

TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW



# LIFE

"It's just a joy, it's like a new life and all you want to do is keep going and going.

You have your heart back." william



TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

# RESTORED

HeartMate II® marks a new era in the treatment of advanced heart failure, bringing new hope to thousands of patients and families.





TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW



# 

"I'm really blessed with getting this HeartMate II. It's changed my life." Art



TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

# RESTORED

HeartMate II is the first and only continuous flow device approved by the FDA for both the Bridge-to-Transplantation and Destination Therapy indications.





**TECHNOLOGY** 

CLINICAL

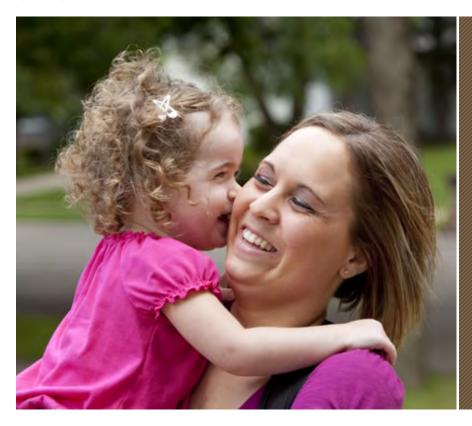
PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW



# LIFE

"Now, I am able to resume my life as a wife, mother and physical therapist." Laura



TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

# RESTORED

Thoratec's products and support have enabled clinicians to restore life to over 15,000 heart failure patients worldwide.





TECHNOLOGY

CLINICAL

**PARTNERSHIP** 

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

Thoratec had another strong year in 2010 as we continued to build upon our leadership in mechanical circulatory support (MCS) and serve our mission of enhancing the lives of advanced-stage heart failure patients.

#### Dear Shareholders:

2010 was highlighted by the successful commercial launch of the HeartMate II for Destination Therapy (DT) following its approval in January. HeartMate II provides clinicians with the first and only continuous flow device approved for both Bridge-to-Transplantation (BTT) and DT, enabling the field to transform care and restore life for patients in these under-served populations. In 2010, our clinician education, center training and market development programs demonstrated their value, as we realized improving patient outcomes, broader utilization of the HeartMate II for DT, increased referral activity from cardiologists and the addition of new HeartMate II centers. At the same time, we continued to build a foundation for future growth through investments in our organization and product development pipeline.

During the year, our devices provided extended survival and improved quality of life for thousands of new patients suffering from advanced-stage heart failure. HeartMate II alone is currently supporting over 3,000 patients and has provided over 6,000 years of enhanced life to heart failure patients worldwide.





**TECHNOLOGY** 

CLINICAL

**PARTNERSHIP** 

A LOOK AHEAD

CORPORATE **INFORMATION**  FINANCIAL INFORMATION

2010 ANNUAL REVIEW

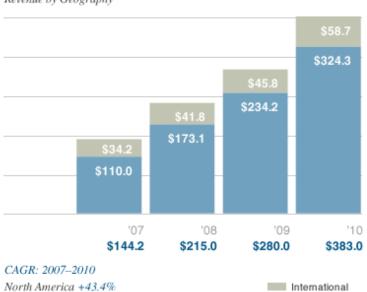
The Company generated a strong financial performance during the year, with revenues from continuing operations of \$383.0 million, an increase of 37 percent over 2009. We achieved a meaningful improvement to our bottom line as we realized improved gross margin and operating leverage, while continuing to make significant investments in our programs designed to create long-term value for Thoratec. We also completed the disposition of International Technidyne Corporation, which provided us cash proceeds of \$55 million and enabled the Company to increase its focus on the MCS market opportunity.

We added 43 new HeartMate II centers during 2010, ending the year with 254, including 29 open-heart centers, which we believe will assume an increasingly important role in the utilization of MCS. In addition, a total of 90 centers in the U.S. had achieved Medicare certification for DT reimbursement from the Joint Commission at the end of the year, with a number of others in the final stages of the certification process.

Our new GoGear® HeartMate® external peripherals, introduced in late 2009, experienced widespread adoption with more than 200 centers utilizing them at the end of 2010. These offerings, which include an improved battery, charger and power module, are providing patients increased freedom and mobility, and an enhanced quality of life. We continued the advancement of the HeartMate II platform with the full commercial launch of sealed inflow and outflow grafts in March 2011. By eliminating the need for preclotting, these grafts should reduce operating time, reduce costs, and lower intraoperative bleeding rates.

#### Cardiovascular Revenue Growth

Revenue by Geography



International +19.7%

Excludes ITC division in all periods

North America

Total +38.5%



**TECHNOLOGY** 

CLINICAL

**PARTNERSHIP** 

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

#### **Market Development**

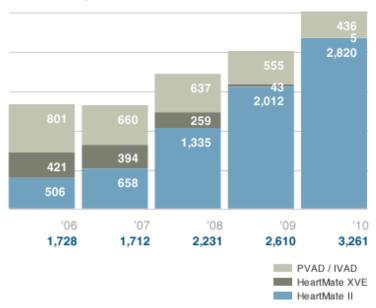
During the year, we increased the size of our worldwide sales force to more than 100, and these team members successfully implemented our clinician education and market development programs. These efforts led to increased patient referrals, increased implant activity and the addition of new HeartMate II DT centers.

To facilitate adoption, we held a number of successful educational events, including fellows programs, VAD program coordinator training and well-attended user meetings in the U.S., Europe, and Asia Pacific. We also implemented programs focused on educating high-potential referring cardiologists about the advantages of MCS, and we will increase our efforts in this regard during 2011. Our patient-directed efforts generated HeartMate II success stories in leading national and local media outlets, and we implemented effective consumer-oriented, web-based programs.

A primary objective of our market development efforts in 2010 was the generation of increased data detailing the positive clinical and economic outcomes from the use of HeartMate II for both DT and BTT. A highlight of this effort was an update on HeartMate II DT Continued Access Protocol (CAP) patients presented at the 2010 American Heart Association Scientific Sessions. The data showed continued improvements in survival and adverse events when compared to the early trial experience from the study's primary cohort. Survival for the CAP patients improved six percentage points at both 12 and 24 months, to 74 percent and 64 percent, respectively. The CAP patients also experienced significant reductions in a number of key adverse events, including a greater than 50 percent reduction in hemorrhagic stroke, a more than 35 percent reduction in device related infections, and a greater than 25 percent reduction in sepsis. CAP patients also demonstrated significant improvements in quality of life.

#### Thoratec Pumps Shipped

Worldwide Analysis





**TECHNOLOGY** 

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

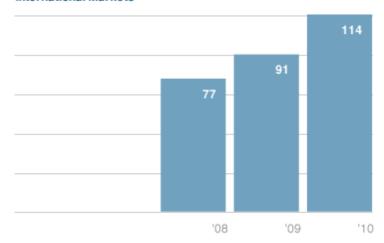
FINANCIAL INFORMATION

2010 ANNUAL REVIEW

We were also pleased with the outcomes from the BTT post-approval study, which have been included in the HeartMate II product label and will be published in a major medical journal this spring. Compared to the BTT pivotal trial experience, the post-market study data demonstrated continued efficacy and improving outcomes for HeartMate II BTT patients in the commercial setting, including significantly improved survival rates and very meaningful declines in the rate of adverse events—particularly stroke, device replacements and right heart failure. These findings are particularly impressive considering the fact that over 60% of the HeartMate II population was characterized as INTERMACS\* profile I or II, indicating end-stage heart failure patients either in critical cardiogenic shock or in progressive decline on inotropes. It is also encouraging to note that these positive outcomes continue to be mirrored by the broad registry data being collected by INTERMACS.

The HeartMate II also gained a stronger foothold in international markets, such as Europe and Asia Pacific, as we expanded our commercial presence to 35 countries as of year-end and grew our HeartMate II unit volume by 35 percent. We furthered our market leadership position in Europe, where we added a number of new HeartMate II centers and continued to drive the development of the DT market. And in Asia, our partner Nipro completed the confirmatory HeartMate II clinical trial in Japan and expects to make a regulatory submission in the first half of 2011. We also achieved regulatory approval in Australia and Taiwan for the HeartMate II for commercial use and experienced encouraging initial adoption of the device in Singapore, Malaysia, and Hong Kong.

#### HeartMate II Centers: International Markets



<sup>\*</sup> INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) is the national registry for patients receiving MCS therapy in the commercial setting.



TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

#### **Growth Strategies**

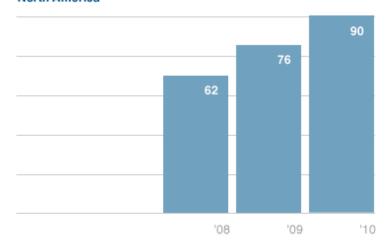
We will build upon our success in 2010 with strategies to both further develop the MCS market in the near-term and bolster our leadership position over the long-term as we leverage our solid balance sheet and strong technology, as well as our established infrastructure for clinical support, training and education, reimbursement, and market development.

Our expanded efforts targeted to the referring cardiologist community will highlight the advances HeartMate II has brought to the field of MCS through a wide range of education and training events, which will address patient selection and management. Center development initiatives will be focused not only on initiating activity at new HeartMate II DT centers, but also on helping existing centers increase their capacity for VAD activity. An important initiative will be the implementation of a site-specific clinical outcomes program to help centers realize reduced hospitalization, readmissions, bleeding and infections for VAD patients.

These center development programs will also serve our goal to address opportunities in markets outside North America as we expect to add a number of new HeartMate II centers in both Europe and Asia Pacific during the year. We also plan to increase our commercial presence in newer markets, such as Australia, and expect that the first HeartMate II implants in Korea and India will occur during 2011.

The ongoing generation of data demonstrating the positive outcomes with the HeartMate II will continue to be an integral part of our strategy. During 2011, we expect to see a continuation of impactful HeartMate II data presentations and peer-reviewed articles in leading professional publications. We also expect to initiate a series of

#### Destination Therapy Centers: North America





TECHNOLOGY

CLINICAL

**PARTNERSHIP** 

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

post-market studies that we believe will generate data demonstrating improved clinical and economic outcomes, while also providing support for expanding the patient populations treated with VADs.

#### **Product Development Pipeline**

Our future product and technology development strategy is guided by three principles: continuing to evolve the HeartMate II platform to further our best-in-class technology position; pursuing the development of next-generation pumps; and introducing cross-platform breakthrough technologies that will substantially enhance the HeartMate II, as well as future pumps. We believe these efforts will create broader adoption of MCS, extend Thoratec's market leadership position, and result in improved patient outcomes, enhanced quality of life, less invasive procedures and reduced cost of care.

During 2011, our plans for enhancements to the HeartMate II include the initial clinical utilization of a new controller that is smaller and lighter than currently available controllers and provides added convenience to the patients. We also expect to complete the development of and make a regulatory submission for new surgical implant tools used to attach the device to the left ventricle. These tools are designed to increase ease of use for surgeons and to reduce surgical and bypass time.

This year will be an important one in our development program for the HeartMate III. By combining the benefits of full magnetic levitation in a smaller pump that can be implanted less invasively, we believe the HeartMate III represents a breakthrough VAD technology that has the potential to provide significant clinical benefits, including reduced need for anti-coagulation, as well as reductions in the rates of thrombosis and bleeding. We have made great strides in the development of the pump's key

#### HeartMate III





TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

components, and we look forward to continuing system-level reliability testing and beginning Good Laboratory Practice (GLP) animal studies during 2011, leading to a first-in-man implant at the end of 2012.

Work on HeartMate X, our miniaturized chronic VAD platform, is also well underway. This device, which leverages our proven HeartMate II bearing technology, is designed to provide partial and full support, with highly versatile placement and cannulation options. As envisioned, this device would result in less invasive surgery and provide the capabilities to meet the needs of earlier-stage patients as well as those requiring right ventricular or bi-ventricular support.

With respect to our cross-platform technologies designed to be incorporated across current and future offerings, our key initiatives include the development of a fully implantable system, including an implantable battery and controller and an energy transfer system. These features will eliminate the need for a percutaneous lead and should result in lower infection rates and a significant improvement in patient quality of life. Other programs are addressing the development of infection reduction technologies, remote patient monitoring capabilities, and new tools to facilitate implant procedures.

A critical component of our longer-term growth strategy is the Percutaneous Heart Pump (PHP). PHP is a catheter-based pump designed to address several under-served patient populations, such as unstable acute myocardial infarction and high-risk percutaneous coronary intervention, providing Thoratec with access to a potential market opportunity of more than \$1 billion annually. We have made significant progress in demonstrating PHP's capabilities in bench models, and we expect to finalize design and enter preclinical testing during the coming year, leading to a first-in-man implant at the end of 2012.

#### HeartMate X



#### Percutaneous Heart Pump (PHP)





TECHNOLOGY

CLINICAL

PARTNERSHIP

CORPORATE A LOOK AHEAD INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

#### **Exciting Future**

The past year has been a significant one for the VAD market, with the approval and launch of the HeartMate II for DT, and the continuously improving patient outcomes portend even greater opportunities in the years ahead.

Through market education, clinical support, technology innovation and geographic expansion, we will continue to build out this market in the near term as we develop next-generation devices and technologies that should support growth later this decade as well. In addition, we will begin to develop new market opportunities for Thoratec, such as those available to us with our PHP device.

We look forward to driving the expansion of the MCS market and to advancing our leadership position in the sector, as we seek to bring new, life-restoring technology to a wider range of patients.

In closing, we appreciate your support and look forward to reporting on the Company's progress as it pursues an exciting future.

Gerhard F. Burbach

President, Chief Executive Officer and Director

Suhr J. Bush



TECHNOLOGY

CLINICAL

PARTNERSHIP

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ HeartMate II

+ Clinician Insight

2010 ANNUAL REVIEW

"We had the vision, we had the dream... and we can change the lives of people and the whole paradigm of congestive heart failure."

J. Donald Hill, M.D. Senior Medical and Clinical Advisor Company Founder Clinical Professor of Cardiac Surgery (retired)

For over three decades, Thoratec Corporation has been singularly devoted to delivering unparalleled medical innovation and state-of-the-art solutions for patients with advanced heart failure. Today, we are a world leader in proven technologies to address cardiovascular disease, offering the broadest range of advanced circulatory support options available for acute, interim and chronic care needs.

Looking forward, Thoratec remains focused on advancing next-generation MCS technologies. We are committed to discovering new, groundbreaking ways to serve an expanded patient population through improved clinical outcomes, less invasive procedures, reduced cost of care and significant enhancements to patient quality of life.



A LOOK AHEAD



TECHNOLOGY CLINICAL

+ HeartMate II + Clinician Insight PARTNERSHIP

**Technology Design** 

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

### The HeartMate II

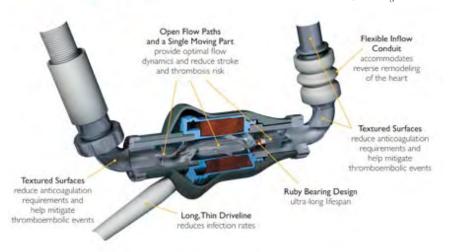
The HeartMate II left ventricle assist device (LVAD), the gold standard in LVAD therapy, combines precision engineering with simple and elegant design—a single moving part, open flow paths for optimized blood flow, highly durable ruby bearings, a flexible inflow conduit to accommodate reverse remodeling of the heart, and textured surfaces to reduce the risk of thrombosis. The result: maximized reliability, minimized adverse events, and restored life for thousands of patients.

The HeartMate II pumps blood throughout the body at up to ten liters per minute, the full output of a healthy heart—and with a dramatically reduced footprint compared to other approved LVADs, the HeartMate II is suitable for a broad range of patients, including women and persons of smaller stature.

Since receiving the European CE Mark in November 2005, allowing for commercial sale in Europe, the HeartMate II has continued to break barriers, becoming the first and only continuous flow device approved by the FDA for both the Bridge-to-Transplantation (BTT) and Destination Therapy (DT) indications.



HMII Technology Design Click image to reduce





TECHNOLOGY

CLINICAL PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ HeartMate II

+ Clinician Insight

2010 ANNUAL REVIEW

"What I find very exciting about this technology is that there are very few things in medicine where you can go beyond the promise, that you can actually make people better than even they think they're going to be."

Thomas MacGillivray, M.D., Cardiac Surgeon

With the advances that Thoratec has made in technologies to support long term patients, physicians now have the potential to offer solutions to the sickest heart failure patients—more than 250,000 Americans each year who are refractory to optimal medical management, ineligible for cardiac transplantation and who have no viable alternative. <sup>1</sup>

HeartMate II restores life to patients who were previously incapacitated with very limited activity levels prior to receiving an LVAD, enabling them to breathe more easily, feel less fatigued and resume normal activities that they were unable to do—in some cases for years—prior to receiving the device. This marked improvement in functional capacity and symptoms of heart failure provides hope to the patients that we serve—empowering them to regain enjoyment and quality of life that would not have been possible before.

#### Quality of Life Enhancement: HeartMate II DT CAP

Percent of Patients Improving to NYHA Functional Class I & II



Park SJ. AHA Scientific Sessions, November 2010

"The HeartMate II has allowed me to breathe, so I can sing again. It's given me my strength back. My wife and I have reconstructed our careers. I'm now 78 and back to where I was 10 years ago—literally. I have my life back!"

William, age 78, NYHA Class I



<sup>&</sup>lt;sup>1</sup> Heart Disease and Stroke Statistics—2010 Update, American Heart Association



**TECHNOLOGY** 

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

- + Bridge-to-Transplantation
- + Destination Therapy

**CLINICAL** 

+ Stories of Life Restored

2010 ANNUAL REVIEW



With HeartMate II, Thoratec has advanced LVAD technology into the realm of mainstream clinical therapy.

HeartMate II is the most widely used, most extensively studied, most proven and trusted LVAD—providing a powerful treatment option to clinicians and hope to thousands of patients.

Thoratec's dedication to rigorous clinical evaluation has yielded more clinical evidence supporting HeartMate II than any previous LVAD—with published clinical results demonstrating substantial improvements in survival and quality of life for hundreds of patients, and with ongoing patient follow-up continuing for five years.

