THORATEC CORP
Form 10-K
February 27, 2008

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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 29, 2007

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 check mark whether the registrant is a large accelerated filer, an accelerated filer, a non- accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer þ	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o

(Do not check if a smaller reporting company)

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, 2007, the last business day of the Registrant s second fiscal quarter, was $819,285,295.

As of January 26, 2008, the Registrant had 54,101,466 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of Thoratec s definitive proxy statement for its 2008 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

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PART I

OVERVIEW

Thoratec Corporation (we, our, us, or the Company) is a world leader in therapies to address advanced heart fail (HF) and point-of-care diagnostics. Our business is comprised of two operating divisions: Cardiovascular and International Technidyne Corporation (ITC), a wholly owned subsidiary.

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.

For advanced HF, our Cardiovascular division develops, manufactures and markets proprietary medical devices used for mechanical circulatory support (MCS). Our primary product lines are our ventricular assist devices (VADs): the Thoratec Paracorporeal Ventricular Assist Device (PVAD), the Thoratec Implantable Ventricular Assist Device (IVAD), the HeartMate Left Ventricular Assist System (HeartMate XVE), and the HeartMate II Left Ventricular Assist System (HeartMate II). We refer to the PVAD and the IVAD collectively as the Thoratec product line and we refer to the HeartMate XVE and the HeartMate II collectively as the HeartMate product line. The PVAD, IVAD 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. In addition, for acute HF we market the CentriMag Blood Pumping System (CentriMag), which is manufactured by Levitronix LLC (Levitronix) and distributed by us in the U.S. under a distribution agreement with Levitronix. We also manufacture a vascular access graft for renal dialysis.

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. 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 acute, intermediate and chronic support. Collectively, our MCS devices are FDA-approved for the following indications: bridge-to-transplantation (BTT), long-term support for patients suffering from advanced stage HF who are not eligible for heart transplantation (Destination Therapy or DT), post-cardiotomy myocardial recovery, and support during cardiac surgery. 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 placed inside or outside the body, that can be used for left, right or biventricular support and that are suitable 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.

Several private payors have issued positive coverage decisions related to our products. The majority of local Blue Cross and Blue Shield plans cover procedures for both bridge-to-transplantation and long-term therapy indications. In addition, 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 Destination Therapy. The Centers for Medicare & Medicaid Services (CMS) covers reimbursement of many of the procedures using our VADs for FDA-approved indications, including reimbursement for the use of a Left Ventricular Assist System for Destination Therapy .

Our ITC division develops, manufactures and markets two product lines: point-of-care diagnostic test systems for hospital point-of-care and alternate site point-of-care markets, including diagnostic test systems that monitor blood coagulation while a patient is being administered certain anticoagulants, and to monitor blood gas/electrolytes, oxygenation and chemistry status; and incision products including devices used to obtain a patient s blood sample for diagnostic testing and screening for platelet function.

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OUR PRODUCTS

Cardiovascular Division

VADs supplement 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).

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

Our product portfolio of implantable and external MCS devices and graft products are described below.

The Paracorporeal Ventricular Assist Device

The PVAD is an external, pulsatile, ventricular assist device, FDA approved for BTT, including home discharge, and post-cardiotomy myocardial recovery and provides left, right and biventricular MCS. 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 benefits including shorter 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 short-to-intermediate duration use of a few weeks to several months, although this device has supported numerous patients for six to eighteen 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 BTT and home discharge. This characteristic is significant since approximately 50% of bridge-to-transplant patients treated with the PVAD require right as well as left-sided ventricular assistance. The PVAD is also the only device approved for both bridge-to-transplantation and recovery following cardiac surgery. The PVAD incorporates our proprietary biomaterial, Thoralon, which has excellent tissue and blood compatibility and is resistant to blood clots.

The Implantable Ventricular Assist Device

The IVAD is an implantable, pulsatile, ventricular assist device FDA approved for BTT, including home discharge, and post-cardiotomy myocardial recovery and provides left, right, or biventricular MCS. The IVAD maintains the same blood flow path, valves and blood pumping mechanism as the PVAD, but has an outer housing made of a titanium alloy that makes it suitable for implantation.

