THORATEC CORP
Form 10-K
February 27, 2009

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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 January 3, 2009

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 þ No o

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 27, 2008, the last business day of the Registrant s second fiscal quarter, was $939,126,565.

As of January 31, 2009, the Registrant had 56,413,279 shares of common stock outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of Thoratec s definitive proxy statement for its 2009 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

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PART I

BUSINESS

OVERVIEW

Thoratec Corporation (we, our, us, or the Company) is the world leader in mechanical circulatory support with a product portfolio to treat the full range of clinical needs for advanced heart failure patients. We develop, manufacture and market proprietary medical devices used for circulatory support. We also develop, manufacture and market point-of-care diagnostic test systems and skin incision products. 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.

OUR PRODUCTS

Cardiovascular Division

For advanced heart failure (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, HeartMate XVE and HeartMate II are approved by the U.S Food and Drug Administration (FDA) and Conformite Europeene (CE) Mark approved in Europe. 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.

VADs supplement the pumping function of the heart in patients with advanced 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).

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

The Paracorporeal Ventricular Assist Device

The PVAD is an external, pulsatile, ventricular assist device, FDA approved for bridge-to-transplantation (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 nine 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 BTT. This characteristic is significant since approximately 50% of BTT patients treated with the PVAD and the IVAD require right as well as left-sided ventricular assistance. The PVAD and the IVAD are also the only devices approved for both BTT 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.

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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 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 than 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 long-term support for patients suffering from advance stage HF who are not eligible for heart transplantation (Destination Therapy or DT). The enhanced version of the product, called the HeartMate XVE, received FDA approval in December 2001 for BTT. In April 2003, the HeartMate XVE received FDA approval for DT.

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 HF 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. In April 2008, we received FDA approval for the HeartMate II for BTT. In addition, the HeartMate II is in a Phase II pivotal trial in the U.S. for DT. In December 2008, we announced that the HeartMate II had demonstrated superiority in a pre-specified interim analysis to the HeartMate XVE, the control device in the DT pivotal study. This allowed us to gain FDA approval to end randomization in the ongoing continuous access protocol (CAP) phase of the DT study. We also announced that we are preparing a PreMarket Approval (PMA) for DT and we are targeting our submission to the FDA by mid-year 2009. 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 by the FDA to provide MCS for up to six hours for patients suffering from severe, but 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 2007, 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 has recently commenced a U.S. pivotal trial to demonstrate safety and effectiveness of the CentriMag for periods of support up to thirty days. In November 2008, Levitronix received approval from the FDA for a humanitarian device exemption for the CentriMag Right Ventricular Assist System for temporary circulatory support up to thirty days for patients in cardiogenic shock due to acute right ventricular failure.

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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 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 that 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.

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.

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 physician 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.

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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. These 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 69%, 61% and 62% of our product sales in 2008, 2007, and 2006, respectively. Our point-of-care blood diagnostics test systems and services and incision products represented 31%, 39% and 38% of our total product sales in 2008, 2007, and 2006, 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.

OUR MARKETS

Cardiovascular Division

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 American Heart Association, 5.7 million people suffer from HF in the U.S. and approximately 670,000 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 angiotensin-converting enzyme (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.

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 2,300 hearts available for transplant in the U.S. in the most recent twelve months reported. At any given time, approximately 2,700 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.

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Bridge-to-Transplantation

VADs provide additional cardiac support for patients with late-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 as surgeons level of comfort with the technology increases, particularly for longer-term support cases. There are currently five devices approved in the U.S. as a bridge-to-transplantation in adults that are commercially marketed, four of which are Thoratec devices.

Destination Therapy

In April 2003, we received approval to market the HeartMate XVE for patients with late-stage HF who are not candidates for heart transplantation due to other degenerative illnesses or advanced age, referred to as Destination Therapy. The National Institute 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 and alternate site point-of-care segments of the market including 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 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 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.

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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. Our Market Development Managers work in partnership with our VAD centers to increase the awareness of MCS and VADs in the cardiology community.

Expand the use of VADs in existing segments. 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 segment. 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 Centers for Medicare and Medicaid Services (CMS) reimbursement approval is limited to sixty-seven 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 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 HF segment. 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.

Point-of-Care segment. 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. 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 segment. In December 2007, we made a nominal investment in Acorn Cardiovascular, Inc., a medical device company that has intellectual property rights to the CorCapTM 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 Mark in Europe and is in clinical trials in the United States.

In February 2009, we announced that we entered into a definitive merger agreement to acquire HeartWare International Inc. (HeartWare). The transaction is subject to approval of HeartWare s stockholders and satisfaction of other customary closing conditions, including regulatory clearance. If the transaction is completed, we believe that it will enable us to build upon our mechanical support technologies, giving better options to a broader heart failure patient population.

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Obtain approval for new products. We are currently enrolling in a trial seeking DT approval for the HeartMate II. 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. In early December, 2008, we announced that a pre-specified interim analysis of data from the trial showed that patients implanted with the HeartMate II achieved statistically superior outcomes versus those in the control group who were implanted with our HeartMate XVE. As a result, the study s Data Safety Monitoring Board concurred with our plan to eliminate randomization for all additional patients enrolled in the DT study under FDA-authorized CAP. We plan to file our PMA seeking FDA approval of the HeartMate II for DT in late May of 2009, leading to an expected approval in the first half of 2010. As of January 23, 2009, there were 648 patients enrolled in the DT arm of the trial.