- Implanted in more than 7,000 patients\*
- Supported over 800 patients for 2+ years and over 90 patients for 4+ years\*
- Extensively studied and featured in over 120 peer-reviewed articles, including The New England Journal of Medicine and Journal of American College of Cardiology\*
- Consistently strong clinical outcomes in challenging BTT and DT patient populations<sup>1, 2, 3</sup>
  - Lowest published anticoagulation regimen
  - Lowest reported stroke rate
  - Lowest reported rate of pump thrombosis
  - Lowest reported rate of pump exchanges
- <sup>1</sup> Slaughter MS, Pagani FD, Rogers JG, et al. Clinical management of continuousflow left ventricular assist devices in advanced heart failure. J Heart Lung Transplant. 2010;29:S1–39.
- <sup>2</sup> Boyle AJ, Russell SD, Teuteberg JJ, et al. Low thromboembolism and pump thrombosis with the HeartMate II left ventricular assist device: analysis of outpatient anticoagulation. J Heart Lung Transplant. 2009;28:881–7.
- <sup>3</sup> Slaughter MS, Yoshifumi N, John R, et al. Postoperative heparin may not be required for transitioning patients with a HeartMate II left ventricular assist system to long-term warfarin therapy. J Heart Lung Transplant. 2010;29:616–24.
- \* As of March 2011



**TECHNOLOGY** 

CLINICAL

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Bridge-to-Transplantation

**PARTNERSHIP** 

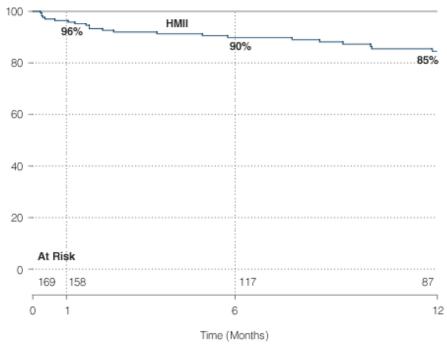
- + Destination Therapy
- + Stories of Life Restored

2010 ANNUAL REVIEW

After FDA approval of the HeartMate II for BTT in 2008, the first post-approval study utilizing the national Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) was initiated to assess outcomes with the HeartMate II in a broader patient care environment.

- The HeartMate II BTT Post-Approval Study included 338 patients (169 HeartMate II) across 77 institutions
- 62% were INTERMACS profile 1 (critical cardiogenic shock) or profile 2 (progressive decline on inotropes), representing the sickest heart failure patients
- The study demonstrated superior survival for HeartMate II patients—90% survival at 6 months versus 79% for the comparator group, and 85% survival at 12 months versus 71% for the comparator group
- Additionally, the HeartMate II BTT Post-Approval Study illustrated a lower rate of adverse events and a marked improvement in quality of life over the course of follow-up as measured by the EuroQol instrument, with scores doubling

# Kaplan-Meier Survival: HeartMate II Bridge-to-Transplantation Post-Approval Study



HeartMate II Left Ventricular Assist System Instructions for use #105747. Pleasanton, Calif: Thoratec Corp; Oct 2010.



**TECHNOLOGY** 

CLINICAL PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

- + Bridge-to-Transplantation
- + Destination Therapy
- + Stories of Life Restored

2010 ANNUAL REVIEW

2010 was truly a breakout year for Destination Therapy (DT), following FDA approval of the HeartMate II for this indication in January. Commercial utilization of HeartMate II accelerated, and clinical outcomes continued to improve.

"The Thoratec HeartMate II has enabled us to offer mechanical circulatory support to a broader range of patients than ever before. The size and characteristics of the HMII has allowed us to treat smaller, older and sicker patients. This advanced technology has enabled them to recapture their lives and interests in an unprecedented fashion."

Scott Silvestry, M.D.
Associate Professor of Surgery
Surgical Director
Cardiac Transplantation and Ventricular Assist Device Program
Washington University / Barnes Jewish Hospital





**TECHNOLOGY** 

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

- + Bridge-to-Transplantation
- + Destination Therapy

**CLINICAL** 

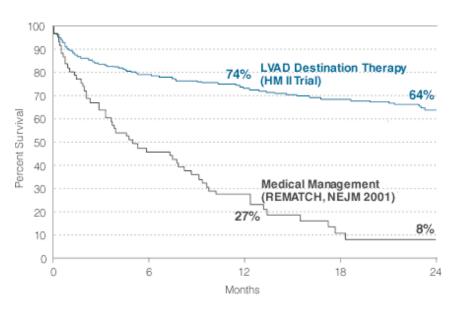
+ Stories of Life Restored

2010 ANNUAL REVIEW

The initial HeartMate II DT clinical trial, published in 2009 in *The New England Journal of Medicine*, had already demonstrated that HeartMate II provides long-term survival greater than the earlier generation DT-approved device as well as previously reported outcomes with medical therapy alone. <sup>1, 2</sup> Results have continued to improve, though, as was shown in late 2010 at the American Heart Association Scientific Sessions, where a key update from the HeartMate II Destination Therapy Continued Access Protocol (CAP) was presented. Survival for the CAP patients improved six percentage points at both 12 and 24 months relative to the early trial experience—to 74% percent survival at 12 months and 64% at 24 months. <sup>3</sup>

In addition, CAP patients experienced significant reductions in a number of key adverse events, including: >50% reduction in hemorrhagic stroke, >35% reduction in device related infections, and >25% reduction in sepsis. CAP patients also demonstrated considerable improvements in quality of life, with 85% classified as NYHA Class I or II patients at two years versus 78% of the primary trial cohort patients.<sup>3</sup>

# LVAD Survival Compared to Optimal Medical Management



Park SJ. AHA Scientific Sessions, November 2010.

<sup>&</sup>lt;sup>1</sup> Slaughter MS, Rogers JG, Milano CA, et al. Advanced heart failure treated with continuous-flow left ventricular assist device. *N Engl J Med.* 2009;361(23):2241–51.

<sup>&</sup>lt;sup>2</sup> Fang JC. Rise of the machines—left ventricular assist devices as permanent therapy for advanced heart failure. *N Engl J Med.* 2009;361(23):2282–84.

<sup>&</sup>lt;sup>3</sup> Park SJ, AHA Scientific Sessions, November 2010.



**TECHNOLOGY** 

CLINICAL

PARTNERSHIP A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

- + Bridge-to-Transplantation
- + Destination Therapy
- + Stories of Life Restored

2010 ANNUAL REVIEW

For advanced heart failure patients, the challenges of daily activities can outweigh the pleasures of life. HeartMate II offers new hope for patients who have exhausted other medical therapies.

After implantation, many patients return to daily life with restored blood flow and more energy—enabling them to regain activity levels that they were unable to achieve, in some cases for years, prior to receiving the device.



"...now I am fully recovered and enjoying life to its fullest." Salina



"You never realize how sick you were until you get better." Art



"I feel really good with the HeartMate II.

I don't feel limited at all." Laura

Please consult the Instructions for Use for indication for use, contraindications, warnings, and adverse events. Individual experiences, symptoms, situations, and circumstances may vary.

Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment.



**TECHNOLOGY** 

CLINICAL

PARTNERSHIP A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Bridge-to-Transplantation

+ Destination Therapy

+ Stories of Life Restored

2010 ANNUAL REVIEW

# "I just felt normal. There was nothing wrong with me. I can do anything again."

Salina

In 2006, I was 29 years old and I had a beautiful 19-month-old baby boy. My world was turned upside down when I was diagnosed with congestive heart failure and given less than a month to live. I was days from being sent home on hospice care to die comfortably with my loved ones. Then a remarkable, intelligent piece of technology was introduced to me that would keep me alive. It was the HeartMate II. I carried my LVAD for 17 months and now I am fully recovered and enjoying life to its fullest. I am so fortunate to be alive through the help of this invention.



Please consult the Instructions for Use for indication for use, contraindications, warnings, and adverse events. Individual experiences, symptoms, situations, and circumstances may vary. Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment.



**TECHNOLOGY** 

CLINICAL PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Bridge-to-Transplantation

+ Destination Therapy

+ Stories of Life Restored

2010 ANNUAL REVIEW

# "You never realize how sick you were until you get better."

Art

I was running out of breath at work and one day after a meeting, I sat down at the desk and I couldn't breathe anymore. I went to the doctor and we found out that I had a greatly enlarged heart. I couldn't do anything physically—I could hardly walk the 100 feet to the mailbox, I couldn't sleep, I was gasping for breath.

When I heard about the HeartMate II, I was excited about it. My kidneys were starting to fail and I really thought this was my last chance. I'm really blessed with getting this HeartMate II—it's changed my life all around. I knew what the technology could do, and I have confidence in the equipment. You never realize how sick you were until you get better. Once I got the HeartMate II, I feel so much better that I thought, 'Why'd I put up with that before'—I would never hesitate to do it again; I would do it right away.

Please consult the Instructions for Use for indication for use, contraindications, warnings, and adverse events. Individual experiences, symptoms, situations, and circumstances may vary. Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment.





**TECHNOLOGY** 

CLINICAL

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Bridge-to-Transplantation

**PARTNERSHIP** 

+ Destination Therapy

+ Stories of Life Restored

2010 ANNUAL REVIEW

# "I feel really good with the HeartMate II. I don't feel limited at all."

Laura

A week after my daughter was born, I was hospitalized with symptoms of pneumonia that developed into symptoms of heart failure. Eventually, I was diagnosed with postpartum cardiomyopathy—I was shocked. After failed attempts with multiple medications, I went into multiple organ failure and needed the HeartMate II to survive. I was part of the decision, with my husband and family. We were educated on the LVADs that were available and selected the HeartMate II as the best choice.

It was a normal recovery after heart surgery; I was doing a little more each day and was progressing my activity. Now, I am able to resume my life as a wife, mother and physical therapist. I feel really good with the HeartMate II; I don't feel limited at all. I have a lot of confidence in the technology and feeling as I do with it, I would easily be able to live the rest of my life with it.

Please consult the Instructions for Use for indication for use, contraindications, warnings, and adverse events. Individual experiences, symptoms, situations, and circumstances may vary. Please consult your physician or qualified health provider regarding your condition and appropriate medical treatment.





**TECHNOLOGY** 

CLINICAL

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Clinical Support

**PARTNERSHIP** 

+ Global Reach

2010 ANNUAL REVIEW

The successful collaboration between Thoratec and clinicians is vital to the goal of elevating awareness of the life-restoring benefits of MCS, delivering the therapy in a safe and effective way, and addressing a vastly underserved patient population.

To that end, Thoratec dedicates significant resources toward providing broadbased services and support for our partners in the medical community, including:

- A team of over 30 individuals providing 24/7 clinical/technical support;
- A team of over 25 individuals focused on market development and cardiology outreach;
- Extensive training and education programs, materials and personnel;
- Reimbursement and Joint Commission certification support;
- Ongoing post-market research activities; and
- Comprehensive programs aimed at continually improving clinical outcomes.

Partnering with the clinical community isn't just something we do. It's who we are.





2011 Thoratec MCS Users Conference

"The relationship we have with our clinicians and patient ambassadors is really unique—and it's one where there's a great sense of camaraderie, different than what you may see in other industries. There's really a sense of teamwork in that we're all in this together, trying to advance VAD therapy."

Ed Smith, Territory Manager, Thoratec Corporation



TECHNOLOGY

CLINICAL

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Clinical Support

+ Global Reach

**PARTNERSHIP** 

2010 ANNUAL REVIEW

"Thoratec's clinical support team gives us the resources we need to develop our programs into stories of great success. Their dedication to heart failure therapy has greatly improved my patients' quality of life."

Marcia Stahovich, RN, CCRN Advanced Clinician Mechanical Assist Device Department Sharp Memorial Hospital

Thoratec is committed to providing heart failure therapies that not only increase patient survival, but also improve the quality of life. To that end, Thoratec partners with clinicians through an extensive training and education effort and through clinical support initiatives that span the continuum of VAD patient care—from helping patients and physicians understand the benefits of VAD therapy, to ensuring the finest clinical outcomes in the operating room and beyond, to assisting VAD recipients and caregivers in their return home, and to restoring a lifestyle they never thought was possible prior to VAD therapy.

For every leading heart center that provides Thoratec VAD therapy, a Thoratec Clinical Specialist is responsible for assisting with training, clinical outcomes consultation, operating room support, and ensuring the best possible patient outcomes.





**TECHNOLOGY** 

CLINICAL

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Clinical Support

+ Global Reach

**PARTNERSHIP** 

2010 ANNUAL REVIEW

# Clinical Support / Training:

- New Account Training
- Off-site Surgical Training Program
- In-house Training and Education
- VAD Coordinator Training Course
- Implant and Post-operative Support
- Outcome-based Consultation
- Discharge Planning Guidance
- 24-hour Support via HeartLine

### Additional Educational Offerings:

- Thoratec eUniversity provides on-line education for hospital staff and community clinicians.
   Access at www.ThoratecU.com
- Reference materials available at www.Thoratec.com





TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Clinical Support

+ Global Reach

2010 ANNUAL REVIEW

"HeartMate II has allowed us to bring VAD technology to the Asian population with impressive results. The size of the previous generation VAD was a major issue for our patients."

Dr. Cumaraswarmy Sivathasan Program Director, Mechanical Heart Device Program Co-Director, Heart and Lung Transplant Program National Heart Center, Singapore

Five Continents. 254 Centers.\* HeartMate II has quickly become the gold standard pump, not just in the United States but on a global scale as well. This growth has been disciplined—for each new center, Thoratec provides the same, unrivaled level of service and clinical support. But it's been steady, and there's more to come. 2011 will see a continued drive to build the Destination Therapy market in Europe, a regulatory submission for HeartMate II in Japan, commercial expansion in Australia, and the first HeartMate II implants in Korea and India.

There are over 5 million heart failure patients in the United States. But there are millions more worldwide. Our mission extends to them all.



<sup>\*</sup> As of the end of 2010.

<sup>&</sup>lt;sup>1</sup> Heart Disease and Stroke Statistics—2010 Update, American Heart Association



TECHNOLOGY

CLINICAL

**PARTNERSHIP** 

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

"I have a tremendous amount of confidence in our team's ability to continue to bring new technologies to market, be those innovations to advance our existing platforms, like the HeartMate II, or entirely new pump platforms like the HeartMate III."

Gary Burbach, President and CEO

As we look ahead, Thoratec is committed to furthering the use of MCS therapies to achieve dramatically improved outcomes for a broader range of patients. A major priority for the company is continuing our industry leadership in technology innovation. We will build upon our successes with strategic programs focused on advancing our HeartMate II platform, crossplatform initiatives, and the development of future pump platforms, such as the HeartMate III, the HeartMate X, and the Percutaneous Heart Pump (PHP).

To meet the expanding needs of patients, including those in earlier stage heart failure, Thoratec will drive cross-platform innovation that includes tools to facilitate an easier, less invasive implantation; technology to reduce the risk of infection; and a fully implantable system. Our focus is on the continual development of treatment options that will deliver improved outcomes, expanded choice, and enhanced quality of life for the patients that we serve.

In this new era of heart failure treatment, Thoratec's medical technologies will help make it possible for thousands of people to resume everyday activities, spend meaningful time with their loved ones, and live better, longer.

Thoratec: Life Restored.



#### **HM II Evolution**

- Sealed Grafts
- Next-Generation Controller
- Advanced Surgical Tools

#### **Cross-Platform**

- Fully Implantable System
- Automated Anastomosis
- Infection Reduction
- Remote Monitoring



**TECHNOLOGY** 

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

### HeartMate III

Ultra-compact, fully magnetically-levitated LVAD, designed to provide enhanced clinical benefits to patients.

- Next-generation LVAD product attributes
  - Full magnetic levitation
  - Ability to induce pulsatility
  - Optimized for efficient, low-power operation
- Full support LVAD (10L / min) in ultra-compact size; simple, intrathoracic placement
- · Potential for reduced anti-coagulation, pump thrombosis, and bleeding
- Incorporates critical HeartMate family design elements (e.g. large gaps, textured surfaces)
- System will include next-generation modular driveline and next-generation controller





TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

### HeartMate X

Versatile, miniaturized platform technology capable of providing partial and full circulatory support.

- Dramatic size reduction
  - · Rapid, less invasive implant
  - Versatile cannulation options
- Meets needs of expanded patient pool
  - Earlier-stage patients
  - RVAD/BiVAD population
- High-efficiency motor and hydraulics
  - Potential for smaller external batteries and components
- Leverages core HeartMate II bearing technology





**TECHNOLOGY** 

CLINICAL

PARTNERSHIP

A LOOK AHEAD CORPORATE INFORMATION

FINANCIAL INFORMATION

2010 ANNUAL REVIEW

# Percutaneous Heart Pump (PHP)

Innovative catheter-based pump; a potentially breakthrough technology addressing a new market opportunity for Thoratec—percutaneous acute cardiac support.

- Low-profile percutaneous device
- Collapsible elastomeric impeller and nitinol cannula; expands to full size (~24F) once in position
- Designed to deliver over 4L per minute of flow under normal physiologic conditions







TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Forward-Looking Statements

2010 ANNUAL REVIEW

### **Board of Directors**

#### Neil F. Dimick

Chairman of the Board, Executive Vice President and Chief Financial Officer, AmerisourceBergen Corporation (Retired) Laguna Hills, California

#### Elisha W. Finney

Senior Vice President and Chief Financial Officer, Varian Medical Systems, Inc. Palo Alto, California

#### Gerhard F. Burbach

President, Chief Executive Officer and Director

#### D. Keith Grossman

Managing Director, TPG Biotech, L.P. San Francisco, California

#### J. Daniel Cole

General Partner, Spray Venture Fund Boston, Massachusetts

#### Paul A. LaViolette

Partner, SV Life Sciences Boston, Massachusetts

#### Steven H. Collis

President and Chief Operating Officer, Amerisource Bergen Corporation and President, Amerisource Bergen Specialty Group Philadelphia, Pennsylvania

#### Daniel M. Mulvena

Founder and Owner, Commodore Associates Wilmington, Delaware

### **Executive Officers**

#### Gerhard F. Burbach

President, Chief Executive Officer and Director

#### David V. Smith

Executive Vice President, Chief Financial Officer

#### David A. Lehman

Senior Vice President, General Counsel and Secretary



TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD

CORPORATE INFORMATION

FINANCIAL INFORMATION

+ Forward-Looking Statements

2010 ANNUAL REVIEW

## **Corporate Directory**

#### Independent Registered Public Accounting Firm

Deloitte & Touche LLP San Francisco, California

#### Stock Transfer Agent

Computershare Trust Company, N.A. 250 Royal Street Canton, Massachusetts 02021 1.800.962.4284

#### Additional Information

For more information, please write to: Corporate Secretary Thoratec Corporation 6035 Stoneridge Drive Pleasanton, California 94588 www.thoratec.com

#### **Annual Meeting**

The Company's annual meeting of shareholders will be held May 25, 2011 at 8:00 a.m.

#### Trademarks

Thoratec, the Thoratec logo, HeartMate, GoGear, and HeartMate II are registered trademarks of Thoratec Corporation.