We received CE Mark approval to market the 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 VAD that can provide left, right or biventricular support.

The HeartMate XVE

The HeartMate XVE is an implantable, pulsatile, left ventricular assist device for intermediate and longer-term MCS and is the only device approved in the U.S., Europe and Canada for long term support of patients ineligible for heart transplantation. Patients with a HeartMate XVE do not require anticoagulation drugs, other then aspirin, because of the product s incorporation of proprietary textured surfaces and tissue valves. The system is comprised of the blood pump and a wearable controller and batteries providing a high degree of patient freedom and mobility.

The HeartMate VE initially received FDA approval in September 1998 for BTT and in November 2002 for DT. The enhanced version of the product, called the HeartMate XVE, received FDA approval in December 2001 for bridge-to-transplantation. In April 2003, the HeartMate XVE received FDA approval for Destination Therapy.

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The HeartMate II

The HeartMate II is an implantable, electrically powered, continuous flow, left ventricular assist device consisting of a miniature rotary blood pump designed to provide intermediate and long-term MCS. 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. Significantly smaller than the HeartMate XVE and with only one moving part the HeartMate II is simpler and designed to operate more quietly than pulsatile devices. More than 1,150 patients worldwide have been implanted with the HeartMate II as of the end of 2007. In November 2007 the FDA Circulatory System Devices Advisory Panel recommended unanimously that the FDA approve, with conditions, the Pre-Market Approval (PMA) application allowing the use of its HeartMate II as a BTT. In addition, the HeartMate II is in a Phase II pivotal trial in the U.S. for Destination Therapy. 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 MCS for up to six hours for patients suffering from severe, 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. The CentriMag is 510(k) cleared 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 thirty days. 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 longer periods of support.

Vascular Graft Products

The Vectra Vascular Access Graft (*Vectra*) 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 Division

Our product portfolio of point-of-care diagnostic test systems and incision products includes the following:

Hospital point-of-care

The HEMOCHRON Whole Blood Coagulation System

The HEMOCHRON Whole Blood Coagulation System (HEMOCHRON) is used to quantitatively monitor a patient s coagulation status while the patient is being administered anticoagulants. It may be used in various hospital settings. For instance, it is used in the cardiovascular operating room and cardiac catheterization lab to monitor the drug Heparin, and in an anticoagulation clinic to monitor the drug warfarin. The system consists of a small portable instrument and disposable test cuvettes or tubes and delivers results in minutes.

The IRMA TRUpoint Blood Analysis System

The IRMA TRUpoint Blood Analysis System (IRMA) is used to quantitatively monitor a patient s blood gas, electrolyte and chemistry status. This instrument is a self-contained, portable system which uses disposable test cartridges and delivers results in minutes.

The AVOXimeter Whole Blood Co-Oximeter/Oximeter System

The AVOXimeter Whole Blood Co-Oximeter/Oximeter System (AVOXimeter) is used to assess a patient s oxygenation status and is commonly used in the cardiac catherization lab, the intensive care unit (ICU), the neonatal intensive care unit (NICU) and the emergency department. This portable instrument uses small, single-use test cuvettes and delivers results in less than ten seconds.

Our integrated data management system connects the HEMOCHRON, IRMA and AVOXimeter products.

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Alternate site point-of-care

The ProTime Microcoagulation System

The ProTime Microcoagulation System (ProTime) is designed to safely monitor blood clotting activity in patients on anticoagulation therapy, specifically warfarin. The system can be prescribed for patient use at home or can be used in the physician s office or clinic. The system consists of a portable, quantitative instrument and disposable test cuvettes and delivers results in minutes.

The Hgb Pro Professional Hemoglobin Testing System

The Hgb Pro Professional Hemoglobin Testing System (Hgb Pro) is used by professionals, mainly in the doctor s office, to test for anemia. Hgb Pro delivers quick results from a small blood sample placed on a disposable test strip inserted into a hand-held test meter.