In November 2008, Levitronix received approval from the FDA for a humanitarian device exemption for the CentriMag Right Ventricular Assist System for temporary circulatory support up to thirty days for patients in cardiogenic shock due to acute right ventricular failure.

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 2009, we will continue to redefine the HeartMate III program to focus on these unmet clinical needs.

Increase cost effectiveness of the therapies that employ our products. While Medicare data indicates the cost of implanting a VAD for DT is tracking similarly to that of a heart, liver or other major organ transplant, cost remains a 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-seven centers to develop the Destination Therapy market through either previous recognition by Medicare or the Joint Commission certification program for DT, 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 January 3, 2009, seventeen experienced cardiovascular sales specialists who sell our circulatory support systems throughout the world. Our sales force is complemented by twenty-two direct clinical specialists and thirteen 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.

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.

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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 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-one 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 sales people selling principally to third party distributors.

Incision Products

Our incision products are sold worldwide by distributors. In 2008, our largest incision distributor in the U.S. market was Cardinal Healthcare.

COMPETITION

Competition from pharmaceutical companies, medical device companies and medical device divisions of health care 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. During the third quarter of 2008 Ventracor Limited announced that it had enrolled 122 patients in the BTT trial and 54 patients in the DT trial and filed the first module of its PMA. In addition, in 2008, HeartWare began a clinical trial for BTT for its HVAD device with enrollment occurring at two centers. HeartWare, also announced in January 2009, that it received CE mark approval for the HVAD device. In 2008, Terumo Heart, Inc. began a clinical trial for BTT for its DuraHeart device. 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.

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 increased our test menu offering, and has also offered 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 product line.

We hold several patents on the HeartMate II axial blood flow pump and transcutaneous energy transmission technology, the remaining duration of which ranges from six to thirteen years. In August 1998, we obtained a license to incorporate technology developed by Sulzer Electronics Ltd. (Sulzer) and Lust Antriebstechnik GmbH (Lust) 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 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 GMBH. We believe that the license remains in full force and effect.

In addition, 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. Several patents cover aspects of our proprietary biomaterials technology, and skin incision products from four to sixteen years. The duration remaining on some of our skin incision related patents ranges from four to thirteen years, and four to sixteen years on our blood coagulation, blood gas, blood electrolytes, oxygenation and blood chemistry patents. In addition, the duration remaining on our graft related patents range from eleven to thirteen 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.

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 position* 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.

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GOVERNMENT REGULATIONS

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

U.S. Regulations

In the 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 MCS systems, blood coagulation testing devices, skin incision devices, and Vectra graft products are regulated as medical devices. To obtain FDA approval to market VADs similar to those under development, the FDA requires proof of safety and efficacy in human clinical trials performed under an Investigational Device Exemptions (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. 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 (QSR). The Medical Device Reporting, (MDR), regulations require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our

product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Furthermore, the FDA may at any time inspect our facilities to determine whether we have adequate compliance with FDA regulations, including the QSR, which requires manufacturers to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process. Following an inspection of our facilities, ITC received in January 2009 an FDA Form 483 that listed a significant number of observations related to the adequacy of our quality system. We are in the process of preparing a response to address each of FDA s concerns.

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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 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 and manufacturing activities. 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 related procedures performed.

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-seven centers are now reimbursed for providing DT through either previous recognition by Medicare or the Joint Commission certification program for DT.

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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 BTT 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.

Effective March 2008, CMS approved coverage for the use of home Prothombin Time and International Normalized Ratio monitoring for patients with mechanical heart valves, chronic atrial fibrillation or venous thromboembolism on warfarin. Previously, only mechanical heart valve patients were covered. This expanded coverage decision increases the market opportunity for our ProTime system.

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 2008, the Cardiovascular division continued 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 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, blood oxygenation 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.

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 2008 and 2007 was $0.2 million and zero, respectively, for our Cardiovascular division, and $1.7 million and $2.3 million, respectively, for our ITC division.

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RESEARCH AND DEVELOPMENT

Our research and development expenses in 2008, 2007 and 2006 totaled $52.9 million, $43.8 million and $39.8 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. 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.

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 2008, 2007 and 2006.

Sales originating outside the U.S. and U.S. export sales accounted for approximately 26%, 28% and 24% of our total product sales for fiscal year 2008, 2007 and 2006, 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 January 3, 2009, we had a total of 1,209 employees, consisting of 1,110 full-time employees and 99 temporary employees. Of our total employees, 1,186 are employed in the U.S. and 23 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 comply with government regulations, including FDA Quality System Regulations, or our products experience certain adverse events, the FDA or foreign regulatory authorities may withdraw our market clearance or take other enforcement 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 (FDCA), 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.

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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, a new PMA, 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.