TECHNOLOGY

CLINICAL

PARTNERSHIP

A LOOK AHEAD IN

CORPORATE FINANCIAL INFORMATION

+ Forward-Looking Statements

2010 ANNUAL REVIEW

## Forward-Looking Statements

This 2010 Annual Review includes forward-looking statements, including our current expected timelines for product development, clinical trials and commercialization. Forward-looking statements should not be read as a guarantee of future performance or results, and may not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved. Forward-looking statements are based on information available at the time those statements are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to those discussed from time to time in Thoratec's public reports filed with the Securities and Exchange Commission, such as those discussed under the heading, "Risk Factors," in Thoratec's most recent annual report on Form 10-K, and as may be updated in subsequent SEC filings. These forward-looking statements speak only as of April 11, 2011. Thoratec undertakes 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 April 11, 2011.

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

## Form 10-K

(Mark on			
(Mark one	ANNUAL REPORT UNDER SECTIO EXCHANGE ACT OF 1934	ON 13 OR 15(d) OF TH	E SECURITIES
		ended January 1, 2011	
	TRANSITION REPORT UNDER SEC EXCHANGE ACT OF 1934		F THE SECURITIES
	For the transition period from	to	
	Commission file	number: 000-49798	
	Thoratec (Exact Name of Registran	Corporation t as Specified in Its Charter)	
	California	94-	-2340464
	(State or Other Jurisdiction of		Employer
602	Incorporation or Organization)		ication No.)
	35 Stoneridge Drive, Pleasanton, California (Address of Principal Executive Offices)		<b>94588</b> ip Code)
	Registrant's telephone number, i	`	* /
	Securities registered pursuant to	Section 12(b) of the Exchange	e Act:
_	Title of Each Class	Name of Each Exchange	
	Common Stock, no par value per share	NASDAQ Global	Select Market
	Securities registered pursuant to Securities	ction 12(g) of the Exchange A	ct: None
Indic Act. Yes	ate by a check mark if the registrant is a well-known No $\square$	wn seasoned issuer, as defined	in Rule 405 of the Securities
	ate by a check mark if the registrant is not require nge Act. Yes $\square$ No $\boxtimes$	ed to file reports pursuant to S	Section 13 or Section 15(d) of
of the Sec	ate by a check mark whether the registrant: (1) has turities Exchange Act of 1934 during the preceding o file such reports), and (2) has been subject to su	g 12 months (or for such short	er period that the registrant was
any, every	ate by check mark whether the registrant has subranteractive Data File required to be submitted at 12 months (or for such shorter period that the restor $\square$	nd posted pursuant to Rule 405	5 of Regulation S-T during the
herein, an	ate by a check mark if disclosure of delinquent filed will not be contained, to the best of registrant's ted by reference in Part III of this Form 10-K or a	knowledge, in definitive proxy	or information statements
or a small	ate by check mark whether the registrant is a larger reporting company. See the definitions of "larger in Rule 12b-2 of the Exchange Act. (Check one):	e accelerated filer," "accelerat	ted filer, a non-accelerated filer, ted filer" and "smaller reporting
Large acc	elerated filer ⊠ Accelerated filer □	Non-accelerated filer  (Do not check if a smaller reporting company)	Smaller Reporting Company
Indic Yes □ N	ate by a check mark whether the registrant is a sh to $\boxtimes$	ell company (as defined in Ex	change Act Rule 12(b)-2)
	aggregate market value of the voting stock held by ock on July 3, 2010, the last business day of the R		

As of January 29, 2011, the Registrant had 58,654,792 shares of common stock outstanding.

## TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	3
Item 1A. Risk Factors	17
Item 1B. Unresolved Staff Comments	29
Item 2. Properties	29
Item 3. Legal Proceedings	29
Item 4. Reserved	29
PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of	
Equity Securities	31
Item 6. Selected Consolidated Financial Data	33
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	35
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	49
Item 8. Financial Statements and Supplementary Data	51
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	94
Item 9A. Controls and Procedures	94
Item 9B. Other Information	95
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	96
Item 11. Executive Compensation	96
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder	
Matters	96
Item 13. Certain Relationships and Related Transactions, and Director Independence	96
Item 14. Principal Accounting Fees and Services	96
PART IV	
Item 15. Exhibits, Financial Statement Schedules	97
Evhibit Index	99

## DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of Thoratec's definitive proxy statement for its 2011 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

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

CentriMag is a registered trademark of Levitronix LLC.

#### Item 1: Business

#### **OVERVIEW**

Thoratec Corporation ("we," "our," "us," or the "Company") is a 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.

Heart failure 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.

On November 4, 2010, we sold our wholly-owned subsidiary, International Technidyne Corporation ("ITC"), to ITC Nexus Holding Company, Inc. ("Nexus"). As a result, ITC is presented as discontinued operations in the consolidated financial statements.

#### THE COMPANY AND BACKGROUND

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 principal executive offices are located at 6035 Stoneridge Drive, Pleasanton, California, 94588. The telephone number at that address is (925) 847-8600. We make available, free of charge on our website located at www.thoratec.com, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports, as soon as reasonably practicable after filing such reports with the Securities and Exchange Commission. Our code of ethics, corporate governance guidelines, audit and committee charter, corporate governance and nominating committee charter, compensation committee charter, and audit committee complaint procedures are also posted on our website and are each available in print to any shareholder upon request by writing to: Thoratec Corporation, Investor Relations, 6035 Stoneridge Drive, Pleasanton, California, 94588. The contents of our website are not incorporated by reference into this report.

### **OUR PRODUCTS**

For advanced heart failure ("HF"), we develop, manufacture and market proprietary medical devices used for mechanical circulatory support ("MCS"). Our primary product lines are our ventricular assist devices ("VADs"): the HeartMate II Left Ventricular Assist System ("HeartMate II"), the HeartMate Left Ventricular Assist System ("HeartMate XVE"), the Thoratec Paracorporeal Ventricular Assist Device ("PVAD"), and the Thoratec Implantable Ventricular Assist Device ("IVAD"). We refer to the HeartMate II and the HeartMate XVE collectively as the "HeartMate product line," and we refer to the PVAD and the IVAD collectively as the "Thoratec product line." 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. Certain VADs are implanted internally, while others are placed immediately adjacent to the body (paracorporeal). Currently, the power source remains outside the body for all of our VADs approved by the U.S. Food and Drug Administration ("FDA").

Our product portfolio of VADs, blood pumping systems and graft products is described below.

#### 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. In clinical testing and commercial experience, the HeartMate II has demonstrated dramatic improvements in comparison to pulsatile devices, in survival and quality of life 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 and for longer durations of time. Effective January 20, 2010, the HeartMate II can be used in patients with New York Heart Association Class IIIB and IV end-stage left ventricular failure who have received optimal medical therapy for at least forty-five of the last sixty days, and who are not candidates for cardiac transplantation.

The HeartMate II received FDA approval in April 2008 for bridge-to-transplantation ("BTT") and received FDA approval for use in HF patients who are not eligible for heart transplantation ("Destination Therapy" or "DT") in January 2010. In November 2005, the HeartMate II received CE Mark approval, allowing for its commercial sale in Europe. In May 2009, the HeartMate II was approved in Canada.

During the third quarter of 2009 we launched our new HeartMate external peripherals (Go Gear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

#### The HeartMate XVE

The HeartMate XVE is an implantable, pulsatile, left ventricular assist device for intermediate and longer-term MCS. 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 implantable blood pump as well as the external peripherals, including a wearable controller and batteries, which provide a high degree of patient freedom and mobility. We have communicated to our customers that we will be discontinuing the sale of the HeartMate XVE at the end of fiscal 2011.

The HeartMate XVE received FDA approval for BTT in December 2001 and for Destination Therapy in April 2003. In June 2003, the HeartMate XVE received CE Mark approval, allowing for its commercial sale in Europe. In June 2004, the HeartMate XVE was approved in Canada.

## The Paracorporeal Ventricular Assist Device

The PVAD is an external, pulsatile ventricular assist device, FDA approved to provide left, right and biventricular support for BTT, including home discharge, and post-cardiotomy myocardial recovery. The PVAD is a paracorporeal device and is less invasive than implantable VADs, since only the cannula are 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. The PVAD is driven by a pneumatic power source, and it incorporates our proprietary biomaterial, Thoralon, which has excellent tissue and blood compatibility and is resistant to blood clots.

The PVAD is designed for short-to-intermediate duration use of a few weeks to several months, although it 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 important, since approximately 65% 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 received FDA approval for BTT in December 1995 and for recovery (post-cardiotomy) in May 1998. In June 1998, the PVAD received CE Mark approval, allowing for its commercial sale in Europe. In November 1994, the PVAD was approved in Canada.

#### The Implantable Ventricular Assist Device

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

The IVAD received FDA approval for BTT and recovery (post-cardiotomy) in August 2004. In June 2003, the IVAD received CE Mark approval, allowing for its commercial sale in Europe. In November 2004, the IVAD was approved in Canada.

#### The CentriMag

The CentriMag is manufactured by Levitronix and is based on their magnetically levitated bearingless motor technology. We entered into a distribution agreement with Levitronix in August 2006. This agreement to distribute the CentriMag in the U.S. is effective through December 2011. The CentriMag is 510(k) approved by the FDA for use up to six hours in patients requiring short-term extracorporeal circulatory support during cardiac surgery. Additionally, CentriMag is approved under an FDA humanitarian device exemption to be used as a right ventricular assist device for periods of support up to thirty days in patients in cardiogenic shock due to acute right ventricular failure. In May 2008, Levitronix received approval to commence a U.S. pivotal trial to demonstrate safety and effectiveness of the CentriMag for periods of support up to thirty days. Levitronix has CE Mark approval in Europe to market the product to provide support for up to thirty days.

#### 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.

#### DISCONTINUED OPERATIONS

On November 4, 2010, we sold ITC to Nexus for \$55 million in cash pursuant to a Stock Purchase Agreement, dated November 4, 2010, by and between the Company and Nexus ("Purchase Agreement").

We have reclassified the assets and liabilities of ITC as held for sale on the consolidated balance sheets for the prior periods presented and the operating results as discontinued operations on the consolidated statements of operations for all periods presented.

## PRODUCT SEGMENTS

Our functional entities operated in two segments: Cardiovascular and ITC. Due to the sale of ITC, segment disclosure is no longer presented. For a discussion of our ITC segment, which is classified as discontinued operations, refer to Item 8, Note 16, "Discontinued Operations," to our consolidated financial statements. The Cardiovascular segment is classified as continuing operations in our consolidated financial statements and notes thereto.

#### **OUR MARKETS**

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 5.8 million people suffer from HF in the U.S. and approximately 610,000 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. 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 2,600 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 Destination Therapy and as a BTT. In addition to the chronic HF markets, MCS devices are also approved for use for acute HF following and during cardiac surgery. All four indications are summarized below.

### Destination Therapy

In April 2009, we filed a premarket approval ("PMA") supplement with the FDA seeking HeartMate II approval for Destination Therapy, HF patients who are not eligible for heart transplantation that included two-year data on a pivotal study cohort of 200 randomized patients enrolled at 38 centers. Patients in the HeartMate II Destination Therapy trial were randomized to the HeartMate II or the HeartMate XVE on a 2:1 basis, respectively.

On January 20, 2010, we received approval to market the HeartMate II for DT in patients with New York Heart Association Class IIIB and IV end-stage left ventricular failure who have received optimal medical therapy for at least forty-five of the last sixty days, and who are not candidates for cardiac transplantation. The FDA approval required as a condition of approval, a 247 patient post market study. The first 247 consecutive commercial patients to receive the HeartMate II for Destination Therapy has been entered into the Interagency Registry for Mechanically Assisted Circulatory Support ("INTERMACS"), a nationally recognized agency, and will be followed for a period of two years. At the end of the two-year follow-up period, outcomes including survival, adverse events and quality of life will be compared to those in the clinical trial that led to FDA approval.

The National Institute for Health estimated that the Destination Therapy application represents a market opportunity of 50,000 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 two-year survival rate for these patients is approximately 8%. We believe that the success in transitioning this market from maximum drug therapy to VADs is partially dependent on the development of the market for our HeartMate product line.

## Bridge-to-Transplantation

VADs provide additional cardiac support for patients with late-stage HF waiting for a donor heart. Approximately 40%-50% 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 that are commercially marketed and approved in the U.S. for BTT support in adults, four of which are Thoratec devices.

## 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.

#### 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.

#### **OUR STRATEGY**

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

Focus on and partner with leading heart centers. We have developed long-standing relationships with leading cardiovascular surgeons, heart failure cardiologists 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 utilization of VAD therapy, in particular as a destination therapy. We plan to increase the penetration of VAD therapy within the population of patients in advanced stage HF. Enabling this increased penetration, we believe, is the approval and reimbursement for HeartMate II as a Destination Therapy device. On January 20, 2010, we received FDA approval to market the HeartMate II for Destination Therapy in the treatment of late-stage HF patients who are not candidates for heart transplant. In November 2010, The Centers of Medicare and Medicaid Services ("CMS") expanded its existing National Coverage Decision for Destination Therapy to include effectively all of the Class IV HF patient population studied in the HeartMate II DT clinical trial.

- Clinician education and outreach. We continue to expand awareness of MCS through education and outreach programs, both at implanting centers and with the referring cardiology community. We are building upon our existing relationships with leading cardiac surgeons and heart failure cardiologists in both transplant and open heart centers and using our existing sales channels, in order to gain acceptance and adoption of our products in the major hospitals that perform open heart surgery. Additionally, we are educating community cardiologists and other potential referring clinicians of the benefits of MCS, through our team of over 25 Market Development Managers in the U.S. as well as through clinical symposia, on-line education programs, and other outreach efforts.
- *Center expansion*. In 2010, we added 20 new HeartMate II centers, bringing the total to 140 centers in North America. Outside of North America, we added 23 new HeartMate II centers, bringing the total to 114 centers. We plan to continue to expand the number of centers utilizing HeartMate II in the coming years.

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.

Develop and obtain approval for new products and new indications for our products. Our product pipeline includes new technologies to augment the performance and ease of use of the HeartMate II system, cross-platform technologies such as a fully implantable system, and next-generation pump platforms.

As part of our ongoing evolution of the HeartMate product line, in the third quarter of 2009 we launched our new external peripherals, Go Gear, including new batteries, charger and power module. These enhancements are designed to provide an improved quality of life to patients by offering them additional freedom and mobility. We have also received FDA approval for sealed inflow and outflow grafts for the HeartMate II, which we plan to commercialize in the first quarter of 2011. Additionally, we are working on a new controller, advanced surgical implant tools, and remote monitoring capabilities for the HeartMate II system.

Our cross-platform technologies in development include an infection reduction system, automated anastomotic tools, and a fully implantable system. These technologies could be designed for use with multiple pump platforms, although for regulatory purposes it is likely that we would choose to conduct clinical trials using one of our current pump systems, for example the HeartMate II. We have not yet entered human clinical testing with these cross-platform technologies.

We also continue to invest aggressively in next-generation pump platforms, including the HeartMate III, HeartMate X, and Percutaneous Heart Pump ("PHP"). HeartMate III is a magnetically levitated, centrifugal, continuous flow pump. We are continuing to advance the development of the system, combining the benefits of full magnetic levitation in a smaller pump capable of being implanted less invasively, which we believe will have important clinical benefits including reduced rates of adverse events. In addition, we are developing a miniaturized pump called HeartMate X, which will leverage our already proven HeartMate II platform but with a significant reduction in the size of the device. The reduced size should facilitate flexibility for implantation while addressing the need for either full or partial flow. We believe this will have a significant impact on continuing to advance the HeartMate II platform and enable us to address a broadening population of advanced-stage HF patients in the coming years. We are also developing the PHP, which we acquired from Getinge AB in January 2010. PHP is a catheter-based axial flow heart pump for application in unstable acute myocardial infarction, high-risk percutaneous coronary intervention, and potentially other patient populations. The device includes a collapsible elastomeric impeller and a nitinol cannula that expands to more than double the size of the insertion sheath. Under normal physiologic conditions, PHP is designed to deliver over four liters of blood flow.

Increase the cost effectiveness of the therapies that employ our products. While Medicare data indicates the cost of implanting a VAD for Destination Therapy 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 use as a Destination Therapy in late-stage HF patients, and in November 2010, CMS broadened its DT coverage policy to reflect the entire Class IV patient population treated in the HeartMate II DT clinical trial. We work closely with VAD centers to develop the Destination Therapy market through either previous recognition by Medicare or the Joint Commission certification program for Destination Therapy, 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.

Increase our market presence through strategic alliances, joint ventures and acquisitions. In addition to increasing our presence in heart failure and other cardiovascular disease markets through internal growth, we continue to evaluate strategic alliances, joint ventures, acquisitions and related business development opportunities. Recently, we acquired the intellectual property assets of Orqis Medical in the fourth quarter of 2009, certain assets from Ventracor Limited in the first quarter of 2010, and PHP from Getinge AB in the first quarter of 2010.

#### 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 we sell into 140 of these centers, including 29 open heart centers in which we believe there are over 100,000 in North America. We are in 114 heart transplant centers outside of North America.

We have recruited and trained experienced cardiovascular sales specialists who sell our circulatory support systems throughout the world. Our sales force is complemented by direct clinical specialists and 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. In addition to our direct selling efforts, we have a network of international distributors who cover other geographic markets.

Our sales and marketing initiatives include direct mail, education seminars, symposia, equipment purchase and rental programs and journal advertisements, all common in the cardiovascular device market. We partner with universities, experienced clinicians and opinion leaders to assist with expanding clinical educational needs.

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. 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 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. We believe that these VAD-related services are an important part of the value that we provide to hospitals and patients.

### Vascular Graft Products

We market Vectra through distributors in the U.S., and selected countries in Europe, the Middle East, Northern Africa and Japan.

### COMPETITION

Competition from medical device and medical device divisions of healthcare companies, pharmaceutical companies and gene- and cell-based therapies is intense and is expected to increase. The vast majority of VAD-eligible patients still receive pharmacological treatment instead of a VAD. We therefore continue to expect new competitors both from the pharmacological and the medical device space. Among the medical device competitors are Terumo Heart, Inc., HeartWare International Inc., 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.

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, provide high-quality, ongoing support, and manufacture and sell commercial quantities of our products.

### PATENTS AND PROPRIETARY RIGHTS

We seek to protect our technology and intellectual property rights through obtaining and maintaining patent, copyright and trade secret protection.