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

Incision Products

The Tenderfoot Heel Incision Device (Tenderfoot), the Tenderlett Finger Incision Device (Tenderlett) and the Surgicutt Bleeding Time Device (Surgicutt) are used by medical professionals to obtain a patient s blood sample for diagnostic testing. The Tenderfoot is a heel stick used for infant testing, the Tenderlett is used for finger incisions and the Surgicutt is used to perform screening tests to determine platelet function. These devices feature permanently retracting blades for safe incision with minimal pain, as compared to traditional lancets, which puncture the skin.

These products are sold to both the hospital point-of-care and alternate site point-of-care segments of the market. Our products offer certain advantages, command a premium over the competition and are sold in the higher end of the market. Our growth in this segment is limited due to lower priced products competing for the same customers.

PRODUCT SEGMENTS

Our MCS and vascular graft products and services represented 61%, 62% and 62% of our product sales in 2007, 2006, and 2005, respectively. Our point-of-care blood diagnostics test systems and services and incision products represented 39%, 38% and 38% of our total product sales in 2007, 2006, and 2005, respectively. For financial information related to our segments for each of the past three years, please see Item 8, Note 14 to our Consolidated Financial Statements.

OUR MARKETS

Cardiovascular Division

Our VAD products primarily serve patients suffering from advanced 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 people suffer from HF in the U.S. and approximately 550,000 new cases are diagnosed each year. While the number of treatment options for earlier stage HF has increased in recent years, pharmacologic therapies 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. In addition to the use of VADs, other procedures addressing HF include angioplasty, biventricular pacing, valve replacement, bypass and left ventricular reduction surgery.

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Despite attempts to manage HF through drug therapy, the only curative treatment for advanced 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 2007. 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 time 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 BTT and as Destination Therapy. In addition to the chronic HF markets, MCS devices are also approved for use for acute HF during and following cardiac surgery. All four indications are summarized below.

Bridge-to-Transplantation

VADs provide additional cardiac support for patients with advanced stage HF waiting for a donor heart. Approximately 30% 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-transplantation in adults that are commercially marketed, three of which are Thoratec devices.

Destination Therapy

In April 2003, we received approval to market the HeartMate XVE for patients with advanced stage HF who are not candidates for heart transplantation due to other degenerative illnesses or advanced age referred to as Destination Therapy. The National Institutes for Health estimated that the Destination Therapy application represents a market opportunity of up to 100,000 patients in the U.S. For these late-stage HF patients, drug therapy is currently the only other treatment available. With drug therapy, the 12-month survival rate for these patients is approximately 25%. We believe that the HeartMate XVE 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 partially dependent on the development of our HeartMate product line.

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 addition to the longer term mechanical circulatory support indications, the CentriMag is approved to provide MCS for periods appropriate to cardiopulmonary bypass and for circulatory support when complete cardiopulmonary bypass is not necessary, for example during valvuloplasty, mitral valve reoperation, surgery of the vena cava or aorta, or liver transplants.

ITC Division

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 segment of the market, into the alternate site point-of-care segment of the market 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, in the case of the ProTime monitoring of oral anticoagulants, clinical studies have shown that more frequent monitoring results in patients staying 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.

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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 segments of the market. 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 is comprised of the following market and product development activities:

Offer a broad range of products. Our MCS devices provide 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 MCS devices 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 continue our investment in building these relationships through cardiology education outreach programs, 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 MCS 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 in transplant centers and using our existing sales channels to gain acceptance and adoption of our products in the major hospitals that perform open heart surgery.

Destination Therapy market. In April 2003, we received approval to market the HeartMate XVE for Destination Therapy in the treatment of late-stage HF patients who are not candidates for heart transplants. While the initial CMS reimbursement approval is limited to sixty-three centers, we estimate the market penetration for this indication could eventually comprise a meaningful portion of the 100,000 patients diagnosed with late-stage HF, as we introduce new technologies that increase the useful life of our VADs and improve clinical outcomes.

Increase our presence in Cardiovascular and ITC markets. 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 HF 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) clearance 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 longer periods of support.