In addition, our medical device products and operations are subject to extensive regulation by the FDA pursuant to the Federal Food, Drug and Cosmetic Act and various other federal, state and foreign governmental authorities. Government regulations and foreign requirements specific to medical devices are wide ranging and govern, among other things, design, development, manufacture, testing, labeling, storage, marketing, distribution, promotion, record keeping, and approval or clearance. The FDA requires us to adhere to Quality System Regulations (QSR), which include production design controls, testing, quality control, labeling, packaging, sterilization, and storage and documentation procedures. The FDA may at any time inspect our facilities to determine whether we have adequate compliance with the FDA s QSR and other regulatory requirements. Compliance with QSR 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.

Following an inspection of our facilities, ITC received in January 2009 an FDA Form 483 that listed a significant number of observations relating to the adequacy of ITC s quality system. We are in the process of preparing a response to address each of the FDA s concerns. If we do not adequately address the FDA s concerns, or we do not maintain compliance with the FDA s QSR in the future, the FDA may issue untitled letters, warning letters, impose fines, injunctions, consent decrees, civil or criminal penalties, withdraw marketing clearance or approvals, require product recalls, or take other enforcement action against ITC, which in each case would harm our business.

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;

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

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

the economics for individual hospitals of not conducting a Destination Therapy procedure, including the costs and related reimbursements of long-term hospitalization.

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

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

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

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

We depend on a number of custom-designed components and materials supplied by other companies including, in some cases, single source suppliers for components, instruments and materials used in our VAD products and blood testing products. For example, single source suppliers 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.

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

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

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

As part of our growth strategy, we intend to develop and introduce a number of new products and product improvements. We also intend to develop new indications for our existing products. For example, we are currently developing updated versions of our HeartMate and point-of-care blood diagnostics products. If we fail to commercialize 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.

A majority of our 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.

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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 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, which could harm our ITC business.

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 January 3, 2009, 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 and results of operations 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 pharmaceutical companies, medical device companies and medical device divisions of health care 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. During the third quarter of 2008 Ventracor Limited announced that it had enrolled 122 patients in the BTT trial and 54 patients in the DT trial and filed the first module of its PMA. In addition, in 2008, HeartWare began a clinical trial for BTT for its HVAD device with enrollment occurring at two centers. HeartWare, also announced in January 2009, that it received CE mark approval for the HVAD device. In 2008, Terumo Heart, Inc. began a clinical trial for BTT for its DuraHeart device. 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 than we do, 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.

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

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

New competitors might enter the market with broader test menus.

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

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

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

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

sales agreements with foreign customers may be difficult to enforce;

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

foreign customers may have longer payment cycles;

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

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

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

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

fluctuations in exchange rates may affect product demand and adversely affect the profitability, in U.S. dollars, of products sold in foreign markets where payments are made in local currencies.

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

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

Because some of our international sales are denominated in local currencies and not in U.S. dollars, our reported sales and earnings are subject to fluctuations in foreign currency exchange rates. At present, we use forward foreign currency contracts to protect the gains and losses created by the re-measurement of non-functional currency denominated assets and liabilities. However, we do not hedge foreign currency exposures that will arise from future sales. As a result, sales occurring in the future that are denominated in foreign currencies may be translated into U.S. dollars at a less favorable rate than our current exchange rate resulting in reduced revenues and earnings.

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

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

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

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

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

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

We have a substantial level of debt in the form of our senior subordinated convertible notes. The terms of our senior subordinated convertible notes do not restrict our ability to incur additional indebtedness, including indebtedness senior to the convertible notes. Our current level of indebtedness, among other things, could:

make it difficult for us to make payments on our debt;

make it difficult for us to obtain any necessary financing in the future for working capital, capital expenditures, debt service, acquisitions or general corporate purposes;

limit our flexibility in planning for or reacting to changes in our business;

reduce funds available for use in our operations;

make us more vulnerable in the event of a downturn in our business or an increase in interest rates;

impair our ability to incur additional debt because of financial and other restrictive covenants proposed for any such additional debt; or

place us at a possible competitive disadvantage relative to less leveraged competitors and competitors that have better access to capital resources.

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

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

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

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

Commencing October 1, 2008, holders of the senior subordinated convertible notes may convert their notes through the final maturity date of the notes into shares of our common stock. The conversion of some or all of the senior subordinated convertible notes will dilute the ownership interest of our existing shareholders. Any sales in the public market of the common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, future sales of substantial amounts of our stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our stock. Sales of our shares and the potential for such sales could cause our stock price to decline. Further, the existence of the convertible notes may encourage short selling of our common stock by market participants because the conversion of the convertible notes could depress the price of our common stock.

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

A substantial portion of our assets is comprised of goodwill and purchased intangible assets, recorded as a result of our merger with Thermo Cardiosystems, Inc. (TCA) in 2001. We may not receive the recorded value for our intangible assets if we sell or liquidate our business or assets. The material concentration of intangible assets increases the risk of a large charge to earnings if recoverability of these intangible assets is impaired. For example, in the first quarter of 2004, we completed an assessment of the final results from the feasibility clinical trial for the Aria CABG graft, which was ongoing through fiscal 2003. Based on the clinical trial results, we decided not to devote additional resources to development of the Aria graft. Upon the decision to discontinue product development, we recorded an impairment charge of approximately $9 million as of January 3, 2004 to write off purchased intangible assets related to the Aria graft. In the event of another such charge to net income, the market price of our common stock could be adversely affected.