We own, or have exclusive rights to, various U.S. and foreign patents. U.S. patents are typically granted for a term of twenty years from the date a patent application is filed. The remaining durations on our patents range from less than one year to seventeen years. The actual protection afforded by a foreign patent, which can vary from country to country, depends upon the type of patent, the scope of its coverage and the availability of legal remedies in the country. In those instances where we have acquired technology from third parties, we have sought to obtain rights of ownership to the technology through the acquisition of underlying patents or licenses.

Our patents and patent applications relate to a number of important aspects of our technology. We intend to continue to file additional patent applications both in the U.S. and in foreign jurisdictions to seek protection for our technology.

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

While we believe design, development, clinical performance and regulatory aspects of the medical device business represent the principal barriers to entry, we also recognize that our patents and license rights may make it more difficult for others to market products similar to those we manufacture and market. Despite our patents and license rights and our 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.

#### **GOVERNMENT REGULATIONS**

Regulation by governmental authorities in the U.S. 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 ("FDCA") and its regulations. Our MCS systems and Vectra graft products are regulated as medical devices. To obtain FDA approval to market VADs similar to those under development, the FDA requires proof of safety and efficacy in human clinical trials performed under an Investigational Device Exemption ("IDE"). An IDE application must contain pre-clinical test data supporting the safety of the product for human investigational use, information on manufacturing processes and procedures, proposed clinical protocols and other information. If the IDE application is accepted, human clinical trials may begin. The trials must be conducted in compliance with FDA regulations and with the approval of one or more institutional review boards. Clinical trials are subject to central registration requirements, such as on www.clinicaltrials.gov (although none of this information is, or should be deemed to be, incorporated by reference into this Annual Report on Form 10-K). The results obtained from these trials, if satisfactory, are accumulated and submitted to the FDA in support of either a PMA application, a PMA Supplement 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. 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 FDCA 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.

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.

## Healthcare Regulation

Our business is subject to extensive federal and state government regulation. This includes the federal Anti-Kickback Law and similar state anti-kickback laws, the federal False Claims Act, and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and similar state laws addressing privacy and security. Although we believe that our operations materially comply with the laws governing our industry, it is possible that non-compliance with existing laws or the adoption of new laws or interpretations of existing laws could adversely affect our financial performance.

#### Fraud and Abuse Laws

The healthcare industry is subject to extensive federal and state regulation. In particular, the federal Anti-Kickback Law prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including for example gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests, and providing anything at less than its fair market value. In addition, there is no one generally accepted definition of intent for purposes of finding a violation of the Anti-Kickback Law. For instance, one court has stated that an arrangement will violate the Anti-Kickback Law where any party has the intent to unlawfully induce referrals. In contrast, another court has opined that a party must engage in the proscribed conduct with the specific intent to disobey the law in order to be found in violation of the Anti-Kickback Law. The lack of uniform interpretation of the Anti-Kickback Law makes compliance with the law difficult. The penalties for violating the Anti-Kickback Law can be severe. These sanctions include criminal penalties and civil sanctions, including fines, imprisonment and possible exclusion from the Medicare and Medicaid programs.

The Anti-Kickback Law is broad, and it prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Law is broad and may technically prohibit many innocuous or beneficial arrangements within the healthcare industry, the U.S. Department of Health and Human Services issued regulations in July of 1991, which the Department has referred to as "safe harbors." These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Law. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Our arrangements with physicians, physician practice groups, hospitals and other persons or entities who are in a position to refer may not fully meet the stringent criteria specified in the various safe harbors. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Law, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Law will be pursued. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities such as the U.S. Department of Health and Human Services Office of Inspector General ("OIG").

Many states have adopted laws similar to the federal Anti-Kickback Law. Some of these state prohibitions apply to referral of patients for healthcare services reimbursed by any source, not only the Medicare and Medicaid programs. Although we believe that we comply with both federal and state anti-kickback laws, any finding of a violation of these laws could subject us to criminal and civil penalties or possible exclusion from federal or state healthcare programs. Such penalties would adversely affect our financial performance and our ability to operate our business.

HIPAA created new federal statutes to prevent healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment or exclusion from government sponsored programs. Both federal and state government agencies are continuing heightened and coordinated civil and criminal enforcement efforts. As part of announced enforcement agency work plans, the federal government will continue to scrutinize, among other things, the billing practices of hospitals and other providers of healthcare services. The federal government also has increased funding to fight healthcare fraud, and it is coordinating its enforcement efforts among various agencies, such as the U.S. Department of Justice, the OIG and state Medicaid fraud control units. We believe that the healthcare industry will continue to be subject to increased government scrutiny and investigations.

#### Federal False Claims Act

Another trend affecting the healthcare industry is the increased use of the federal False Claims Act and, in particular, actions under the False Claims Act's "whistleblower" provisions. Those provisions allow a private individual to bring actions on behalf of the government alleging that the defendant has defrauded the federal government. After the individual has initiated the lawsuit, the government must decide whether to intervene in the lawsuit and to become the primary prosecutor. If the government declines to join the lawsuit, then the individual may choose to pursue the case alone, in which case the individual's counsel will have primary control over the prosecution, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. If the litigation is successful, the individual is entitled to no less than 15%, but no more than 30%, of whatever amount the government recovers. The percentage of the individual's recovery varies, depending on whether the government intervened in the case and other factors. Recently, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states are considering or have enacted laws modeled after the federal False Claims Act. Under the Deficit Reduction Act of 2005 ("DRA") states are being encouraged to adopt false claims acts similar to the federal False Claims Act, which establish liability for submission of fraudulent claims to the State Medicaid program and contain whistleblower provisions. Even in instances when a whistleblower action is dismissed with no judgment or settlement, we may incur substantial legal fees and other costs relating to an investigation. Future actions under the False Claims Act may result in significant fines and legal fees, which would adversely affect our financial performance and our ability to operate our business.

Further, on May 20, 2009, President Obama signed into law the Fraud Enforcement and Recovery Act of 2009, which greatly expanded the types of entities and conduct subject to the False Claims Act. We strive to ensure that we meet applicable billing requirements. However, the costs of defending claims under the False Claims Act, as well as sanctions imposed under the Act, could significantly affect our financial performance.

## Health Insurance Portability and Accountability Act of 1996

In addition to creating the new federal statutes discussed above, HIPAA also establishes uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses. Three standards have been promulgated under HIPAA with which we currently are required to comply. We must comply with the Standards for Privacy of Individually Identifiable Health Information ("Privacy Standards"), which restrict our use and disclosure of certain individually identifiable health information. We have been required to comply with the Privacy Standards since April 14, 2003.

The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, signed into law on February 17, 2009, dramatically expanded, among other things, (1) the scope of HIPAA to also include "business associates," or independent contractors who receive or obtain protected health information ("PHI") in connection with providing a service to the covered entity, (2) substantive security and privacy obligations, including new federal security breach notification requirements to affected individuals and Department of Health and Human Services and potentially media outlets, (3) restrictions on marketing communications and a prohibition on covered entities or business associates from receiving remuneration in exchange for PHI, and (4) the civil and criminal penalties that may be imposed for HIPAA violations, increasing the annual cap in penalties from \$25,000 to \$1.5 million per year. We believe that we are not generally a business associate under HIPAA and we believe that we are in compliance with all of the applicable HIPAA standards, rules and regulations. However, if we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions. In addition to federal regulations issued under HIPAA, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA. In those cases it may be necessary to modify our operations and procedures to comply with the more stringent state laws, which may entail significant and costly changes for us. We believe that we are in compliance with such state laws and regulations. However, if we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions.

#### 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 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 COVERAGE AND REIMBURSEMENT

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 Medicare, Medicaid, private health insurance companies and managed care organizations, reimburse our customers based on established payment formulas that take into account part or all of the cost associated with these devices and the related procedures performed.

The agency responsible for administering the Medicare program, CMS, and a majority of private insurers have approved reimbursement for our VADs and diagnostic and vascular graft products. Effective October 1, 2003, CMS issued a National Coverage Determination for the use of the HeartMate XVE for treating Destination Therapy in late-stage HF patients. With approval by the FDA for HeartMate II for DT on January 20, 2010, CMS expanded coverage effective November 9, 2010 to a slightly broader population. Ninety centers are now Joint Commission certificated for Destination Therapy and eligible for reimbursement by Medicare.

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, which is reflected in their coverage policies. 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.

Healthcare laws in the U.S. are subject to ongoing changes, including changes to the amount of reimbursement for hospital services. Federal legislative proposals can substantially change the way healthcare is financed by both governmental and private insurers and may negatively impact payment rates for our products. We are unable to predict whether any circulating congressional proposals will become law or in what form. Also, from time to time there are a number of legislative, regulatory and other proposals both at the federal and state levels; it remains uncertain whether there will be any future changes that will be proposed or finalized and what effect, if any, such legislation or regulations would have on our business.

#### **MANUFACTURING**

VADs and grafts 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 ongoing supply of product.

During 2009 and 2010, we expanded the manufacturing facility located in Pleasanton, California. The main focus of the expansion project was to provide adequate manufacturing capacity to meet the proposed volumes created by FDA DT approval of the HeartMate II product line. The renovated facility has the necessary capacity to meet the requirements for our VAD products for the next five to seven years.

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

We typically have been able to fill orders from inventory and historically have not had significant backlog orders. With the expanded manufacturing capacity we are in a position to accommodate the increased demand for our products. Total backlog as of the end of fiscal 2010 and 2009 was \$0.2 million and zero, respectively. All backlog orders outstanding as of the end of fiscal 2010 are expected to be filled in fiscal 2011.

## RESEARCH AND DEVELOPMENT

Our research and development expenses in fiscal years 2010, 2009 and 2008 totaled \$58.8 million, \$42.7 million and \$40.0 million, respectively. Research and development costs are largely project driven, and fluctuate based on the level of project activity planned and subsequently approved and conducted. The primary components of our research and development costs are employee salaries and benefits, outside consulting and equipment and supplies. Projects include advancing the HeartMate II platform, such as efforts to improve the operation and performance of our VAD products and accessories, along with efforts to develop new products, such as the development of the HeartMate X, HeartMate III and our acquisition and development of PHP pump technology in 2010. Research and development costs also include regulatory and clinical costs associated with our compliance with FDA regulations and clinical trials such as the completed HeartMate II DT pivotal trial completed in 2009.

### 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 years 2010, 2009 and 2008.

Sales originating outside the U.S. and U.S. export sales accounted for approximately 17%, 20% and 22% of our total product sales for fiscal years 2010, 2009 and 2008, 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 1, 2011, we had a total of 714 employees, consisting of 662 full-time employees and 52 temporary employees. Of our total employees, 681 are employed in the U.S. and 33 are employed outside the U.S. None of our employees are covered by a collective bargaining agreement. We consider relations with our employees to be good.

## **SEASONALITY**

Our quarterly net sales are influenced by many factors, including new product introductions, divestitures, regulatory approvals, and other factors. Net sales in the third quarter are typically lower than other quarters of the year due to the seasonality of the United States and European markets, where summer vacation schedules can result in fewer procedures.

#### 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 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.

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 FDCA 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 and certain of our third-party suppliers 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. If our facilities or those of our suppliers fail to take satisfactory corrective action in response to an adverse QSR inspection, the FDA could take enforcement action. The FDA also strictly regulates labeling, advertising, promotion, and other types of information on products that are placed on the market. Medical devices may be promoted only for their approved indications and in accordance with the provisions of the approved label. It is possible that federal or state enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under a variety of statutory authorities, including under the FDCA as well as laws prohibiting false claims for reimbursement. 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.

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 products 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 coverage and reimbursement by the CMS, the agency responsible for administering the Medicare program, in late 2003. We received FDA approval for the HeartMate II in Destination Therapy on January 20, 2010.

The number of Destination Therapy procedures actually performed depends on many factors, many of which are out of our direct control, including, but not limited to, the following:

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

The different outcomes of these and other factors, and their timing, will have a significant impact on our future 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 healthcare payors, or use of alternative therapies including pharmacological, gene- and cell-based therapies, and other device based alternatives. 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 heart valves used in our HeartMate XVE product. 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 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 expect to have a replacement product developed and approved by the FDA; or
- stop shipping the product in which the legacy component is used once our inventory of the discontinued component is exhausted.

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

## We may encounter problems manufacturing our products.

We may encounter difficulties manufacturing products in quantities sufficient to meet demand. We do not have experience in manufacturing some of our products in the commercial quantities that might be required with 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.

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

Competition from medical device and medical device divisions of healthcare companies, pharmaceutical companies and gene- and cell-based therapies is intense and is expected to increase. The vast majority of VAD-eligible patients still receive pharmacological treatment instead of a VAD. We therefore continue to expect new competitors both from the pharmacological and the medical device space. Among the medical device competitors are Terumo Heart, Inc., HeartWare International Inc., 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.

Some of our competitors 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 provide additional alternatives to 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.

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 our market share.

#### 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 material deficiencies or defects in design or manufacture or labeling can result in the recall and replacement, generally free of charge, of substantial amounts of product already implanted or otherwise in the marketplace. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. We may initiate certain voluntary recalls involving our products in the future. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. If we determine that certain of those recalls do not require notification of the FDA, the FDA may disagree with our determinations and require us to report those actions as recalls. A future recall announcement could harm our reputation with customers, negatively affect our sales, and subject us to additional FDA enforcement actions.

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 product line. 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.

# If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support our PMA applications or PMA supplements, our ability to obtain new approvals will be limited.

Before submitting a PMA application, we must successfully complete pre-clinical studies and clinical trials to demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the trial may be inadequate to support approval of a PMA application. The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate we expect;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to our product candidates;
- institutional review boards and third-party clinical investigators may delay or reject our trial protocol;

- third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other regulatory requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of a clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

The results of pre-clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the approval of our products. If we are unable to demonstrate the safety and efficacy of our products in our clinical trials, we will be unable to obtain regulatory approval to market our products. The data we collect from our current clinical trials, our pre-clinical studies and other clinical trials may not be sufficient to support FDA approval.

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

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

## 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 one of our competitors) in the U.S. and selected countries in Europe, the Middle East and Africa, and through Goodman Co. Ltd. in Japan.

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.

### 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.

# 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 HeartMate XVE for Destination Therapy have been lower than we had originally anticipated, and we cannot predict what level of revenues our HeartMate II product will generate.

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 healthcare 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 healthcare 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 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 healthcare system may affect the reimbursability of future products. If coverage were partially or completely reduced, our revenues and results of operations would be harmed.

Healthcare laws and regulations may change significantly in the future which could adversely affect our financial condition and results of operations. We continuously monitor these developments and modify our operations from time to time as the legislative and regulatory environment changes. Currently, there are a number of pending federal legislative proposals that could substantially change the way healthcare is financed by both governmental and private insurers and may negatively impact payment rates for our products. We are unable to predict whether any currently circulating congressional proposals will become law or in what form, whether any additional or similar changes to statutes or regulations (including interpretations) will occur in the future, or what effect any such legislation or regulation would have on our business. The federal government may, however, have greater involvement in the healthcare industry than in prior years, and such greater involvement may adversely affect our financial condition and results of operations.

# Complying with federal and state regulations is an expensive and time-consuming process, and any failure to comply could result in substantial penalties.

We are directly or indirectly through our clients subject to extensive regulation by both the federal government and the states in which we conduct our business, including the federal Anti-Kickback Law and similar state anti-kickback laws, the federal False Claims Act, HIPAA and similar state laws addressing privacy and security, state unlawful practice of medicine and fee splitting laws, state certificate of need laws, the Medicare and Medicaid statutes and regulations, and the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

Both federal and state government agencies have heightened and coordinated civil and criminal enforcement efforts as part of numerous ongoing investigations of healthcare companies, as well as their executives and managers. These investigations relate to a wide variety of matters, including referral and billing practices. The OIG and the Department of Justice have, from time to time, established national enforcement initiatives that focus on specific billing practices or other suspected areas of abuse. Some of our activities could become the subject of governmental investigations or inquiries.

If our operations are found to be in violation of any of the laws and regulations to which we are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines and the curtailment of our operations. Any penalties, damages, fines or curtailment of our operations, individually or in the aggregate, could adversely affect our ability to operate our business and our financial results. Our risk of being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. For a more detailed discussion of the various state and federal regulations to which we are subject see "Business-Government Regulations" and "Business-Third Party Coverage and Reimbursement."

#### We depend on HeartMate II for a significant portion of our revenues.

We derive, and expect to continue to derive, a significant portion of our revenues from sales of our HeartMate II product. While we cannot predict what level of revenues our HeartMate II product will generate, we anticipate that HeartMate II pump sales will continue to account for a significant portion of our revenues in the foreseeable future, and we anticipate that sales of this product will likely represent an even greater portion of our revenues now that we have received FDA approval for HeartMate II for Destination Therapy. Implementation of our strategy depends on continued sales of our HeartMate II product. Sales of our HeartMate II product are subject to the factors described in this "Risk Factors" section, including, but not limited to, the following:

- failure to obtain approval from the FDA and foreign regulatory authorities or to comply with government regulations, or the withdrawal of market clearance or other the taking of other enforcement actions;
- lack of Destination Therapy procedures conducted by hospitals using our VADs;
- lack of acceptance or continued acceptance by physicians;
- reliance on specialized suppliers for certain components and materials;
- manufacturing problems;
- any identified quality problems;
- inability to protect our proprietary technologies or an infringement of others' patents;
- loss of a distributor or distributor failure to perform;
- failure to compete successfully against our existing or potential competitors;
- special risks associated with non-U.S. sales;
- long and variable sales and deployment cycles;
- failure by third party payors to provide appropriate levels of reimbursement;
- failure to comply with federal and state regulations; and
- · product liability claims.

The outcomes of these and other factors will have a significant impact on our future HeartMate II product sales.

### Federal and state anti-kickback laws may adversely affect our operations and income.

Various federal and state laws govern financial arrangements among healthcare providers. The federal Anti-Kickback Law prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce, the referral of Medicare, Medicaid or other federal healthcare program patients, or in return for, or to induce, the purchase, lease or order of items or services that are covered by Medicare, Medicaid or other federal healthcare programs. Many state laws also prohibit the solicitation, payment or receipt of remuneration in return for, or to induce, the referral of patients in private as well as government programs. Violation of these laws may result in substantial civil or criminal penalties and/or exclusion from participation in federal or state healthcare programs. While we believe that we are operating in compliance with applicable laws and believe that our arrangements with providers would not be found to violate the federal and state anti-kickback laws, it is possible that these laws could be interpreted in a manner that could have an adverse effect on our operations.