Point-of-Care market. In October 2006, we acquired A-VOX Systems, Inc. (Avox), a point-of-care company that developed and manufactured portable, bedside AVOXimeter 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. We 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.

Chronic HF market. In December 2007, we made a nominal investment in Acorn Cardiovascular, Inc., a medical device company that has intellectual property rights to the CorCap™ Cardiac Support Device (CSD), to support patients with heart failure. The CorCap CSD is a mesh wrap that is placed around the heart to support and relieve stress on the heart muscle. The CorCap CSD is intended to improve the heart s size, shape and function. The CorCap CSD received CE Marking in Europe and is in clinical trials in the United States.

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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. The Phase II trial enrolled 133 BTT patients with twenty-six centers participating. 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 fifty-seven years of cumulative support; days of support ranged from 1-568 days. In 2007, we obtained the unanimous recommendation of the FDA Circulatory System Devices Advisory Panel that the FDA would approve, with conditions, the PMA allowing the use of the HeartMate II for BTT. As of December 29, 2007, enrollment in this arm was over 430 patients.

In addition, we have a separate arm of the trial seeking approval for DT. This trial calls for patients randomized to Thoratec s HeartMate XVE on a 2:1 basis. During 2007 we exceeded the initial 200 patient limit and continued to enroll patients through Continued Access Protocol (CAP). The two year follow up on the initial pivotal trial will be completed in May 2009. As of December 29, 2007, we enrolled over 290 patients under the randomized portion of the trial and total enrollment in the DT arm was over 470 patients.

Develop new products. The HeartMate III is a magnetically levitated centrifugal continuous flow pump. The initial design goal for the device was ten years or more of durability in patients with late-stage HF, including DT, BTT and therapeutic recovery. In light of the very positive HeartMate II clinical trial results, beginning the fourth quarter of 2006, we initiated a process to evaluate various options to enhance the clinical utility of HeartMate III compared to HeartMate II. During 2008, we will be redefining the HeartMate III program to focus on these unmet clinical needs.

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 covering reimbursement 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-three 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 will continue to make improvements that enhance the performance and cost effectiveness of our products.

SALES AND MARKETING

Mechanical Circulatory Support Products

Hospitals that perform open heart surgery and heart transplants are the potential customers for our MCS products. We estimate that 104 of the approximately 1,000 hospitals in the U.S. that perform open-heart surgery also perform heart transplants. We actively market to heart transplant hospitals and large cardiac surgery centers as well as to the approximately 100 heart transplant hospitals in Europe.

We have recruited and trained, as of December 29, 2007, twenty-three experienced cardiovascular sales specialists who sell our circulatory support systems throughout the world. Our sales force is complemented by twenty-one direct clinical specialists and eleven Market Development Managers. The clinical specialists conduct clinical educational seminars, assist with VAD implants 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 MCS. We partner with universities, experienced clinicians and opinion leaders to assist with expanding clinical educational needs.

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 rental programs and journal advertisements, all common in the cardiovascular device market.

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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 surgeon s 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 twenty-four 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 distributors in the U.S., and selected countries in Europe, the Middle East, Northern Africa and Japan.

Point-of-Care Diagnostics

We currently maintain a direct sales staff of approximately thirty people in the U.S. that sell directly to hospitals. In the alternate site market segment, we have seventeen 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 six salespeople selling principally to third party distributors.

Incision Products

Our incision products are sold worldwide by distributors. In 2007, our largest incision distributor in the U.S. market was Cardinal Healthcare.

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 continue to expect new competitors. In June 2007, Ventracor Limited began a new clinical trial for BTT and DT for its Ventrassist device, and others are expected to begin new clinical trials in the U.S. in 2008. Our incumbent competitors include AbioMed, Inc., Jarvik Heart, Inc., MicroMed Technology, Inc., SynCardia Systems, Inc., and WorldHeart Corporation in the U.S. and Europe and Berlin Heart GmbH in Europe. 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 Dickinson and Company. Competitors in the alternate site point-of-care diagnostics market include Inverness Medical Innovation, 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 DT indications, we estimate that we have a majority of the VAD market share domestically and internationally. We believe that potential competitors are several years from completion of the clinical trials required before their products will become commercially available and compete with our products in the U.S.