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

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

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

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

The price of our common stock may fluctuate significantly.

The price of our common stock has been, and is likely to continue to be, volatile, which means that it could decline substantially within a short period of time. For example, our closing stock price ranged from $13.09 to $32.49 during the twelve months ended January 3, 2009. The price of our common stock could fluctuate significantly for many reasons, including the following:

- future announcements concerning us or our competitors;
- regulatory developments, enforcement actions bearing on advertising, marketing or sales, and disclosure regarding completed ongoing or future clinical trials;
- quarterly variations in operating results, which we have experienced in the past and expect to experience in the future;
- introduction of new products or changes in product pricing policies by us or our competitors;
- acquisition or loss of significant customers, distributors or suppliers;
- reaction to estimates of business operations, product development or financial performance made public by our management;
- business acquisitions or divestitures;
- changes in earnings estimates by analysts;
- changes in third party reimbursement practices;
- charges, amortization and other financial effects relating to our business; and
- fluctuations in the economy, world political events or general market conditions, such as the current economic recession.

In addition, stock markets in general and the market for shares of health care stocks in particular, have experienced extreme price and volume fluctuations, especially in the past several months as a result of the current global financial crisis. These fluctuations can be unrelated to the operating performance of the affected companies. These broad market fluctuations may adversely affect the market price of our common stock. The market price of our common stock could decline below its current price and the market price of our stock may fluctuate significantly in the future. These fluctuations may be unrelated to our performance.

Shareholders often have instituted securities class action litigation after periods of volatility in the market price of a company s securities. Securities class action suits have been filed against us in the past, and if other such suits are filed

against us in the future we may incur substantial legal fees and our management s attention and resources may be diverted from operating our business in order to respond to the litigation.

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Current global economic conditions could harm our business and liquidity.

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies continuing into 2009. Continued concerns about the systemic impact of potential long-term and wide-spread recession, energy costs, geopolitical issues, the availability and cost of credit, and the global housing and mortgage markets have contributed to increased market volatility and diminished expectations for western and emerging economies. As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. These factors have lead to a decrease in spending by businesses and consumers alike. Continued turbulence in the U.S. and international markets and economies and prolonged declines in spending may adversely affect our liquidity and financial condition, and the liquidity and financial condition of our customers and suppliers, including our ability to refinance maturing liabilities and access the capital markets to meet liquidity needs.

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

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

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

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

We have a history of net losses.

We were founded in 1976 and we have had some history of incurring losses from operations. We anticipate that our expenses will increase as a result of increased pre-clinical and clinical testing, research and development and selling, general and administrative expenses. We could also incur significant additional costs in connection with our business development activities and the development and marketing of new products and indicated uses for our existing products, as well as litigation and share-based compensation costs. Such costs could prevent us from maintaining profitability in future periods.

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

The number of our employees has substantially increased during the past several years. We expect to continue to increase the number of our employees, and our business may suffer if we do not manage and train our new employees effectively. Our product sales may not continue to grow at a rate sufficient to support the costs associated with an increasing number of employees. Any future periods of rapid growth may place significant strains on our managerial, financial and other resources. The rate of any future expansion, in combination with our complex technologies and products, may demand an unusually high level of managerial effectiveness in anticipating, planning, coordinating and meeting our operational needs, as well as the needs of our customers. If we are unable to meet these demands. our reputation, revenue and results of operations could be harmed.

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Revisions to accounting standards, financial reporting and corporate governance requirements and tax laws could result in changes to our standard practices and could require a significant expenditure of time, attention and resources, especially by senior management.

We must follow accounting standards, financial reporting and corporate governance requirements and tax laws set by the governing bodies and lawmakers in the U.S. and U.K. where we do business. From time to time, these governing bodies and lawmakers implement new and revised rules and laws. These new and revised accounting standards, financial reporting and corporate governance requirements and tax laws may require changes to our financial statements, the composition of our board of directors, the responsibility and manner of operation of various board-level committees, the information filed by us with the governing bodies and enforcement of tax laws, against us. Implementing changes required by new standards, requirements or laws likely will require a significant expenditure of time, attention and resources. It is impossible to completely predict the impact, if any, on us of future changes to accounting standards, financial reporting and corporate governance requirements and tax laws.

Our accounting principles that recently have been or may be affected by changes in the accounting principles are as follows:

accounting for stock-based compensation;

fair value measurement (including convertible debt instruments);

accounting for income taxes; and

accounting for business combinations and related goodwill.

It is possible that changes in the application of certain accounting principles may have a material impact on our consolidated results of operations such as our adoption of FASB issued FSP Accounting Principles Board (APB) 14-1, *Accounting For Convertible Debt Instruments That May Be Settled in Cash Upon Conversion (Including Partial Cash Settlement),* which alters the accounting treatment for convertible debt instruments and allows for either mandatory or optional cash settlements upon conversion. FSP APB 14-1, will impact the accounting associated with our senior subordinated convertible notes recorded at a book value of $143.8 million. FSP APB 14-1 requires the issuer to recognize additional (non-cash) interest expense based on the market rate for similar debt instruments without the conversion feature. This FSP APB 14-1 will be effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years and be applied retrospectively to all periods presented and will be recognized as of the beginning of the first quarter of 2009.