In addition, under the DRA, states are encouraged to adopt false claims acts, similar to the federal False Claims Act, which establish liability for submission of fraudulent claims to the State Medicaid program and contain qui tam or whistleblower provisions. States enacting such false claims statutes will receive an increased percentage of any recovery from a State Medicaid judgment or settlement.

Adoption of new false claims statutes in states where we operate may impose additional requirements or burdens on us.

#### 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 could, among other things:

- 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.

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. If holders elect conversion, we may at our option deliver shares of common stock, pay a holder in cash, or deliver a combination of shares and cash, as determined pursuant to the terms of the notes. The conversion of some or all of the senior subordinated convertible notes into shares of our common stock 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. 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. 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.

#### 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.

## 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 \$24.74 to \$47.08 during the twelve months ended January 1, 2011. The price of our common stock could fluctuate significantly for many reasons, including but not limited to the following:

- future announcements concerning us or our competitors;
- regulatory developments, including ongoing healthcare reform initiatives, 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.

In addition, stock markets in general and the market for shares of healthcare stocks in particular, have experienced extreme price and volume fluctuations, including recently as a result of the 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.

#### 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. Continued concerns about the systemic impact of the recent 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. 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. 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, such as the 2010 sale of our wholly-owned subsidiary, International Technidyne Corporation. 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 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.

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 and the information filed by us with the governing bodies, as well as 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:

- fair value measurement;
- accounting for convertible debt instruments;
- · accounting for income taxes;
- · accounting for leases; and
- · accounting for business combinations.

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.

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.

## Item 2. Properties

We are headquartered in Pleasanton, California, where we own an approximately 67,000 square-foot corporate office building. We consider our operating properties to be in satisfactory condition and adequate to meet our needs for the next several years without making capital expenditures materially higher than historical levels.

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 24,400 square feet of warehouse space in San Ramon, California, expiring in 2015.
- Approximately 13,600 square feet of office and research facilities in Sunnyvale, California, expiring in 2015.
- Approximately 11,000 square feet of office and research facilities in Rancho Cordova, California, expiring in 2012.
- Approximately 39,000 square feet of office and research facilities in Burlington, Massachusetts, expiring in 2014.
- Approximately 8,700 square feet of office and warehouse facilities in the U.K., 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).

We utilize all of the facilities in California, Massachusetts and the U.K.

## Item 3. Legal Proceedings

None.

#### Item 4. Reserved

#### **OUR EXECUTIVE OFFICERS**

Gerhard F. Burbach, 48, 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 from April 2005 to January 2006. 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, 51, 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 U.S. and Europe.

David A. Lehman, 50, 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

#### 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 29, 2011 there were 58,654,792 shares of our common stock outstanding with approximately 437 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 2010		
First Quarter	\$33.99	\$25.38
Second Quarter	47.08	33.78
Third Quarter	44.97	32.20
Fourth Quarter	37.26	24.74
Fiscal Year 2009		
First Quarter	\$31.72	\$20.40
Second Quarter	30.38	23.83
Third Quarter	31.08	23.96
Fourth Quarter	31.06	26.26

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 1, 2011.

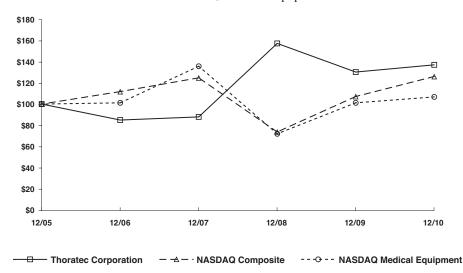
Information regarding securities authorized for issuance under equity compensation plans is incorporated by reference to the information in Item 12 of this Annual Report on Form 10-K.

## Stock Price Performance Graph

The graph below compares the cumulative total shareholder return on an investment in our common stock, the NASDAQ Composite Index (U.S. companies only) and the NASDAQ Medical Equipment Index for the five-year period ended December 30, 2010, the last trading day in our 2010 fiscal year.

The graph assumes the value of an investment in our common stock and each index was \$100 at December 31, 2005 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



<sup>\* \$100</sup> invested on December 31, 2005 in stock or index-including reinvestment of dividends.

	12/05	12/06	12/07	12/08	12/09	12/10
Thoratec Corporation	100.00	84.97	87.92	157.03	130.11	136.88
NASDAQ Composite	100.00	111.74	124.67	73.77	107.12	125.93
NASDAQ Medical Equipment	100.00	101.15	135.54	72.03	101.17	106.70

## Issuer Purchases of Equity Securities

The following table sets forth certain information about our common stock repurchased during the three months ended January 1, 2011

	Total number of shares purchased(2)	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	s, except per share data)			
October 3, 2010 through October 30, 2010.	1	\$34.74	_	\$—		
October 31, 2010 through November 27,						
2010	44	32.76	_	_		
November 28, 2010 through January 1,		02.70				
2011	4	28.43				
2011	_4	20.43	<u>=</u>	_		
Total	49	\$32.48	_	<b>\$</b> —		
	<u></u>	<del></del>		<u>-</u>		

<sup>(1)</sup> 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 1, 2011. As of January 1, 2011 we had \$10.1 million remaining on our share repurchase programs.

#### Item 6. Selected Consolidated Financial Data

The selected consolidated financial data presented below for the five fiscal years ended January 1, 2011 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.

<sup>(2)</sup> Shares purchased that were not part of our publicly announced repurchase programs represent the surrender value of shares of restricted stock awards and restricted stock units 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.

We report on a 52-53 week fiscal year, which ends on the Saturday closest to December 31. Accordingly, our fiscal year contains more or less than 365 days. For example, fiscal 2006 ended December 30, 2006, fiscal 2007 ended December 29, 2007 and each contained 52 weeks, fiscal 2008 ended January 3, 2009 and contained 53 weeks, and fiscal 2009 ended on January 2, 2010 and fiscal 2010 ended on January 1, 2011 and each contained 52 weeks. Our fiscal year 2011 will include 52 weeks and will end on December 31, 2011. As previously mentioned, the operating results of ITC have been segregated and presented as discontinued operations for all periods.

	Fiscal Years									
	2010 2009				2008	08 2007			2006	
	(In thousands, except per share data)									
Statements of Operations Data:										
Continuing Operations:										
Product sales	\$3	382,973	\$2	279,968	\$2	214,975	\$1	44,220	\$1	33,710
Gross profit	2	259,264	1	184,413		144,406		93,695		87,779
Amortization of purchased intangible assets		9,772		9,834		12,346		11,736		11,736
Net income (loss) from continuing operations	\$	59,005	\$	28,905	\$	16,393	\$	(4,523)	\$	(2,084)
Net income (loss) per share from continuing operations:										
Basic	\$	1.02	\$	0.51	\$	0.30	\$	(0.08)	\$	(0.04)
Diluted	\$	0.99	\$	0.50	\$	0.30	\$	(0.08)	\$	(0.04)
Discontinued Operations:										
Net income (loss) from discontinued operations	\$	(5,839)	\$	(321)	\$	1,938	\$	3,920	\$	2,554
Net income (loss) per share from discontinued operations:										
Basic	\$	(0.10)	\$	(0.01)	\$	0.03	\$	0.07	\$	0.05
Diluted	\$	(0.10)	\$	(0.01)	\$	0.03	\$	0.07	\$	0.05
Consolidated Operations:										
Net income (loss)	\$	53,166	\$	28,584	\$	18,331	\$	(603)	\$	470
Net income (loss) per share:										
Basic	\$	0.92	\$	0.50	\$	0.33	\$	(0.01)		0.01
Diluted	\$	0.89	\$	0.49	\$	0.33	\$	(0.01)	\$	0.01
Consolidated Balance Sheet Data:										
Cash and cash equivalents and short-term available-for-sale										
investments(2)	\$4	148,143	\$3	306,961	\$2	249,986	\$2	219,964	\$1	94,734
Working capital(2)	4	103,050	3	379,123	3	302,201	2	270,020	2	240,294
Assets held for sale offset by liabilities related to assets held										
for sale(2)		_		54,981		51,901		53,204		46,168
Total assets(2)	8	337,743	747,883		685,420		614,623		590,470	
Senior subordinated convertible notes	1	138,165	1	131,929	-	124,115	1	16,959	1	10,407
Long-term deferred tax liability(1)(2)		20,109		32,099		38,485		45,287		57,043
Total shareholders' equity(1)	\$6	521,360	\$5	525,128	\$4	466,279	\$4	13,809	\$3	884,691

<sup>(1)</sup> On December 31, 2006, we adopted ASC 740, *Income Taxes*, and as a result we reported a cumulative effect adjustment of \$0.5 million, which increased our December 31, 2006 "Retained earnings (accumulated deficit)" balance offset by a "Long-term deferred tax liability" balance.

<sup>(2)</sup> During the fiscal year 2010, we completed the sale of ITC. We accounted for the transaction as discontinued operations, and, accordingly, we have reclassified the results of operations and any losses resulting from the disposition for all periods presented to reflect them as such. Loss on discontinued operations in fiscal 2010 included a loss on disposal of \$0.6 million. In addition, for all prior periods presented, we reported working capital from continuing operations separately from assets held for sale offset by related liabilities attributable to discontinued operations.

#### 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," "may," "anticipates," "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**

#### Continuing Operations—Cardiovascular Business

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.

For advanced heart failure ("HF"), we develop, manufacture and market 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 are 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).

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

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

#### 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. Effective January 20, 2010, the HeartMate II can be used in patients with New York Heart Association Class IIIB and IV end-stage left ventricular failure who have received optimal medical therapy for at least forty-five of the last ninety days, and who are not candidates for cardiac transplantation.

HeartMate II received FDA approval in April 2008 for bridge-to-transplantation ("BTT") and received FDA approval for use in HF patients who are not eligible for heart transplantation ("Destination Therapy" or "DT") in January 2010. In November 2005, the HeartMate II received CE Mark approval, allowing for its commercial sale in Europe. In May 2009, the HeartMate II was approved in Canada.

During the third quarter of 2009 we launched our new HeartMate external peripherals (Go Gear), including new batteries, charger and power module, which are designed to provide an enhanced quality of life for HeartMate patients by providing them more freedom and mobility and the ability to more easily resume many aspects of a normal lifestyle.

#### The HeartMate XVE

The HeartMate XVE is an implantable, pulsatile, left ventricular assist device for intermediate and longer-term MCS. 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 implantable blood pump as well as the external peripherals, including a wearable controller and batteries, which provide a high degree of patient freedom and mobility. We have communicated to our customers that we will be discontinuing the sale of the HeartMate XVE at the end of fiscal 2011.

The HeartMate XVE received FDA approval for BTT in December 2001 and for Destination Therapy in April 2003. In June 2003, the HeartMate XVE received CE Mark approval, allowing for its commercial sale in Europe. In June 2004, the HeartMate XVE was approved in Canada.

#### The Paracorporeal Ventricular Assist Device

The PVAD is an external, pulsatile, ventricular assist device, FDA approved for BTT, including home discharge, and post-cardiotomy myocardial recovery and provides left, right and biventricular MCS. The PVAD is a paracorporeal device that is less invasive than implantable VADs since only the cannula is implanted. The paracorporeal nature of the PVAD has several benefits including shorter implantation times (approximately two hours) and the ability to use the device in smaller patients.

A pneumatic power source drives the PVAD. It is designed for short-to-intermediate duration use of a few weeks to several months, although this device has supported numerous patients for 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 because approximately 65% 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.

The PVAD received FDA approval for BTT in December 1995 and for recovery (post-cardiotomy) in May 1998. In June 1998, the PVAD received CE Mark approval, allowing for its commercial sale in Europe. In November 1994, the PVAD was approved in Canada.

#### 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.

The IVAD received FDA approval for BTT and recovery (post-cardiotomy) in August 2004. In June 2003, the IVAD received CE Mark approval, allowing for its commercial sale in Europe. In November 2004, the IVAD was approved in Canada.

### The CentriMag

The CentriMag is manufactured by Levitronix and is based on their magnetically levitated bearingless motor technology. We entered into a distribution agreement with Levitronix in August 2006. This agreement to distribute the CentriMag in the U.S. is effective through December 2011. The CentriMag is 510(k) approved by the FDA for use up to six hours in patients requiring short-term extracorporeal circulatory support during cardiac surgery. Additionally, CentriMag is approved under an FDA humanitarian device exemption to be used as a right ventricular assist device for periods of support up to thirty days in patients in cardiogenic shock due to acute right ventricular failure. In May 2008, Levitronix received approval to commence a U.S. pivotal trial to demonstrate safety and effectiveness of the CentriMag for periods of support up to thirty days. Levitronix has CE Mark approval in Europe to market the product to provide support for up to thirty days.

### 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.

## Discontinued Operations—International Technidyne Corporation ("ITC")

On November 4, 2010, we sold our wholly-owned subsidiary, International Technidyne Corporation, to ITC Nexus Holding Company, Inc. ("Nexus") for \$55 million in cash pursuant to a Stock Purchase Agreement, dated as of November 4, 2010, by and between the Company and Nexus.

The ITC division has been reclassified to discontinued operations in the consolidated financial statements.

## **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 to customers and distributors when evidence of an arrangement exists, and title has passed (generally upon shipment) or services have been rendered, the selling price (including pricing discounts) has been fixed or has become determinable, collectability is reasonably assured and there are no further obligations to customers or distributors, as applicable.

We recognize sales of certain products to first-time customers when it has been 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. Revenue under these arrangements is allocated to training 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 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 value 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 one-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.

Estimated excess and obsolete inventory charges are recorded when inventory levels exceed projected sales volume for a certain period of time. In determining the excess obsolete charges, management makes judgments and estimates on matters such as forecasted sales volume. If sales volume does not meet projections, additional write-downs may be required.

Management must make estimates and judgments to determine the amount of reserves to accrue. If any of these decisions proves incorrect, our consolidated financial statements 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.

Deferred income taxes arise from temporary differences between the tax and financial statement recognition of revenue and expense. While we have considered future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the allowance for the deferred tax asset would increase net income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax asset in the future, an adjustment to the valuation allowance for the deferred tax asset would be charged to net income in the period such determination was made.

Changes in tax laws and rates could also affect recorded deferred tax assets and liabilities in the future. In 2009, we recorded a discrete benefit of approximately \$0.9 million to reflect the effect of a change in California tax law which will permit us to make beneficial apportionment elections beginning in fiscal year 2011. We are not aware of any other changes in tax laws or rates that would have a material effect on our consolidated results of operations, cash flows and financial position.

Financial Accounting Standard Board ("FASB") Accounting Standards Codification ("ASC") 740, *Income Taxes*, provides that a tax benefit from an uncertain tax position may be recognized when it is more-likely-than-not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on technical merits. ASC 740 also provides guidance on measurement, derecognition, classification, interest and penalties and disclosure.

We believe we have provided adequate reserves for uncertain tax positions for anticipated audit adjustments by U.S. 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.

## Purchased Intangible Assets and Goodwill

We record goodwill when the purchase price paid for a business that we have acquired exceeds the estimated fair value of the net identified tangible and intangible assets acquired. In addition to intangible assets acquired as part of a business combination, we sometimes purchase patents and other intangible assets for cash or other consideration in individual transactions. Our purchased identifiable intangible assets include patents and trademarks, core technology and developed technology. Identifiable intangible assets with definitive useful lives are amortized on a straight-line basis with estimated lives ranging from eight to twenty years. In addition, our goodwill is not amortized. Our future operating results will be impacted by the future amortization of our purchased intangible assets and potential impairment charges related to these purchased intangible assets and goodwill, should we determine that impairment exists. The allocation of the purchase price paid for a business acquisition to goodwill and other intangible assets involves significant estimates and assumptions by our management and, should future conditions differ significantly from these estimates, our financial condition and results of operations could be adversely affected.

Purchased intangible assets are subject to amortization and are amortized over their estimated period of benefit, ranging from eight to twenty years. We evaluate the recoverability of intangible assets periodically, and take into account events or circumstances that warrant revised estimates of useful lives or indicate that impairment exists, such as when the anticipated identifiable undiscounted cash flows expect to be generated from an intangible asset is 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 intangible asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. No impairments of purchased intangible assets have been identified during the years presented.

Goodwill is not amortized but is subject to annual impairment tests. The impairment test for goodwill is a two-step process. Step one consists of a comparison of the fair value of a reporting unit against its carrying amount. After the sale of ITC, we determined that our reporting unit is the Cardiovascular division and its fair value is based on the present value of its estimated future cash flows. If the carrying value exceeds the fair value, step two is performed to calculate the amount of impairment, which would be recorded as a charge in the consolidated statements of operations. The fair value of a reporting unit is based upon a number of considerations including projections of revenues, earnings and discounted cash flows. The discount rate used for cash flows reflects capital market conditions and the specific risks associated with the business. In addition, we compare the aggregate of our only reporting unit fair values to the Company's market capitalization as a further corroboration of the fair value. The testing requires a complex series of assumptions and judgments by management in projecting future operating results and assessing risks. The use of alternative assumptions and estimates could affect the fair values and change the impairment determinations. Based upon the assumptions as of our fiscal 2010 testing date, our reporting unit was not at risk of the carrying value exceeding the fair value.

#### Valuation of Share-Based Awards

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. When establishing the expected life assumption, we review annual historical employee exercise behavior of option grants with similar vesting periods. The computation of the expected volatility assumption used in the Black-Scholes option pricing model for option grants is based on a combination of our historical volatility and market-based implied volatility. Prior to fiscal 2010, our estimated volatility was based solely on the historical volatility of our common stock and beginning in fiscal 2010 we base our expected volatility on a combination of historical volatility trends and market-based implied volatility because we have determined that this combination of historical volatility trends and market-based implied trends are reflective of market conditions. The decision to incorporate implied volatility was based on our assessment that implied volatility of publicly traded options in Thoratec common stock is reflective of market conditions and is generally reflective of both historical volatility and expectations of how future volatility will differ from historical volatility. In determining the extent of using implied volatility, we considered: (i) the volume of market activity of traded options; (ii) the ability to reasonably match the input variables of traded options to those of stock options granted by us, including the date of grant; (iii) the similarity of the exercise prices; and (iv) the length of term of traded options.

In addition, judgment is also required in estimating the amount of share-based awards that are expected to be forfeited. If actual forfeitures differ significantly from these estimates, share-based compensation expense and our results of operations could be materially affected.