Large medical device companies dominate the markets in which our ITC division 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 the fourth quarter of 2006, we acquired Avox, which has 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.

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New drug therapies under development may not require the intense monitoring of a patient s coagulation necessary with the current anticoagulation 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, our VAD products are 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 systems 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 on some of our biomaterials patents ranges from two to seven years, on our grafts from twelve to fourteen years and on our blood coagulation, blood gas, blood electrolytes, oxygenation, blood chemistry, and skin incision products from one to fifteen 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 seven to fourteen 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.

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.

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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.

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 FDA advisory committee of outside experts may be required to 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 eighteen 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.

On October 26, 2002, the FDA signed into law The Medical Device User Fee and Modernization Act (MDUFMA) of 2002. On September 28, 2007 MDUFMA was reauthorized for fiscal years 2008-2012. 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.

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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 our VAD 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.

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-three centers are now recognized by CMS as Medicare DT centers.

Effective October 1, 2007, Medicare reimbursement payment increased for heart assist devices with CMS LVAD centers receiving on average of a 25% increase for implanted LVADs under Medicare Severity Diagnosis Related Groups One (MSDRG1). Twenty-six Healthcare Common Procedure Coding System codes 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.

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MANUFACTURING

VADs and grafts for the Cardiovascular division are manufactured at our facility located in Pleasanton, California. This facility has been inspected, approved and licensed by the FDA, State of California Department of Health Services Food and Drug Section for the manufacture of medical devices, and has received the ISO 13485:2003 Quality Systems certification. The manufacturing processes consist of utilizing precision components fabricated from a variety of materials and assembling these components into specific configurations governed by the VAD design requirements. During the manufacturing process, the VAD assemblies are rigorously tested to meet rigid operational and quality standards.

The manufacturing process relies on single sources of supply for several of the components used to manufacture VADs. We are working to identify and validate alternate sources of supply for critical components. Where alternate sources are not available, we are working to develop strategic alliances with the supplier and closely manage inventories to assure the on-going supply of product.

The CentriMag product line is manufactured by Levitronix and distributed from our manufacturing facility located in Pleasanton, California.

During 2007, the Cardiovascular division began the expansion of the manufacturing facility located in Pleasanton, California. The main focus of the expansion project is to provide adequate manufacturing capacity to meet the proposed volumes created by the anticipated FDA approval of the HeartMate II product line. When complete, the renovated facility will have the necessary capacity to meet the requirements for our VAD products for the next five to seven years.

Our ITC division 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 division 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.

During 2007, the manufacturing facility for the AVOXimeter was relocated from San Antonio, Texas to ITC s existing facilities in New Jersey. The AVOXimeter relies 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. With the expanded manufacturing capacity for both Cardiovascular and ITC, we will be in a position to accommodate the increased demand for our products. Total backlog as of the end of fiscal 2007 and 2006 was none for both years for our Cardiovascular division, and $2.3 million and $0.2 million, respectively, for our ITC division. At the end of 2007 the increase in order backlog at ITC was due to new customer demand.

RESEARCH AND DEVELOPMENT

Our research and development expenses in 2007, 2006 and 2005 totaled $43.8 million, $39.8 million and $32.3 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 related to our Cardiovascular division typically include clinical trials, such as our HeartMate II pivotal trial, efforts to develop new products, such as the HeartMate II and HeartMate III, and efforts to improve the operation and performance of current products, such as efforts to improve the ease of use of our VAD products and 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 divisions 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 2007, 2006 and 2005.

Sales originating outside the U.S. and U.S. export sales accounted for approximately 28%, 24% and 23% of our total product sales for fiscal years 2007, 2006 and 2005, respectively. No individual foreign country accounted for more than 10% of our net sales in any of the last three fiscal years.