We are subject to taxation in a number of jurisdictions and changes to the corporate tax rate and laws of any of these jurisdictions could increase the amount of corporate taxes we have to pay.

We pay taxes principally in the U.S., U.K., Germany and France and these tax jurisdictions have in the past and may in the future make changes to their corporate tax rates and other tax laws, which changes could increase our future tax obligations.

Unanticipated changes in our tax rates could affect our future results of operations. Our future effective tax rates could be unfavorably affected by changes in tax laws or the interpretation of tax laws, by unanticipated decreases in the amount of revenue or earnings in states with low statutory tax rates, or by changes in the valuation of our deferred tax assets and liabilities. In addition, we are subject to the continual examination of our income tax returns by the Internal Revenue Service and other domestic and foreign tax authorities, primarily related to our intercompany transfer pricing. We regularly assess the likelihood of outcomes resulting from these examinations to determine the adequacy of our provision for income taxes and our reserves for potential adjustments, including tax credits and other tax benefits that can be challenged under audit by various taxing authorities resulting in potential reduction in the amount of credits or other benefits eventually realized. We believe such estimates to be reasonable; however, there can be no assurance that the final determination of any of these examinations will not have an adverse effect on our operating results and financial position.

Future levels of research and development spending, capital investment and export sales may impact our entitlement to related tax credits and benefits which have the effect of lowering our tax rate.

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

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

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

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

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

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

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

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

Item 1B. ***Unresolved Staff Comments***

None.

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Item 2. ***Properties***

We are headquartered in Pleasanton, California, where we own an approximately 67,000 square-foot building that is Thoratec s corporate office building. We also own approximately 66,000 square feet of office, manufacturing and research facilities in Edison, New Jersey.

Additionally, we lease the following facilities:

Approximately 62,000 square feet of office, manufacturing and research facilities in Pleasanton, California, expiring in 2012.

Approximately 6,400 square feet of warehouse space in Dublin, California, expiring in 2011.

Approximately 11,000 square feet of office and research facilities in Rancho Cordova, California, expiring in 2012.

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

Approximately 53,500 square feet of office and research facilities in Piscataway, New Jersey, expiring in 2014.

Approximately 35,000 square feet of office, manufacturing and research facilities in Roseville, Minnesota, expiring in 2013.

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

Approximately 8,700 square feet of office and warehouse facilities in the United Kingdom expiring in 2022.

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

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

Item 3. ***Legal Proceedings***

None.

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

No matters were submitted to a vote of security holders during the quarter ended January 3, 2009.

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Our Executive Officers

Gerhard F. Burbach, 46 President, Chief Executive Officer and Director, joined our company as President, Chief Executive Officer and a director, in January 2006. Prior to joining us, Mr. Burbach served as the President and Chief Executive Officer of Digirad Corporation, a leading provider of solid-stage imaging products and services to cardiologist offices, hospitals and imaging centers. He continues to serve on the Digirad board of directors. Before that he served for two years as president and chief executive officer of Bacchus Vascular Inc, a developer of interventional cardiovascular devices. Previously, he served for three years as chief executive officer of Philips Nuclear Medicine, a division of Philips Medical Systems specializing in nuclear medicine imaging systems. Until its acquisition by Philips Medical Systems, he spent four years at ADAC Laboratories, a provider of nuclear medicine imaging equipment and radiation therapy planning systems, where he became president and general manager of the nuclear medicine division. He also spent six years with the consulting firm of McKinsey & Company, primarily within the firm s healthcare practice.

David V. Smith, 49, Executive Vice President and Chief Financial Officer, joined our company on December 29, 2006 as Executive Vice President and Chief Financial Officer. Prior to joining us, Mr. Smith was Vice President, Chief Financial Officer of Chiron Corporation, a global pharmaceutical company, from April 2003 until April 2006. Mr. Smith served as Chiron s Vice President, Finance from February 2002 until April 2003 and as Chiron s Vice President and Principal Accounting Officer from February 1999 until February 2002. Mr. Smith served as the Vice President, Finance and Chief Financial Officer of Anergen, Inc. from 1997 until he joined Chiron. From 1988 to 1997, Mr. Smith held various financial management positions with Genentech, Inc., in both the United States and Europe. Mr. Smith is a member of the Board of Directors and Chair of the Audit Committee of Perlegen Sciences, Inc.

Lawrence Cohen, 59, President of ITC, joined our company in May 2001 as President of ITC. Prior to joining ITC, Mr. Cohen served as CEO of HemoSense, Inc., a developer of medical diagnostic products, from August 1998 to April 2001. From October 1989 to March 1998, Mr. Cohen held the positions of Vice President Marketing and Sales, Vice President International and Worldwide Executive Vice President at Ortho-Clinical Diagnostics, a Johnson & Johnson company. From 1980 to 1989, Mr. Cohen held executive management positions at Instrumentation Laboratory and Beckman Coulter Corporation. He is a past president of the Biomedical Marketing Association and was on the Board of Trustees of the National Blood Foundation from 1998 to 2004.