#### Fair Value Measurements

Fair value is defined 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. Fair value measurement standards establish 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 quoted securities that are traded in an active market. 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, variable demand notes, corporate bonds, commercial paper, foreign currency forward contracts, certain of our deferred compensation plan securities and our senior subordinated convertible notes.
- 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 auction rate securities, and our purchased intangible asset valuations. 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, "Fair Value Measurements," 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 securities, 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: our ability and intent to hold the investment to maturity, whether it is more-likely-than-not that we would be required to sell the investment before recovery of the investment's amortized cost basis and whether we expect to recover the amortized cost basis of the investment. 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 its value recovers it may result in the recognition of an other-than-temporary impairment.

## **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:

	Fiscal Years					
	2010		2009		2008	
		(in thou	ısands, excep	t percen	tages)	
Product sales	\$382,973	100%	\$279,968	100%	\$214,975	100%
Cost of product sales	123,709	32	95,555	34	70,569	_33
Gross margin	259,264	68	184,413	66	144,406	67
Operating expenses:						
Selling, general and administrative	89,222	23	82,079	29	68,948	32
Research and development(1)	58,831	15	42,743	15	39,997	18
Amortization of purchased intangible assets	9,772	3	9,834	4	12,346	6
Total operating expenses	157,825	41	134,656	48	121,291	56
Income from operations	101,439	27	49,757	18	23,115	11
Interest expense(2)	(12,327)	(3)	(12,307)	(4)	(10,984)	(5)
Interest income and other	5,435	1	5,146	1	9,001	4
Impairment on investment	(2,000)	(1)				
Income before taxes	92,547	24	42,596	15	21,132	10
Income tax expense	33,542	9	13,691	5	4,739	2
Net income from continuing operations	59,005	15	28,905	_10	16,393	_8
Net income (loss) from discontinued operations	(5,839)	(1)	(321)	_	1,938	_1
Net income	\$ 53,166	14%	\$ 28,584	10%	\$ 18,331	9%

<sup>(1)</sup> Includes the write-off of acquired PHP technology of \$8.5 million in 2010.

## Continuing Operations

## **Product Sales**

Product sales consisted of the following:

	Fiscal Years			Annual Percentage Change		
	2010	2009	2008	2010/2009	2009/2008	
		in thousands	)			
Product sales	\$382,973	\$279,968	\$214,975	36.8%	30.2%	

In 2010 as compared to 2009, product sales increased by \$103.0 million primarily due to higher sales driven by increased worldwide HeartMate II volume, including Go Gear peripherals introduced in the third quarter of 2009, and an increase in CentriMag sales. The increase in product sales were partially offset by a decline in sales of the HeartMate XVE and Thoratec product lines as a result of cannibalization by the HeartMate II. In North America, 20 HeartMate II centers were added during 2010 bringing the total to 140 centers. Outside of North America, we added 23 centers in 2010, bringing the total to 114 centers.

<sup>(2)</sup> Includes non-cash interest expense of \$8.4 million, \$7.8 million and \$7.2 million for fiscal years 2010, 2009 and 2008, respectively.

In 2009 as compared to 2008, product sales increased by \$65.0 million primarily due to higher sales driven by increased worldwide HeartMate II volume and the launch of Go Gear peripherals in the third quarter of 2009, partially offset by the decline in stocking revenues as 19 new HeartMate II centers were added in 2009 as compared to 55 new HeartMate II centers in 2008. The increases in product sales were also partially offset by a decline in the sales of the HeartMate XVE and Thoratec product lines as a result of cannibalization by the HeartMate II and unfavorable foreign exchange rates.

Sales originating outside of the U.S. and U.S. export sales accounted for approximately 17%, 20% and 22% of our total product sales in 2010, 2009 and 2008, respectively.

## Gross Profit

Gross profit and gross margin were as follows:

	Fiscal Years				
	2010	2009	2008		
		in thousands)			
Total gross profit	\$259,264	\$184,413	\$144,406		
Total gross margin	67.7%	65.9%	67.2%		

In 2010 as compared to 2009, the gross margin percentage increased by 1.8% primarily due to an increase in HeartMate II sales volume, the roll-out of our external peripherals, and lower inventory write-downs, partially offset by increased warranty reserves and unfavorable pump to non-pump mix.

In 2009 as compared to 2008, the gross margin percentage decreased by 1.3% primarily due to an increase in inventory write-downs, warranty reserves and unfavorable foreign currency exchange rates, partially offset by increased HeartMate II volume and favorable manufacturing variances.

## Selling, General and Administrative

Selling, general and administrative expenses were as follows:

	Fiscal Years			<b>Annual Percentage Change</b>		
	2010	2009	2008	2010/2009	2009/2008	
	(in thousands)					
Total selling, general and administrative expenses	\$89,222	\$82,079	\$68,948	8.7%	19.0%	

In 2010 as compared to 2009, sales and marketing costs increased by \$13.1 million, primarily due to spending on product and market development initiatives, including sales force expansion. Administrative and other costs decreased by \$6.0 million primarily due to \$12.3 million in costs incurred in 2009 in connection with the terminated proposed acquisition of HeartWare International Inc. ("HeartWare") offset by an increase in compensation costs and an increase in legal fees related to business development activity.

In 2009 as compared to 2008, sales and marketing costs increased by \$2.6 million, primarily due to market development initiatives associated with the launch of Go Gear peripherals and the preparation for HeartMate II Destination Therapy approval and higher stock-based compensation expense partially offset by lower bonus. Administrative and other costs increased by \$10.5 million, primarily due to \$12.3 million in costs related to the HeartWare transaction, partially offset by lower compensation costs.

#### Research and Development

Research and development expenses were as follows:

	Fiscal Years			Annual Percentage Change		
	2010	2009	2008	2010/2009	2009/2008	
	(i	in thousand	s)			
Total research and development expenses	\$58,831	\$42,743	\$39,997	37.6%	6.9%	

Research and development costs are largely project driven, and fluctuate based on the level of project activity planned and subsequently approved and conducted.

In 2010 as compared to 2009, research and development costs increased \$16.1 million primarily due to the write-off of acquired PHP technology of \$8.5 million along with the development of the PHP pump, HeartMate X, HeartMate III technologies and HeartMate II peripheral enhancements.

In 2009 as compared to 2008, research and development costs increased \$2.7 million, primarily due to the HeartMate product line peripheral enhancements and new product technology.

## Amortization of Purchased Intangible Assets

Amortization of purchased intangible assets was \$9.8 million in both 2010 and 2009. In 2010, we acquired certain intangible assets, which we started amortizing. This increase in amortization cost was offset by certain of our other intangible assets being fully amortized.

Amortization of purchased intangible assets in 2009 was \$9.8 million as compared to \$12.3 million in 2008. The \$2.5 million decrease is attributable to certain intangible assets being fully amortized in the first quarter of 2009.

## Interest Expense

Interest expense primarily relates to interest on the senior subordinated convertible notes as follows:

	Fiscal Years			<b>Annual Percentage Chang</b>		
	2010	2009	2008	2010/2009	2009/2008	
	(	in thousand	s)			
Interest expense	\$11,813	\$11,897	\$10,574	0.7%	12.5%	
subordinated convertible notes	414	410	410	1.0%	_	
convertible notes	100			_	_	
Total interest expense	\$12,327	\$12,307	\$10,984			

Interest expense, which is comprised primarily of the senior subordinated convertible notes, is calculated using the effective interest rate method which increases interest expense over the term of the debt. However, during 2010, 4,045 bonds were converted (of the 247,427 bonds originally issued), resulting in \$0.1 million less interest expense than in 2009. In addition, we recorded a loss on extinguishment of \$0.1 million from the 4,045 bonds converted.

#### Interest Income and Other

Interest income and other consisted of the following:

	Fiscal Years			Annual Percentage Change		
	2010	2009	2008	2010/2009	2009/2008	
	(in thousands)					
Interest income	\$5,133	\$5,713	\$8,744	10.2%	34.7%	
Foreign currency, net	(17)	(628)	73	97.3%	960.3%	
Other	319	61	184	423.0%	66.8%	
Total interest income and other	\$5,435	\$5,146	\$9,001			

In 2010, interest income declined by \$0.6 million as compared to 2009, primarily due to decline in market interest rates, partially offset by an increase in cash and investment balances. Foreign currency losses decreased by \$0.6 million in 2010 as compared to 2009 due to favorable fluctuations in foreign currency exchange rates. Other income increased by \$0.3 million in 2010 as compared to 2009 primarily due to higher royalty income earned and the change in the mark-to-market value of our deferred compensation plan assets during the year.

In 2009, interest income declined by \$3.0 million as compared to 2008, primarily due to decline in market interest rates and shortened maturities on our investment portfolio, partially offset by higher investment balances. Foreign currency exchange gains and losses decreased by \$0.7 million in 2009 as compared to 2008 due to certain foreign currency transactions related to inventory for our foreign operations, which were not hedged in our foreign currency contracts.

## Impairment on Investment

In 2010 we recorded an impairment charge of \$2.0 million for our entire investment in Acorn Cardiovascular, Inc., a start-up medical device company.

## Income Taxes

Our effective tax rate was 36.2% in 2010 compared to 32.1% in 2009. This increase in the annual effective tax rate of 4.1% was primarily due to an increase in pre-tax income, fluctuations in return-to-provision adjustments including a benefit recognized in 2009 attributable to changes in state apportionment rates and an increase in the valuation allowance, offset by a reduction in non-deductible compensation. During the fourth quarter of 2010, we realized a tax benefit related to the full year impact of the federal research and development tax credit, which was in part offset by a revaluation of the 2010 state apportionment rates due to the divestiture of ITC.

Our effective tax rate was 32.1% in 2009 compared to 22.4% in 2008. This increase in the annual effective tax rate of 9.7% was primarily due to an increase in pre-tax income, lower tax-exempt interest and non-deductible compensation, in part offset by a change in state apportionment rates.

### **Discontinued Operations**

On November 4, 2010, we sold our wholly-owned subsidiary, International Technidyne Corporation ("ITC"), to ITC Nexus Holding Company, Inc. ("Nexus") for \$55 million in cash pursuant to a Stock Purchase Agreement, dated as of November 4, 2010, by and between the Company and Nexus. As such, we reclassified the assets and liabilities of ITC as held for sale on the consolidated balance sheets for the prior periods presented and the operating results as discontinued operations on the consolidated statements of operations for all periods presented.

Discontinued operations incurred a loss of \$5.8 million during 2010 compared to a loss of \$0.3 million during 2009. The increase in the loss from discontinued operations was primarily due to increase in transaction costs and compensation costs related to the sale of ITC, lower sales as a result of competitive activity and lower gross margin driven by unfavorable manufacturing variances. In addition, we recorded a loss from the sale of ITC of \$0.6 million.

Discontinued operations incurred a loss of \$0.3 million during 2009 compared to income of \$1.9 million during 2008. The increase in the loss from discontinued operations was primarily due to lower product sales and lower gross margin driven by unfavorable manufacturing variances and unfavorable geographic and product mix.

#### **Liquidity and Capital Resources**

## Cash, Cash Equivalents and Investments

Cash and cash equivalents include highly liquid financial instruments that are readily convertible to cash and have maturities of 90 days or less from the date of purchase.

Investments classified as short-term consist of various financial instruments such as municipal bonds, corporate bonds and variable demand notes. Bonds with high credit quality with maturities of greater than 90 days when purchased are classified as short-term available-for-sale. Investments classified as long-term consist of our investments in auction rate securities.

Following is a summary of our cash, cash equivalents and investments:

	January 1, 2011	January 2, 2010	January 3, 2009
		(in thousands)	
Cash and cash equivalents	\$ 56,887	\$ 27,787	\$108,388
Short-term available-for-sale investments	391,256	279,174	141,598
Long-term available-for-sale investments	21,379	24,634	29,959
Total cash and equivalents and available-for-sale investments	\$469,522	\$331,595	\$279,945

We believe that cash and cash equivalents, short-term available-for-sale investments on hand and expected cash flows from operations will be sufficient to fund our operations, capital requirements and stock repurchase programs for at least the next twelve months.

As of January 1, 2011, we owned approximately \$24.7 million face amount of auction rate securities classified as long-term. The assets underlying these investments are student loans backed by the U.S. government under the Federal Family Education Loan Program or by private insurers and are rated between BBB and AAA. Historically, these securities have provided liquidity through a Dutch auction process that resets the applicable interest rate periodically every seven to thirty-five days. Beginning in February of 2008, these auctions began to fail. The principal amount of these auction rate securities will not be accessible until future auctions for these securities are successful, a secondary market is established, these securities are called for redemption, or they are paid at maturity.

We recorded an estimated cumulative unrealized loss of \$3.3 million (\$2.0 million, net of tax) related to the temporary impairment of the auction rate securities, which was included in accumulated other comprehensive gain/loss within shareholders' equity. In addition, our management reviews impairments and credit loss associated with our investments, including auction rate securities to determine the classification of the impairment as "temporary" or "other-than-temporary" and to bifurcate the credit and non-credit component of an other-than-temporary impairment event. We do not intend to sell any of the auction rate securities prior to maturity at an amount below the original purchase value; intend to hold the investment to recovery and based on a more-likely-than-not probability assessment we will not be required to sell the security before recovery; and deem that it is not probable that we will receive less than 100% of the principal and accrued interest from the issuer. Therefore, 100% of the impairment was charged to other comprehensive income. Further, we continue to liquidate investments in auction rate securities as opportunities arise. During the fiscal year ended January 2, 2010, \$9.4 million in auction rate securities were redeemed at par and during the fiscal year ended January 1, 2011, \$3.0 million in auction rate securities were redeemed at par in connection with issuer calls.

We continue to monitor the market for auction rate securities and consider its impact (if any) on the fair value of our investments. If the current market conditions deteriorate further, or the anticipated recovery in fair values does not occur, we may be required to record additional unrealized losses in other comprehensive income or other-than-temporary impairment charges to the consolidated statements of operations in future periods.

We intend and have the ability to hold these auction rate securities until the market recovers or until maturity. We do not anticipate having to sell these securities in order to operate our business. We believe that, based on our current unrestricted cash, cash equivalents and short-term marketable security investment balances of \$448.1 million as of January 1, 2011, the current lack of liquidity in the credit and capital markets will not have an impact on our liquidity, our cash flow or our ability to fund our operations. If the issuers of the auction rate securities are unable to successfully complete future auctions and their credit ratings deteriorate, we may in the future be required to record an impairment charge on these investments. It could conceivably take until the final maturity of the underlying notes (up to 30 years) to realize our investments' recorded value.

In addition, as illustrated in the contractual obligations section, we have approximately \$11.0 million, including interest and penalties of unrecognized tax positions that have been recorded as liabilities and we are uncertain as to if or when such amounts may be settled. Settlement of such amounts could require the utilization of working capital.

## Senior Subordinated Convertible Notes

In 2004, we completed the sale of \$143.8 million initial principal amount of senior subordinated convertible notes due in 2034. The senior subordinated convertible notes were issued at an issue price of \$580.98 per note, which is 58.098% of the principal amount at maturity of the notes. The senior subordinated convertible notes bear interest at a rate of 1.3798% per year on the principal amount at maturity, payable semi-annually in arrears in cash on May 16 and November 16 of each year, from November 16, 2004 until May 16, 2011. Holders of the senior subordinated convertible notes may convert their convertible notes into shares of our common stock at a conversion rate of 29.4652 shares per \$1,000 principal amount of senior subordinated convertible notes, which represents a conversion price of \$19.72 per share, subject to adjustments upon the occurrence of certain events as set forth in the indenture. Holders have been and are able to convert their convertible notes at any point after the close of business on September 30, 2004 if, as of the last day of the preceding calendar quarter, the closing price of our common stock for at least 20 trading days in a period of 30 consecutive trading days ending on the last trading day of such preceding calendar quarter is more than 120% of the accreted conversion price per share of our common stock. Commencing October 1, 2008, this market price conversion feature was satisfied, such that 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 at a conversion rate of 29.4652 shares per \$1,000 principal amount of senior subordinated convertible notes, subject to adjustments as provided in the indenture. If holders elect conversion, we may, at our option, deliver shares of common stock, pay a holder in cash, or deliver a combination of shares and cash, as determined pursuant to the terms of the notes. As of January 1, 2011, 4,045 of the 247,427 bonds originally issued have been submitted to be converted and we elected to pay cash in lieu of shares for these bonds.

In addition, holders may require us to repurchase all or a portion of their senior subordinated convertible notes on each of May 16, 2011, 2014, 2019, 2024 and 2029 at a repurchase price equal to 100% of the issue price, plus the accrued original issue discount, if any. Due to this redemption feature, where holders may require us to repurchase all or a portion of the senior subordinated convertible notes as early as May 16, 2011, these senior subordinated convertible notes have been classified as current liabilities. Settlement of the senior subordinated convertible notes could require the utilization of short-term investments or common stock.

## Cash Flow Activities

Following is a summary of our cash flow from continuing operating activities:

	Fiscal Years			
	2010 2009		2008	
	(i	n thousands)		
Net cash provided by continuing operating activities	\$ 73,985	\$ 43,965	\$40,309	
Net cash (used in) provided by continuing investing activities	(118,506)	(138,113)	11,720	
Net cash provided by continuing financing activities	24,086	11,727	28,064	
Effect of exchange rate changes on cash and cash equivalents	(119)	(144)	(71)	
Net (decrease) increase in cash and cash equivalents	\$ (20,554)	\$ (82,565)	\$80,022	

#### Cash Provided by Continuing Operating Activities

In 2010, cash provided by continuing operating activities was \$74.0 million. This amount included net income from continuing operations of \$59.0 million increased by positive non-cash adjustments to net income of \$39.5 million primarily comprised of \$6.7 million related to depreciation, \$9.8 million related to amortization, \$8.4 million of non-cash interest expense, \$12.7 million related to share-based compensation expenses, and \$11.2 million of tax benefit related to the exercise of stock options. These positive non-cash contributions were partially offset by a decrease of \$9.5 million related to excess tax benefits from share-based compensation and a decrease of \$8.0 million in our net deferred tax liability. Changes in assets and liabilities used additional cash of \$24.6 million primarily due to the increase in receivables, inventory and a decrease in accrued income taxes, partially offset by an increase in accounts payable and accrued compensation.

## Cash Provided by or Used in Continuing Investing Activities

In 2010, cash used in continuing investing activities was \$118.5 million, due to net purchases of investments of \$115.6 million, purchase of a patent portfolio for \$1.4 million, and purchases of property, plant and equipment of \$4.3 million. The purchases of property, plant and equipment primarily relate to equipment purchases and the expansion of our research and development facilities and improvements to our Pleasanton office. This was offset in part by \$2.8 million of loan collections.