EMPLOYEES

As of December 29, 2007, we had a total of 1,164 employees, consisting of 1,023 full-time employees and 141 part-time employees. Of our total employees, 1,139 are employed in the U.S. and 25 are employed in the United Kingdom and other European countries. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

ADDITIONAL INFORMATION

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

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

Our businesses face many risks. 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 do not meet the requirements to obtain clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, then we will be required to file a PMA application. The process for a PMA application is lengthy, expensive and typically requires extensive pre-clinical and clinical trial data.

We may not obtain clearance of a 510(k) notification or approval of a PMA application with respect to any of our products on a timely basis, if at all. If we fail to obtain timely clearance or approval for our products, we will not be able to market and sell them, thereby harming our ability to generate sales. The FDA also may limit the claims that we can make about our products. We also may be required to obtain clearance of a 510(k) notification or a PMA Supplement from the FDA before we can market products 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 may 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 existing products. For example, we are currently developing updated versions of our HeartMate and point-of-care blood diagnostics products. If we fail to commercialize any of these new products, product improvements and new indications on a timely basis, or if they are not well accepted by the market, our future growth may suffer.

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

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

Our commercially available VAD products 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 the 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, AVOXimeter and Hgb Pro disposable test strips.

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

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

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

A significant amount of our product sales are generated by our VADs implanted temporarily in patients awaiting heart transplants. The number of heart transplants conducted worldwide depends on the number of hearts available to transplant.

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

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

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

With the exception of Canada and the larger countries in Europe, we sell our Thoratec and HeartMate product lines in foreign markets through distributors. In addition, we sell our vascular access graft products through the Bard Peripheral Vascular division of C.R. Bard Corporation (which is also a competitor of ours) in the U.S. and selected countries in Europe, the Middle East and Africa, and through Goodman Co. Ltd. in Japan. Substantially all of the international operations and a large portion of the alternate site domestic operations of ITC are conducted through distributors. For the year ended December 29, 2007, 64% of ITC s total product sales were through distributors.

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

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

Competition from medical device companies and medical device divisions of health care and pharmaceutical companies is intense and is expected to increase. In our Cardiovascular division, we continue to expect new competitors. In June 2007, Ventracor Limited began a new clinical trial for BTT and DT for its Ventrassist device, and others are expected to begin new clinical trials in the U.S. in 2008. Our incumbent competitors include AbioMed, Inc., Jarvik Heart, Inc., MicroMed Technology, Inc., SynCardia Systems, Inc., and WorldHeart Corporation in the U.S. and Europe and Berlin Heart GmbH in Europe. 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 Dickinson and Company. Competitors in the alternate site point-of-care diagnostics market include Inverness Medical Innovation, Inc. and Roche Diagnostics.

Some of our competitors, especially those of our ITC division, have substantially greater financial, technical, distribution, marketing and manufacturing resources, while other competitors have different technologies that may achieve broader customer acceptance or better cost structures than our products. Accordingly, our competitors may be able to develop, manufacture and market products more efficiently, at a lower cost and with more market acceptance than we can. In addition, new drugs or other devices may reduce the need for VADs. We expect that the key competitive factors will include the relative speed with which we can:

develop products;

complete clinical testing;

receive regulatory approvals;

achieve market acceptance; and

manufacture and sell commercial quantities of products.

Large medical device companies dominate the markets in which ITC competes. We expect that any growth in this market will come from expanding our market share at the expense of other companies and from testing being shifted away from central laboratories to the hospital and alternate site point-of-care. However, this market segment is very competitive and includes the following potential drivers:

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

New competitors might enter the market with broader test menus.

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

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

A substantial portion of our total sales occurs outside the U.S. We anticipate that sales outside the U.S. and U.S. export sales will continue to account for a significant percentage of our product sales and we intend to continue to expand our presence in international markets. Non-U.S. sales are subject to a number of special risks. For example:

we sell some of our products at a lower price outside the U.S.;

sales agreements may be difficult to enforce;

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

foreign customers may have longer payment cycles;

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

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

intellectual property rights may be (and often are) more difficult to enforce in foreign countries;

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

fluctuations in exchange rates may affect product demand and adversely affect the profitability, in U.S. dollars, of products sold in foreign markets where paymen