David A. Lehman, 48, Senior Vice President, General Counsel and Secretary, joined our company as Vice President and General Counsel in May 2003. Mr. Lehman was appointed as Secretary in December 2004 and became Senior Vice President in February 2007. Prior to joining us, Mr. Lehman served as Vice President and General Counsel of Brigade Corporation, a provider of business process outsourcing services, from June 2000 to May 2003. From November 1997 to June 2000, Mr. Lehman was Assistant General Counsel at Bio-Rad Laboratories, Inc., a diagnostic and life science products company. Prior to November 1997, Mr. Lehman was in the legal department of Mitsubishi International Corporation, in New York and Tokyo, for more than seven years. Mr. Lehman started his career as an associate attorney at the law firm of Hall, Dickler, Kent, Friedman and Wood.

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PART II

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

Our common stock is traded on the NASDAQ Global Select Market under the symbol THOR. The following table sets forth, for the periods indicated, the high and low closing sales price per share of our common stock, as reported by the NASDAQ Global Select Market. As of January 31, 2009, there were 56,413,279 shares of our common stock outstanding with approximately 556 holders of record, including multiple beneficial holders at depositories, banks, and brokerages listed as a single holder in the street name of each respective depository, bank or broker.

	High	Low
Fiscal Year 2007		
First Quarter	$21.17	$17.44
Second Quarter	21.68	17.36
Third Quarter	21.02	18.67
Fourth Quarter	21.25	17.60
Fiscal Year 2008		
First Quarter	$18.44	$13.09
Second Quarter	18.50	14.08
Third Quarter	28.87	16.67
Fourth Quarter	32.49	19.48

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

There were no unregistered sales of our equity securities during the three months ended January 3, 2009.

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Stock Price Performance Graph

The graph below compares the cumulative total shareholder return on an investment in our common stock, the NASDAQ Stock Market Index (U.S. companies only) and the NASDAQ Medical Equipment Index for the five-year period ended January 2, 2009, the last trading day in our 2008 fiscal year.

The graph assumes the value of an investment in our common stock and each index was $100 at December 31, 2003 and the reinvestment of all dividends, if any.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Thoratec Corporation, The NASDAQ Composite Index
And The NASDAQ Medical Equipment Index
(PERFORMANCE GRAPH)

* $100 invested on December 31, 2003 in stock or index-including reinvestment of dividends.

	12/03	12/04	12/05	12/06	12/07	12/08
Thoratec Corporation	100.00	80.59	160.02	135.96	140.68	251.28
NASDAQ Composite	100.00	110.08	112.88	126.51	138.13	80.47
NASDAQ Medical Equipment	100.00	120.01	136.96	142.08	181.26	99.84

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Issuer Purchases of Equity Securities

The following table sets forth certain information about our common stock repurchased during the three months ended January 3, 2009:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs (1)	Approximate dollar value of shares that may yet be purchased under the plans or programs
		(in thousands, except per share data)		
September 28, 2008 through October 25, 2008	2.0	$ 25.55		$
October 26, 2008 through November 22, 2008	2.6	21.86		
November 23, 2008 through January 3, 2009	4.0	29.80		
Total	8.6(2)	$ 26.37		$

(1) Our share repurchase programs, which authorized us to repurchase up to a total of $130 million of the Company s common shares, were announced on February 11, 2004 as a $25 million program, on May 12, 2004 as a $60 million program, on July 29, 2004 as a $25 million program and on February 2,

2006 as a $20 million program. These programs authorize us to acquire shares in the open market or in privately negotiated transactions and do not have an expiration date. No shares were repurchased under these programs during the three months ended January 3, 2009. As of January 3, 2009, we have $10.1 million remaining on our share repurchase programs.

(2) Shares purchased that were not part of our publicly announced repurchase programs represent the surrender value of shares of restricted stock used to pay income taxes due upon vesting, and do not reduce the dollar value that may yet be purchased under our publicly announced repurchase programs.

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

The selected consolidated financial data presented below for the five fiscal years in the period ended January 3, 2009 are derived from our audited financial statements. The data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations below and our audited consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K in item 7.

We report on a 52-53 week fiscal year, which ends on the Saturday closest to December 31. Accordingly, our fiscal year will periodically contain more or less than 365 days. For example, fiscal 2004 ended January 1, 2005, fiscal 2005 ended December 31, 2005, fiscal 2006 ended December 30, 2006 and fiscal 2007 ended December 29, 2007. Our fiscal year 2008 contained 53 weeks and ended on January 3, 2009 and our fiscal 2009 will include 52 weeks and will end on January 2, 2010.

	Fiscal Year				
	2008(1)	**2007(1)**	**2006(1)**	**2005**	**2004**
	(In thousands, except per share data)				
Statement of Operations:					
Product sales	$313,564	$234,780	$214,133	$201,712	$172,341
Gross profit	185,998	136,264	125,485	123,340	100,222
Amortization of goodwill and purchased intangible assets	13,183	12,582	12,055	11,204	11,724
In-process research and development			1,120		
Litigation, merger, restructuring and other costs			447	95	733
Net income	$ 22,532	$ 3,235	$ 3,973	$ 13,198	$ 3,564
Basic net income per share	$ 0.41	$ 0.06	$ 0.08	$ 0.27	$ 0.07
Diluted net income per share	$ 0.39	$ 0.06	$ 0.07	$ 0.26	$ 0.07
Balance Sheet Data:					
Cash and cash equivalents and short term available-for-sale investments	$248,651	$218,350	$194,478	$210,936	$145,859
Working capital	332,378	301,736	265,691	269,293	206,250
Total assets	684,584	613,719	591,135	573,918	518,034
Subordinated convertible debentures	143,750	143,750	143,750	143,750	143,750
Long-term deferred tax liability (2)	31,285	35,953	46,421	48,765	62,016
Total shareholders equity (2)	$454,700	$398,029	$365,073	$348,147	$292,108

(1) On January 1, 2006, we adopted Statement of Financial Accounting Standards (SFAS) No. 123 (R) and included

share-based compensation for employee stock-based awards in our results of operations.