## Cash Provided by Continuing Financing Activities

In 2010, cash provided by financing activities was \$24.1 million, which was primarily comprised of \$26.3 million in proceeds related to stock option exercises and purchases under our Employee Stock Purchase Plan and \$9.5 million from excess tax benefits from share-based compensation. This was partially offset by \$6.3 million of restricted stock repurchased for payment of income tax withholding due upon vesting and \$5.4 million related to the extinguishment of our senior subordinated convertible notes.

## Cash Flow Activities from Discontinued Operations

Following is a summary of the cash flow activities from discontinued operations:

	Fiscal Years				
	2010	2009	2008		
	(i	(in thousands)			
Net cash provided by discontinued operating activities	\$ 357	\$ 5,100	\$10,452		
Net cash (used in) provided by discontinued investing activities	49,297	(3,136)	(4,389)		
Net (decrease) increase in cash and cash equivalents	\$49,654	\$ 1,964	\$ 6,063		

In 2010, cash provided by discontinued operating activities was \$0.4 million. This amount included net loss from discontinued operations of \$5.8 million increased by positive non-cash items to net loss of \$2.8 million comprised of \$0.6 million of loss on sale from the sale of discontinued operations, \$1.4 million of depreciation and amortization and \$4.2 million of share-based compensation expense, partially offset by \$3.4 million of deferred tax liability. Changes in assets and liabilities provided cash of \$3.4 million primarily due to decreases in receivables offset by a decrease of accounts payable and other liabilities.

In 2010, cash provided by discontinued investing activities was \$49.3 million, comprised of net proceeds from the sale of ITC of \$52.7 million offset by \$3.4 million of purchases of property, plant and equipment.

## **Off Balance Sheet Arrangements**

Letter of Credit—We maintain an Irrevocable Standby Letter of Credit as part of our workers' compensation insurance program. The Letter of Credit is not collateralized. The Letter of Credit automatically renews on June 30th of each year, unless terminated by one of the parties. As of January 1, 2011, our Letter of Credit balance was approximately \$0.8 million.

## **Contractual Obligations**

As of January 1, 2011, we had the following contractual obligations:

	Total	2011	2012	2013	2014	2015	Thereafter
			(iı	n million	s)		
Long-term debt obligations(a)	\$143.1	\$143.1	\$ —	\$ —	\$ —	\$ —	\$ —
Operating lease obligations(b)	21.1	2.5	2.4	2.3	1.8	1.5	10.6
Deferred compensation obligations(c)	3.3	0.3	0.2	0.1	0.3	0.1	2.3
Purchase obligations(d)	112.3	73.7	7.7	7.8	3.5	3.8	15.8
Total	\$279.8	\$219.6	\$10.3	\$10.2	\$5.6	\$5.4	\$28.7

<sup>(</sup>a) Includes interest of \$1.7 million. Based on a redemption feature of our senior subordinated convertible notes, we reclassified the net carrying amount of the notes to current liabilities in our consolidated financial statements in 2010. See note 10 to our consolidated financial statements included in this Annual Report on Form 10-K related to our senior subordinated convertible notes.

- (b) Our operating lease obligations of \$21.1 million are comprised primarily of our various leased facilities.
- (c) Our deferred compensation obligations of \$3.3 million are comprised of future distributions to plan participants.
- (d) Our purchase obligations include \$112.3 million of supply agreements in effect at January 1, 2011.

As of January 1, 2011, the liability for uncertain tax positions was \$11.0 million including interest and penalties. Due to the high degree of uncertainty regarding the timing of potential future cash flows associated with these liabilities, we are unable to make a reasonably reliable estimate of the amount and period in which these liabilities might be paid.

## Recently Issued Accounting Pronouncements

In April 2010, the FASB issued ("ASU") No. 2010-17, Revenue Recognition (Topic 605): Milestone Method. ASU No. 2010-17 provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. Under the milestone method of revenue recognition, consideration that is contingent upon achievement of a milestone in its entirety can be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. ASU No. 2010-17 provides the criteria to be met for a milestone to be considered substantive which includes: (i) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; and (ii) past performance be reasonable relative to all deliverables and payment terms in the arrangement. ASU No. 2010-17 is effective on a prospective basis for us for milestones achieved on or after January 2, 2011. We do not expect the adoption of this new guidance to have a material impact on our consolidated financial position, results of operations or cash flows.

## Item 7A. Quantitative and Qualitative Disclosures About Market Risk

## **Interest Rate Risk**

Our investment portfolio is made up of marketable investments in money market funds, auction rate securities, U.S. Treasury securities and debt instruments of government agencies, local municipalities, and high quality corporate issuers. All investments are carried at market value and are treated as available-for-sale. Investments with maturities beyond one year may be classified as short-term based on their highly liquid nature due to the frequency with which the interest rate is reset and because such marketable securities represent the investment of cash that is available for current operations. Our holdings of the securities of any one issuer, except government agencies, do not exceed 10% of the portfolio.

Our investment portfolio and cash equivalents that bear variable interest would have an immaterial impact to interest income, on the consolidated statements of operations, if interest rates would have fallen by 50 basis points.

In addition, if interest rates rise, the market value of our investment portfolio may decline, which could result in a loss if we choose or are forced to sell an investment before its scheduled maturity. If interest rates were to rise or fall from current levels by 100 basis points and by 125 basis points, the change in our net unrealized loss on investments would be \$1.9 million and \$2.3 million, respectively. We do not utilize derivative financial instruments to manage interest rate risks.

Our senior subordinated convertible notes do not bear interest rate risk as the notes were issued at a fixed rate of interest.

As of January 1, 2011 we owned approximately \$24.7 million of auction rate securities, which is part of our investment portfolio. The assets underlying these auction rate securities are student loans which are rated between BBB and AAA, and backed by the U.S. government under the Federal Family Education Loan Program or private insurers. Historically, these securities have provided liquidity through a Dutch auction process that resets the applicable interest rate, periodically every seven to thirty-five days. Beginning in February of 2008, these auctions began to fail. Although we have realized at or below market interest rates for many of these auction rate securities than we otherwise would have, the principal amount will not be accessible until future auctions for these securities are successful, a secondary market is established, or these securities are called for redemption. Therefore, our auction rate securities are classified as long-term and are valued at \$21.4 million, net of a \$3.3 million impairment, using significant unobservable inputs. Based on our expected operating cash flows, and our other sources of cash, we do not anticipate the potential lack of liquidity of these investments will affect our ability to execute our current business plan.

## **Foreign Currency Rate Fluctuations**

We use forward foreign currency contracts to mitigate the gains and losses generated by the re-measurement of non-functional currency assets and liabilities. Our contracts typically have maturities of four months or less.

Effective January 3, 2010, we changed our functional currency for our U.K. subsidiary from U.K. pounds to euros. This change did not have a material impact on our consolidated financial statements. As of January 1, 2011, we had forward contracts to sell euros to U.S. dollars with a notional value of \$1.4 million, to sell U.S. dollars to euros with a notional value of \$5.4 million, and to sell U.K. pounds to euros with a notional value of \$1.9 million. As of January 2, 2010, we had forward contracts to sell euros to U.S. dollars with a notional value of \$1.6 million and to sell U.K. pounds to U.S. dollars with a notional value of \$0.3 million. As of January 1, 2011, our forward contracts to sell had an average exchange rate of one U.S. dollar to 1.3372 euros and one euro to 1.1690 U.K. pounds. The potential fair value loss for a hypothetical \$1.0% adverse change in foreign currency exchange rates as of January 1, 2011 would be approximately \$1.4 million.

## Item 8. Financial Statements and Supplementary Data

## THORATEC CORPORATION

## INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Financial Statements:	
Reports of Independent Registered Public Accounting Firm	52
Consolidated Balance Sheets	54
Consolidated Statements of Operations	55
Consolidated Statements of Shareholders' Equity	56
Consolidated Statements of Cash Flows	57
Notes to Consolidated Financial Statements	58

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Thoratec Corporation:

We have audited the accompanying consolidated balance sheets of Thoratec Corporation and its subsidiaries (the "Company") as of January 1, 2011 and January 2, 2010, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three fiscal years in the period ended January 1, 2011. Our audits also included the consolidated financial statement schedule listed in the Index at Item 15(a)2. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Thoratec Corporation and subsidiaries as of January 1, 2011 and January 2, 2010, and the results of their operations and their cash flows for each of the three fiscal years in the period ended January 1, 2011, in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, such consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of January 1, 2011, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 23, 2011 expressed an unqualified opinion on the Company's internal control over financial reporting.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California February 23, 2011

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of Thoratec Corporation:

We have audited the internal control over financial reporting of Thoratec Corporation and its subsidiaries (the "Company") as of January 1, 2011, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's Board of Directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of January 1, 2011, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements and consolidated financial statement schedule as of and for the fiscal year ended January 1, 2011 of the Company and our report dated February 23, 2011 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California February 23, 2011

# THORATEC CORPORATION CONSOLIDATED BALANCE SHEETS

(In thousands)

	January 1, 2011	January 2, 2010
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 56,887	\$ 27,787
Short-term available-for-sale investments	391,256	279,174
Receivables, net of allowances of \$1,334 in 2010 and \$322 in 2009	57,213	48,058
Inventories	59,790	44,635
Deferred tax assets	9,677	8,846
Income tax receivable	9,538 5,706	1,234 4,831
Prepaid expenses and other assets	3,700	67,644
Total current assets	590,067	482,209
Property, plant and equipment, net	38,077	37,115
Goodwill	95,015	95,015
Long-term available-for-sale investments	88,518 21,379	96,876 24,634
Other long-term assets	4,687	12.034
Total Assets	\$837,743	\$747,883 
LIABILITIES AND SHAREHOLDERS' EQUITY Current liabilities:		
Accounts payable	\$ 13,495	\$ 6,222
Accrued compensation	20,753	17,417
Other accrued liabilities	14,604	11,803
Senior subordinated convertible notes	138,165	´—
Liabilities related to assets held for sale		12,663
Total current liabilities	187,017	48,105
Senior subordinated convertible notes	_	131,929
Long-term deferred tax liability	20,109	32,099
Other long-term liabilities	9,257	10,622
Total Liabilities	216,383	222,755
Commitments and contingencies (Note 9)		
Shareholders' equity:		
Common shares: no par, authorized 100,000; issued and outstanding 58,571 in		
2010 and 57,043 in 2009	(0)(792	
Additional paid-in-capital	606,782 18,603	557,418 (30,321)
Accumulated other comprehensive loss:	10,003	(30,321)
Unrealized loss on investments	(1,660)	(648)
Cumulative translation adjustments	(2,365)	(1,321)
Total accumulated other comprehensive loss	(4,025)	(1,969)
Total Shareholders' Equity	621,360	525,128
Total Liabilities and Shareholders' Equity	\$837,743	\$747,883
Total Englishes and Shareholders Equity	ΨΟΣΤ,ΤΙΣ	Ψ717,003 =====

## CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share data)

		Fiscal Years	
	2010	2009	2008
Product sales	\$382,973	\$279,968	\$214,975
Cost of product sales	123,709	95,555	70,569
Gross profit	259,264	184,413	144,406
Operating expenses: Selling, general and administrative Research and development	89,222 58,831	82,079 42,743	68,948 39,997
Amortization of purchased intangible assets	9,772	9,834	12,346
Total operating expenses	157,825	134,656	121,291
Income from operations	101,439	49,757	23,115
Interest expense	(12,327) 5,435 (2,000)	(12,307) 5,146 —	(10,984) 9,001 —
Income before taxes	92,547 33,542	42,596 13,691	21,132 4,739
Net income from continuing operations	59,005 (5,839)	28,905 (321)	16,393 1,938
Net income	\$ 53,166	\$ 28,584	\$ 18,331
Net income (loss) per common share—Basic: Continuing operations	\$ 1.02	\$ 0.51	\$ 0.30
Discontinued operations	\$ (0.10)	\$ (0.01)	\$ 0.03
Net income	\$ 0.92	\$ 0.50	\$ 0.33
Net income (loss) per common share—Diluted: Continuing operations	\$ 0.99	\$ 0.50	\$ 0.30
Discontinued operations	\$ (0.10)	\$ (0.01)	\$ 0.03
Net income	\$ 0.89	\$ 0.49	\$ 0.33
Shares used to compute net income (loss) per common share(1):  Basic	57,670 59,071	55,910 57,322	54,144 55,243

<sup>(1)</sup> See Note 17, "Net Income (Loss) Per Share," for the computation of basic and diluted calculation using the two-class method.

# THORATEC CORPORATION CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(In thousands)

	Common Shares	Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity	Total Comprehensive Income (Loss)
BALANCE, DECEMBER 29, 2007	54,108	\$486,845	\$(74,259)	\$ 1,223	\$413,809	
Exercise of common stock options for cash	1,768	22,914			22,914	
Employee Stock Purchase Plan Tax benefit related to employees' and	149	2,062			2,062	
directors' stock plans	370	6,926 (715) 10,625	(706)		6,926 (1,421) 10,625	
investments (net of taxes of \$2,436) Foreign currency translation adjustment . Net income			18,331	(3,654) (3,313)	(3,654) (3,313) 18,331	(3,654) (3,313) 18,331
Total comprehensive income						\$11,364
BALANCE, JANUARY 3, 2009	56,395	\$528,657	\$(56,634)	\$(5,744)	\$466,279	
Exercise of common stock options for cash	652	9,184			9,184	
Issuance of common shares under Employee Stock Purchase Plan Tax benefit related to employees' and	133	2,898			2,898	
directors' stock plans	(137)	3,932 (1,236) 13,983	(2,271)		3,932 (3,507) 13,983	
Unrealized gain on available-for-sale investments (net of taxes of \$1,753) Foreign currency translation adjustment . Net income			28,584	2,689 1,086	2,689 1,086 28,584	2,689 1,086 28,584
Total comprehensive income						\$32,359
BALANCE, JANUARY 2, 2010 Exercise of common stock options for	57,043	\$557,418	\$(30,321)	\$(1,969)	\$525,128	
cash	1,430	22,840			22,840	
Employee Stock Purchase Plan	140 250	3,431			3,431	
directors' stock plans	(292)	11,235 (2,046) 17,025	(4,242)		11,235 (6,288) 17,025	
extinguished		(3,121)			(3,121)	
Unrealized loss on available-for-sale investments (net of taxes of \$625) Foreign currency translation adjustment . Net income			53,166	(1,012) (1,044)	(1,012) (1,044) 53,166	(1,012) (1,044) 53,166
Total comprehensive income						\$51,110
BALANCE, JANUARY 1, 2011	58,571	\$606,782	\$ 18,603	\$(4,025)	\$621,360	

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Fiscal Years		
	2010	2009	2008
Cash flows from continuing operating activities:	<b>* * * * * * * * * *</b>		
Net income from continuing operations	\$ 59,005	\$ 28,905	\$ 16,393
Depreciation and amortization	16,503	17,334	19,142
Investment premium amortization (net)	5,135 99	3,115	2,307
Loss on extinguishment of senior subordinated convertible notes	395	1,050	893
Non-cash interest expense	8,420	7,814	7,156
Write-down of investment	2,000	2 022	6.026
Tax benefit related to stock options	11,235 12,654	3,932 10,290	6,926 7,964
Excess tax benefits from share-based compensation	(9,462)	(3,152)	(4,509)
Loss on disposal of asset	533	(12.068)	573
Change in net deferred tax liability	(7,981) (10,375)	(12,968) (10,418)	(9,063) (12,757)
Inventories	(18,929)	(4,664)	(9,400)
Prepaid expenses and other assets	(954)	(1,576)	(185)
Accounts payable	7,336 7,639	(2,597) 301	854 14,498
Accrued income taxes	(9,268)	6,366	(483)
Net cash provided by continuing operating activities	73,985	43,965	40,309
Cash flows from continuing investing activities:	(550.050)	(2.46.51.5)	(4.52.220)
Purchases of available-for-sale investments  Sales and maturities of available-for-sale investments	(572,252) 456,653	(346,715) 215,731	(153,238) 170,946
Issuance of HeartWare loan	-50,055	(20,000)	- 170,540
Purchased intangibles	(1,414)	(1,440)	_
Loan collections  Purchases of property, plant and equipment, net	2,756 (4,249)	23,000 (8,689)	(5,988)
Net cash (used in) provided by continuing investing activities	(118,506)	(138,113)	11,720
Cash flows from continuing financing activities:			
Proceeds from stock option exercises	22,840	9,184	22,914
Proceeds from stock issued under employee stock purchase plan	3,431	2,898	2,062
Excess tax benefits from share-based compensation	9,462 (6,289)	3,152 (3,507)	4,509 (1,421)
Extinguishment of senior subordinated convertible notes	(5,358)	_	(1,121)
Net cash provided by continuing financing activities	24,086	11,727	28,064
Effect of exchange rate changes on cash and cash equivalents	(119)	(144)	(71)
Net cash (used in) provided by continuing operations	(20,554)	(82,565)	80,022
Cash flows from discontinued operations:	257	£ 100	10.452
Net cash provided by operating activities	357 49,297	5,100 (3,136)	10,452 (4,389)
Net cash provided by discontinued operations	49,654	1,964	6,063
Net increase (decrease) in cash and cash equivalents  Cash and cash equivalents at beginning of fiscal year	29,100 27,787	(80,601) 108,388	86,085 22,303
Cash and cash equivalents at end of fiscal year	\$ 56,887	\$ 27,787	\$ 108,388
Supplemental disclosure of consolidated cash flow information:			
Cash paid for taxes	\$ 38,396	\$ 15,178	\$ 8,947
Cash paid for interest	\$ 3,386	\$ 3,414	\$ 3,414
Supplemental disclosure of consolidated non-cash investing and financing activities:  Transfers of equipment from inventory	\$ 4,123	\$ 2,642	\$ 3,055
Purchases of property, plant and equipment through accounts payable and other accrued liabilities	\$ 231	\$ 1,573	\$ 1,938
Purchase of intangibles through other accrued liabilities	\$ —	\$ 500	\$

# THORATEC CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## 1. Operations and Significant Accounting Policies

The Company and Basis of Presentation

Thoratec Corporation (referred to in these Notes as "we," "our," "us," "Thoratec" or the "Company"), is headquartered in Pleasanton, California and is a manufacturer of mechanical circulatory support products for use by patients with heart failure ("HF"). We develop, manufacture and market products that are used by physicians and hospitals for cardiac assist, vascular and diagnostic applications. We conduct business both domestically and internationally.

