of our VAD products. ITC research and development projects

typically involve developing instruments and disposable test cuvettes or cartridges that will be used at the point-of-care. One such system is the Hemochron Signature Elite, which was introduced in September 2005. In addition, ITC devotes research and development efforts to maintain and improve current products based on customer feedback. Research and development costs for both segments also include regulatory and clinical costs associated with our compliance with FDA regulations and clinical trials such as the Phase II HeartMate II pivotal trial.

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MAJOR CUSTOMERS AND FOREIGN SALES

We sell our products primarily to large hospitals and distributors. No customer accounted for more than 10% of total product sales in fiscal year 2006.

Sales originating outside the U.S. and U.S. export sales accounted for approximately 24%, 23% and 23% of our total product sales for fiscal years 2006, 2005 and 2004, respectively. No individual foreign country accounted for a material portion of our net sales in any of the last three fiscal years.

EMPLOYEES

As of December 30, 2006, we had a total of 934 employees, consisting of 925 full-time employees and 9 part-time employees. Of our total employees, 909 are employed in the U.S. and 25 are employed in the United Kingdom and other European countries. None of our employees is covered by a collective bargaining agreement. We consider relations with our employees to be good.

ADDITIONAL INFORMATION

Additional information about Thoratec is available on our website at http://www.thoratec.com (although none of this information is, or should be deemed to be, incorporated by reference into this Annual Report on Form 10-K). We make filings of our periodic reports to the Securities and Exchange Commission (SEC), including annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as amendments to those reports, available free of charge on our website as soon as reasonably practicable following electronic filing of those reports with the SEC.

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

Our businesses face 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 ,and 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, 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, they may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. If any of the events or circumstances described in the following risk factors actually occur, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline significantly. Investors should consider the following risks, as well as the other information included in this Annual Report on Form 10-K, and other documents we file from time to time with the SEC, such as our quarterly reports on Form 10-Q, our current reports on Form 8-K and any public announcements we make from time to time.

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

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

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

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The FDA also requires us to adhere to Quality System Regulations, which include production design controls, testing, quality control, and 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 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 U.S. are subject to foreign regulatory requirements that vary from country to country. The time required to obtain approvals from foreign countries may be longer or shorter than that required for FDA approval, and requirements for foreign licensing may differ from FDA requirements. In any event, if we fail to obtain the necessary approvals to sell any of our products in a foreign country, or if any obtained approval is revoked or suspended, we will not be able to sell those products there.

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

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

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

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

- the number of CMS sites approved for Destination Therapy;
- the clinical outcomes of Destination Therapy procedures;
- cardiologists and referring physicians education regarding, and their commitment to, Destination Therapy;
- the economics of the Destination Therapy procedure for individual hospitals, which include the costs of the VAD and related pre- and post-operative procedures and their reimbursement;
- the impact of changes in reimbursement rates on the timing of purchases of VADs for Destination Therapy; and
- the economics for individual hospitals of not conducting a Destination Therapy procedure, including the costs and related reimbursements of long-term hospitalization.

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

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

The success of our current and future products will require acceptance or continued acceptance by cardiovascular and vascular surgeons, and other medical professionals. Such acceptance will depend on clinical results and the conclusion by these professionals that our products are safe, cost-effective and acceptable methods of treatment. Even if the safety and efficacy of our future products are established, physicians may elect not to use them for a number of reasons. These reasons could include the high cost of our VAD systems, restrictions on insurance coverage,

unfavorable reimbursement from health care payors, or use of alternative therapies. Also, economic, psychological, ethical and other concerns may limit general acceptance of our ventricular assist, graft and other products.

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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 XVE product. The suppliers of our ProTime and Hemoglobin products are located in China and Germany, respectively. We do not have long-term written agreements with most of our vendors and receive components from these vendors on a purchase order basis only. If we need alternative sources for key raw materials or component parts for any reason, such alternative sources may not be available and our inventory may not be sufficient to fill orders before we find alternative suppliers or begin manufacturing these components or materials ourselves. Cessation or interruption of sales of circulatory support products or our point-of-care products would seriously harm our business, financial condition and results of operations.

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

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

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

pay premium prices to our suppliers to keep their production lines open or to obtain alternative suppliers;

buy substantial inventory to last through the scheduled end of life of our product, or through such time that we will have a replacement product developed and approved by the FDA; or

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

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

We may encounter problems manufacturing our products.

We may encounter difficulties manufacturing products in quantities sufficient to meet demand. We do not have experience in manufacturing some of our products in the commercial quantities that might be required if we receive FDA approval of those products and indications currently under development, including the HeartMate II. If we have difficulty manufacturing any of our products, our sales may prove lower than would otherwise be the case and our reputation could be harmed.

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

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

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

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

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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 existi