(2) On December 31, 2006, we adopted Financial Accounting Standards Board (FASB) Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, an interpretation of SFAS No. 109* and as a result we reported a cumulative effect adjustment of $0.5 million, which increased our December 31, 2006 Accumulated deficit balance offset by a Long-term deferred tax liability balance.

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

This Annual Report on Form 10-K, including the documents incorporated by reference in this Annual Report, includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E on Form 10-K 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, m plans, could and other 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 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.

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

Overview

We are a leading manufacturer of mechanical circulatory support products for use by patients with HF. Our VADs are used primarily by HF patients to perform some or all of the pumping function of the heart. We currently offer the widest range of products to serve this market. We believe that our long-standing reputation for quality and innovation, and our excellent relationships with leading cardiovascular surgeons and HF cardiologists worldwide, position us to capture growth opportunities in the expanding HF market. Through our wholly-owned subsidiary ITC, we design, develop, manufacture and market point-of-care diagnostic test systems and incision products that provide fast and accurate blood test results to improve patient management, reduce healthcare costs and improve patient outcomes.

Our Business Model

Our business is comprised of two operating divisions: Cardiovascular and ITC.

The product line of our Cardiovascular division is:

Circulatory Support Products. Our mechanical circulatory support products include the PVAD, IVAD, HeartMate XVE, HeartMate II and CentriMag for acute, intermediate and long-term mechanical circulatory support for patients with advanced HF. 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 division 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/electrolytes, oxygenation and chemistry status.

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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Critical Accounting Policies and Estimates

We have identified the policies and estimates below as critical to our business operations and the understanding of our results of operations. The impact of, and any associated risks related to, these policies and estimates on our business operations are discussed below. Preparation of financial statements in accordance with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amount of assets, liabilities, revenue and expenses and the disclosure of contingent assets and liabilities. There can be no assurance that actual results will not differ from those estimates and assumptions.

Revenue Recognition

We recognize revenue from product sales for our Cardiovascular and ITC business divisions when evidence of an arrangement exists, title has passed (generally upon shipment) or services have been rendered, the selling price is fixed or determinable and collectability is reasonably assured. Sales to distributors are recorded when title transfers upon shipment. A reserve for sales returns is recorded for sales through the distributor applying reasonable estimates of product returns based upon historical experience.

We recognize sales of certain Cardiovascular division products to first-time customers when we have determined that the customer has the ability to use the products. These sales frequently include the sale of products and training services under multiple element arrangements. Training is not considered essential to the functionality of the products. The amount of revenue under these arrangements allocated to training is based upon fair market value of the training, which is typically performed on our behalf by third party providers. Under this method, the total value of the arrangement is allocated to the training and the Cardiovascular division products based on the relative fair market value of the training and products.

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

Reserves

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

The majority of our products are covered by up to a two-year limited manufacturer s warranty from the date of shipment or installation. Estimated contractual warranty obligations are recorded when the related sales are recognized and any additional amounts are recorded when such costs are probable and can be reasonably estimated, at which time they are included in Cost of product sales in our consolidated statements of operations. In determining the warranty reserve estimate, management makes judgments and estimates on such matters as repair costs and probability of warranty obligations. The change in accrued warranty expense is summarized in the following table:

	Balance Beginning of Year	Charges to Costs and Expenses	Warranty Expenditures	Balance End of Year
		(in thousands)		
Fiscal year ended 2008	$1,006	$1,925	$(1,860)	$1,071
Fiscal year ended 2007	$1,032	$ 634	$ (660)	$1,006
Fiscal year ended 2006	$1,073	$ 756	$ (797)	$1,032

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Estimated excess and obsolete inventory reserves are recorded when inventory levels exceed projected sales volume for a certain period of time. In determining the excess obsolete reserve, management makes judgments and estimates on matters such as forecasted sales volume. If sales volume differs from projection, adjustments to these reserves may be required.

Management must make judgments to determine the amount of reserves to accrue. If any of these decisions proves incorrect, our consolidated financial statement could be materially and adversely affected.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of tax credits, benefits, and deductions, such as tax benefits from our non-U.S. operations and in the calculation of certain tax assets and liabilities, which arise from differences in the timing of revenue and expense for tax and financial statement purposes.

We record a valuation allowance to reduce our deferred income tax assets to the amount that is more-likely-than-not to be realized. In evaluating our ability to recover our deferred income tax assets we consider all available positive and negative evidence, including our operating results, on going tax planning and forecasts of future taxable income on a jurisdiction by jurisdiction basis. In the event we were to determine that we would be able to realize our deferred income tax assets in the future in excess of their net recorded amount, we would make an adjustment to the valuation allowance which would reduce the provision for income taxes. Conversely, in the event that all or part of the net deferred tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to earnings in the period such determination is made.

We believe we have provided adequate reserves for uncertain tax positions for anticipated audit adjustments by United States federal, state and local, as well as foreign, tax authorities based on our estimate of whether, and the extent to which, additional taxes, interest and penalties may be due. If events occur which indicate payment of these amounts is unnecessary, the reversal of the liabilities would result in tax benefits being recognized in the period when we determine the accrued liabilities are no longer warranted. If our estimate of tax liabilities proves to be less than the ultimate assessment, a further charge to expense would result.

Evaluation of Purchased Intangibles and Goodwill for Impairment

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

In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, such assets with indefinite lives are not amortized but are subject to annual impairment tests. If there is an apparent impairment, a new fair value would be determined. If the new fair value is less than the carrying amount, an impairment loss would be recognized.

Valuation of Share-Based Awards

We account for share-based compensation expense in accordance with the fair value recognition provisions of SFAS No. 123(R), *Share-Based Payment*. Under SFAS No. 123(R), share-based compensation expense is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of option awards at the grant date requires judgment, including estimating the expected term of stock options, the expected volatility of our stock, expected forfeitures and expected dividends. The computation of the expected volatility assumption used in the Black-Scholes option pricing model for option grants is based on historical volatility. When establishing the expected life assumption, we review annual historical employee exercise behavior of option grants with similar vesting periods. In addition, judgment is also required in estimating the amount of share-based awards that are expected to be forfeited. If actual results differ significantly from these estimates,

share-based compensation expense and our results of operations could be materially affected.

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Fair Value Measurements

We adopted the provisions of SFAS No. 157, *Fair Value Measurements,* on December 30, 2007. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (exit price) in an orderly transaction between market participants at the measurement date.

In determining fair value, we use various approaches, including market, income and/or cost approaches, and each of these approaches requires certain inputs. SFAS No. 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of us. Unobservable inputs are inputs that reflect our assumptions as compared to the assumptions market participants would use in pricing the asset or liability based on the best information available in the circumstances. The hierarchy is broken down into three levels based on the reliability of inputs as follows:

Level 1-Valuations based on quoted prices in active markets for identical assets or liabilities that we have the ability to access. Assets and liabilities utilizing Level 1 inputs include broker-dealer quote securities that can be traded in an active market. We used Level I assumptions for cash and cash equivalents. Since valuations are based on quoted prices that are readily and regularly available in an active market, a significant degree of judgment is not required.

Level 2-Valuations based on quoted prices of similar investments in active markets, of similar or identical investments in markets that are not active or model based valuations for which all significant inputs and value drivers are observable, directly or indirectly. Assets and liabilities utilizing Level 2 inputs primarily include municipal bonds and for the straight convertible debt feature of our senior subordinated convertible notes, except the make-whole provision, using a level 3 input, described below.

Level 3-Valuations based on inputs that are unobservable and significant to the overall fair value measurement. Assets and liabilities utilizing Level 3 inputs include certain auction rate securities, our Levitronix convertible debenture and the make-whole feature of our senior subordinated convertible notes. Given the current credit market illiquidity for auction rate securities, our estimates are subject to significant judgment by management.

Fair value is a market-based measure considered from the perspective of a market participant who holds the asset or owes the liability rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, our own assumptions are developed to reflect those that market participants would use in pricing the asset or liability at the measurement date. See Note 3 to the consolidated financial statements for further information about our financial assets that are accounted for at fair value.

Due to the uncertainty inherent in the valuation process, estimates of fair value may differ significantly from the values that would have been obtained had an active market for the securities existed, and the differences could be material. After determining the fair value of our available-for-sale security, gains or losses on these investments are recorded to other comprehensive income, until either the investment is sold or we determine that the decline in value is other-than-temporary. Determining whether the decline in fair value is other-than-temporary requires management judgment based on the specific facts and circumstances of each investment. For investments in available-for-sale securities, these judgments primarily consider: the financial condition and liquidity of the issuer, the issuer s credit rating, and any specific events that may cause us to believe that the debt instrument will not mature and be paid in full; and our ability and intent to hold the investment to maturity. Given the current market conditions, these judgments could prove to be incorrect, and companies with relatively high credit ratings and solid financial conditions may not be able to fulfill their obligations. In addition, if we decide not to hold an investment until maturity, it may result in the recognition of an other-than-temporary impairment.

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Results of Operations

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

	For the Fiscal Years Ended					
	2008		2007		2006	
	(in thousands, except percentages)					
Product sales	$ 313,564	100%	$ 234,780	100%	$ 214,133	100%
Cost of product sales	127,566	41	98,516	42	88,648	41
Gross margin	185,998	59	136,264	58	125,485	59
Operating expenses:						
Selling, general and administrative	94,142	30	82,044	35	73,687	35
Research and development	52,943	17	43,835	19	39,841	19
Amortization of purchased intangible assets	13,183	4	12,582	5	12,055	6
Purchased in-process research and development					1,120	1
Litigation					447	
Total operating expenses	160,268	51	138,461	59	127,150	61