On April 25, 2010, our board of directors made a decision to sell our wholly-owned subsidiary, International Technidyne Corporation ("ITC") and on November 4, 2010, we sold ITC to ITC Nexus Holding Company, Inc. ("Nexus") for \$55 million in cash pursuant to a Stock Purchase Agreement, dated as of November 4, 2010, by and between the Company and Nexus. As such, as of the second quarter of 2010, ITC met the conditions in Financial Accounting Standards Board ("FASB") Codification ("ASC") 360, *Property, Plant and Equipment*, to be classified as an asset held for sale, as described in Note 16, "Discontinued Operations."

In addition, certain financial statement items have been reclassified to conform to the current fiscal year's format. As discussed in Note 16 "Discontinued Operations," we have reclassified the assets and liabilities of ITC as held for sale on the consolidated balance sheets and presented its operating results as a discontinued operation on the consolidated statement of operations for all periods presented. Unless noted otherwise, discussion in these notes pertains to our continuing operations. These reclassifications had no impact on previously reported total net income.

We report on a 52-53 week fiscal year, which ends on the Saturday closest to December 31. The fiscal year ended January 3, 2009 ("2008") included 53 weeks, the fiscal year ended January 2, 2010 ("2009") included 52 weeks and the fiscal year ended January 1, 2011 ("2010") included 52 weeks.

### Principles of Consolidation

Our consolidated financial statements include the financials statements of ITC prior to November 4, 2010, when it was sold to Nexus and our wholly-owned foreign subsidiary in the U.K. Intercompany transactions and balances have been eliminated in consolidation.

## Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts in the consolidated financial statements and the accompanying notes. The actual amounts could differ from those estimated amounts.

## Major Customers and Concentration of Credit Risk

We primarily sell our products to large hospitals and distributors. No customer accounted for more than 10% of total product sales in fiscal years 2010, 2009 or 2008. No customer had an accounts receivable balance greater than 10% of total accounts receivable at the end of fiscal year 2010 or 2009.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 1. Operations and Significant Accounting Policies (Continued)

Financial instruments that potentially expose us to concentrations of credit risk consist primarily of cash and cash equivalents, short and long-term investments, and trade accounts receivable. Cash and cash equivalents held with financial institutions may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation on such deposits. Investments in municipal bonds, variable demand notes and auction rate securities, backed by U.S Government or private insurers, are subject to credit risk. However, we invest in high-grade instruments and limit our exposure to any one issuer. In addition, we have recorded an impairment loss on our auction rate securities. Concentration of credit risk with respect to our trade accounts receivable to our customers is limited to large hospitals and distributors. Credit is extended to our customers, based on an evaluation of a customer's financial condition and generally collateral is not required. To date, credit losses have not been significant; however, we maintain allowances for potential credit losses.

#### Certain Risks and Uncertainties

We are subject to certain risks and uncertainties and believe that changes in any of the following areas could have a material adverse effect on our future financial position or results of operations: counterparty credit risk in the current market environment; the ability to receive and maintain U.S. Food and Drug Administration ("FDA") and foreign regulatory authorities approval to manufacture, market and sell our products; our ability to adequately and timely address issues raised by the FDA inspections; the ability to direct and manage current and future growth and physician acceptance of our current or future products; our reliance on specialized suppliers; the ability to manufacture products on an efficient and timely basis and at a reasonable cost and in sufficient volume, including the ability to obtain timely deliveries of parts from suppliers; our ability to identify and correct quality issues in a timely manner and at a reasonable cost; new product development and introduction, including FDA approval and market receptiveness; the ability to protect our proprietary technologies or an infringement by us of others' patents; the number of heart transplants conducted; our dependence upon distributors and any changes made to our method of distribution; competition from other products; worldwide demand for circulatory support and graft products and the management of risks inherent in selling in foreign countries; foreign currency fluctuations; the long and variable sales and deployment cycle of our ventricular assist device ("VAD") products; the willingness of third party payors to cover and provide appropriate levels of reimbursement for our products; our subordinated convertible notes, their repayment and potential related dilution from conversion; the ability to realize the full value of our intangible assets; product liability or other claims; the ability to attract and retain talented employees; stock price volatility due to general economic conditions or future issuances and sales of our stock; the integration of any current and future acquisitions of companies or technologies; the occurrence of catastrophic disasters; the ability to achieve and maintain profitability; claims relating to the handling, storage or disposal of hazardous chemicals and biomaterials; changes in legal and accounting regulations and standards; changes in tax regulations; and limitations on potential acquisitions and stock pricing.

## Cash and Cash Equivalents

Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase. The fair value of these investments was determined by using quoted prices for identical investments in active markets which are measured at Level 1 or Level 2 inputs under ASC 820, *Fair Value Measurements and Disclosures*.

## Investments

We hold investments in short-term and long-term available-for-sale securities. Investments in short-term investments consist primarily of municipal bonds, variable demand notes and corporate bonds and investments in long-term investments consist of auction rate securities.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 1. Operations and Significant Accounting Policies (Continued)

Unrealized gains and losses on our investments are included in accumulated other comprehensive income in stockholders' equity. Unrealized losses are charged against "Interest and other income, net" when a decline in fair value is determined to be other-than-temporary. We review several factors to determine whether a loss is other-than-temporary. These factors include but are not limited to: (i) our ability and intent to hold the investment to maturity, (ii) whether it is more-likely-than-not we would be required to sell the investment before recovery of the investments amortized cost basis and (iii) whether we expect to recover the amortized cost basis of the investment. Auction rate securities are classified as long-term.

If the impairment is considered to be other-than-temporary, the security is written down to its estimated fair value. The cost of all securities sold is based on the specific identification method.

#### Fair Value Measurement

The carrying amounts of certain of our financial instruments including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their short maturities. Short-term investments are comprised of available-for-sale securities, which are carried at fair value. Other non-current assets, which include auction rate securities and deferred compensation plan assets, are carried at fair value. Foreign exchange contracts are stated at fair value based on prevailing financial market information.

See Note 3, "Fair Value Measurement" for further information on fair value measurement of our financial and nonfinancial assets and liabilities.

#### Inventories

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

## Property, Plant and Equipment

Property, plant and equipment is stated at cost, net of accumulated depreciation. Depreciation is computed using the straight-line method based on estimated useful lives of two to thirty years. Leasehold improvements are amortized over the lesser of the useful life or the remaining term of the lease. Property, plant and equipment include certain medical devices rented to customers. Depreciation expense of all rental equipment included in our rental program is recognized ratably over two to three years and is recorded in cost of product sales.

## Valuation of Long-Lived Assets and Purchased Intangible Assets

We evaluate the carrying value of long-lived assets, including intangible assets, whenever events or changes in business circumstances or our planned use of long-lived assets indicate that their carrying amounts may not be fully recoverable or that their useful lives are no longer appropriate. Reviews are performed to determine whether the carrying values of long-lived assets are impaired based on a comparison to the undiscounted expected future net cash flows. If the comparison indicates that impairment exists, long-lived assets are written down to their respective fair values. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. Significant management judgment is required in the forecast of future operating results that is used in the preparation of expected undiscounted cash flows.

Purchased intangible assets are subject to amortization and are amortized over their estimated period of benefit, ranging from eight to twenty years. We evaluate the recoverability of intangible assets periodically, and take into account events or circumstances that warrant revised estimates of useful lives or indicate that impairment exists, such as when the anticipated identifiable undiscounted cash flows expect to be generated from an intangible asset is 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 intangible asset. Fair value is determined primarily using the anticipated cash flows discounted at a rate commensurate with the risk involved. No impairments of purchased intangible assets have been identified during the years presented.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 1. Operations and Significant Accounting Policies (Continued)

Goodwill

Goodwill is tested for impairment on an annual basis or more frequently if indicators for potential impairment exist. Impairment testing is conducted at the reporting unit level, for which discrete financial information is available and for which the reporting units management regularly reviews the operating results thereof.

The impairment test for goodwill is a two-step process. Step one consists of a comparison of the fair value of a reporting unit against its carrying amount. After the sale of ITC, we determined that our reporting unit is the Cardiovascular division and its fair value is based on the present value of its estimated future cash flows from operations, discounted at a rate commensurate with the risk involved. If the carrying value exceeds the fair value, step two is performed to calculate the amount of impairment, which would be recorded as a charge in the consolidated statements of operations. The fair value of a reporting unit is based upon a number of considerations including projections of revenues, earnings and discounted cash flows. The discount rate used for cash flows reflects capital market conditions and the specific risks associated with the business. In addition, we compare the aggregate of our only reporting unit fair values to the Company's market capitalization as a further corroboration of the fair value. The testing requires a complex series of assumptions and judgments by management in projecting future operating results and assessing risks. The use of alternative assumptions and estimates could affect the fair values and change the impairment determinations. Based upon the assumptions as of our fiscal 2010 testing date, our reporting unit was not at risk of the carrying value exceeding the fair value. We will continue to make assessments of impairment on an annual basis in the fourth quarter of our fiscal years or more frequently if indicators of potential impairment arise.

## Deferred Compensation Plan

We established a non-qualified, unfunded deferred compensation plan for certain management employees and our Board of Directors. Amounts deferred and contributed under the deferred compensation plan are credited or charged with the performance of investment options offered under the plan as elected by the participants. The liability for compensation deferred under this plan is included in "Other long-term liabilities" on our consolidated balance sheets. We manage the risk of changes in the fair value of the liability for deferred compensation by electing to match our liability under the plan with an investment that offsets a substantial portion of the Company's exposure. The investments associated with the deferred compensation plan is included in "Other long-term assets" on our consolidated balance sheets at the cash surrender value of our corporate owned life insurance policies and the fair value of the mutual fund investments. Changes in the cash surrender value of our corporate owned life insurance policies and the fair value of mutual fund investments are included in our consolidated statements of operations for all periods presented.

## Foreign Currency Translation

Our international operations consist primarily of sales and service personnel who report to our U.S. sales and marketing group. Effective January 3, 2010, we changed our functional currency for our U.K. subsidiary from U.K. pounds to euros. This change did have a material impact on our consolidated financial statements. All assets and liabilities of our non-U.S. operations are translated into U.S. dollars at the period-end exchange rates and the resulting translation adjustments are included in other comprehensive income. The period-end translation of the non-functional currency assets and liabilities at the period-end exchange rates result in foreign currency gains and losses, which are included in "Interest income and other."

## Revenue Recognition and Product Warranty

We recognize revenue from product sales to customers and distributors when evidence of an arrangement exists, and title has passed (generally upon shipment) or services have been rendered, the selling price (including pricing discounts) have been fixed or have become determinable, collectability is reasonably assured and there are no further obligations to customers or distributors, as applicable.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 1. Operations and Significant Accounting Policies (Continued)

The majority of our products are covered by up to a one-year limited manufacturer's warranty. Estimated contractual warranty obligations are recorded when related sales are recognized and any additional amounts are recorded when such costs are probable, can be reasonably estimated and are included in "Cost of product sales." The change in accrued warranty expense from continuing operations is summarized in the following table:

	Balance Beginning of Year	Accruals for Warranties Issued	Settlements Made	Balance End of Year
		(in thous	ands)	
Fiscal 2010	\$1,706	\$6,127	\$(4,776)	\$3,057
Fiscal 2009	\$ 554	\$3,613	\$(2,461)	\$1,706
Fiscal 2008	\$ 398	\$1.564	\$(1,408)	\$ 554

## Research and Development Expense

Research and development costs are charged to expense when incurred. Major components of research and development expenses consist of personnel costs, including salaries and benefits, and regulatory and clinical costs associated with our compliance with FDA regulations. 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.

## Share-Based Compensation

Share-based compensation expense is measured based on the grant-date fair value of the share-based awards. We recognize share-based compensation expense for the portion of the award that will ultimately be expected to vest over the requisite service period for those awards with graded vesting and service conditions. We develop an estimate of the number of share-based awards which will ultimately vest, primarily based on historical experience. The estimated forfeiture rate is reassessed periodically throughout the requisite service period. Such estimates are revised if they differ materially from actual forfeitures. As required, the forfeiture estimates will be adjusted to reflect actual forfeitures when an award vests.

We use the Black-Scholes option pricing model as the method for determining the estimated grant-date fair value of stock options and purchase rights under the ESPP. The Black-Scholes model requires the use of highly subjective and complex assumptions which determine the fair value of share-based awards, including the option's expected term and the price volatility of the underlying stock.

For restricted stock awards and restricted stock units, compensation expense is calculated based on the fair value of our stock at the grant date.

See Note 11, "Share-Based Compensation" for further information on our equity incentive plans.

## Income Taxes

Income taxes are recorded under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 1. Operations and Significant Accounting Policies (Continued)

We record net deferred tax assets to the extent we believe these assets will more likely than not be realized. In making such determination, we consider all available positive and negative evidence including future taxable income and ongoing prudent and feasible tax planning strategies. In the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the valuation allowance for the deferred tax asset would increase net income in the period such determination was made. Likewise, should we determine that we would not be able to realize all or part of our net deferred tax asset in the future, an adjustment to the valuation allowance for the deferred tax asset would be charged to net income in the period such determination was made.

We recognize interest and penalties related to unrecognized tax benefits within the income tax expense line in the accompanying consolidated statements of operations. Accrued interest and penalties are included within the related tax liability line in the consolidated balance sheet.

See Note 14, "Taxes on Income" for further information on our tax position.

### Other Comprehensive Income (Loss)

Other comprehensive income (loss) includes net income, unrealized gains and losses on available-for-sale investments and foreign currency translation adjustments from continuing operations. There are no unrealized gains and losses on available-for-sale investments and foreign currency translation adjustments from discontinued operations.

## Letter of Credit

We maintain an Irrevocable Standby Letter of Credit as part of our workers' compensation insurance program. The Letter of Credit is not collateralized. The Letter of Credit automatically renews on June 30 of each year, unless terminated by one of the parties. As of January 1, 2011, our Letters of Credit balance was approximately \$0.8 million.

## Recently Issued Accounting Pronouncements

In April 2010, the FASB issued ASU No. 2010-17, *Revenue Recognition (Topic 605): Milestone Method.* ASU No. 2010-17 provides guidance on the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. Under the milestone method of revenue recognition, consideration that is contingent upon achievement of a milestone in its entirety can be recognized as revenue in the period in which the milestone is achieved only if the milestone meets all criteria to be considered substantive. ASU No. 2010-17 provides the criteria to be met for a milestone to be considered substantive which includes: (i) performance consideration earned by achieving the milestone be commensurate with either performance to achieve the milestone or the enhancement of the value of the item delivered as a result of a specific outcome resulting from performance to achieve the milestone; and (ii) past performance be reasonable relative to all deliverables and payment terms in the arrangement. ASU No. 2010-17 is effective on a prospective basis for us for milestones achieved on or after January 2, 2011. We do not expect the adoption of this new guidance to have a material impact on our consolidated financial position, results of operations or cash flows.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 2. Investments

Our investment portfolio is comprised of short-term and long-term investments. Investments classified as short-term available-for-sale consist primarily of municipal bonds, corporate bonds and variable demand notes. All investments effective maturity within two years or less from the date of purchase. Investments with maturities beyond one year may be classified as short-term, if they are available and intended for use in current operations, based on their highly liquid nature or due to the frequency with which the interest rate is reset. Investments classified as long-term available-for-sale consist of auction rate securities, whose underlying assets are student loans. In addition, certain of our long-term investments associated with the deferred compensation plan are classified as trading securities and as of January 1, 2011 and consists primarily of mutual fund investments.

Our investments in available-for-sale securities are recorded at estimated fair value on our financial statements, and the temporary differences between cost and estimated fair value are presented as a separate component of accumulated other comprehensive income.

As of January 1, 2011, we had gross unrealized gains from our investment in municipal bonds, variable demand notes and corporate bonds of \$0.6 million offset by gross unrealized losses of \$0.1 million and gross unrealized loss on our auction rate securities of \$3.3 million. As of January 2, 2010, we had gross unrealized gains from our investments in municipal bonds, variable demand notes and corporate bonds of \$1.9 million and gross unrealized losses from our auction rate securities of \$3.1 million.

The aggregate market value, cost basis and unrealized gains and losses of available-for-sale investments for fiscal 2010 and 2009 by major security type are as follows:

	Amortized Cost	Unrealized Gains (Losses)	Fair Value
		(in thousands)	
As of January 1, 2011:			
Short-term investments:			
Municipal bonds	\$255,785	\$ 336	\$256,121
Variable demand notes	119,080	_	119,080
Corporate bonds	15,899	156	16,055
Total short-term investments	\$390,764	\$ 492	\$391,256
Long-term investments:			
Auction rate securities	\$ 24,700	<u>\$(3,321)</u>	\$ 21,379
As of January 2, 2010:			
Short-term investments:			
Municipal bonds	\$196,650	\$ 1,526	\$198,176
Variable demand notes	66,865	_	66,865
Corporate bonds	13,785	348	14,133
Total short-term investments	\$277,300	\$ 1,874	\$279,174
Long-term investments:			
Auction rate securities	\$ 27,700	<u>\$(3,066)</u>	\$ 24,634

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 2. Investments (Continued)

The contractual maturities of our available-for-sale investments are as follows:

	Amortized Cost	Fair Value
	(in thousands)	
As of January 1, 2011:		
Maturing within one year	\$347,833	\$348,404
Due after one year through two years	42,931	42,852
Short-term available-for sale investments	390,764	391,256
Auction rate securities maturing within five years or greater	24,700	21,379
	\$415,464	\$412,635
As of January 2, 2010:		
Maturing within one year	\$179,998	\$180,620
Due after one year through two years	97,302	98,554
Short-term available-for sale investments	277,300	279,174
Auction rate securities maturing within five years or greater	27,700	24,634
	\$305,000	\$303,808

The Company's variable rate demand notes are included in the above table with securities maturing within one year.

As of January 1, 2011 we owned approximately \$24.7 million face amount of auction rate securities classified as long-term. The assets underlying these investments are student loans backed by the U.S. government under the Federal Family Education Loan Program or by private insurers and are rated between BBB and AAA. Historically, these securities have provided liquidity through a Dutch auction process that resets the applicable interest rate periodically every seven to thirty-five days. Beginning in February of 2008, these auctions began to fail. The principal amount of these auction rate securities will not be accessible until future auctions for these securities are successful, a secondary market is established, these securities are called for redemption, or they are paid at maturity.

As of January 1, 2011, we have recorded an estimated cumulative unrealized loss of \$3.3 million (\$2.0 million, net of tax) related to the temporary impairment of the auction rate securities, which was included in accumulated other comprehensive income (loss) within shareholders' equity. In addition, our management reviews impairments and credit loss associated with its investments, including auction rate securities to determine the classification of the impairment as "temporary" or "other-than-temporary" and to bifurcate the credit and non-credit component of an other-than-temporary impairment event. We (i) do not intend to sell any of the auction rate securities prior to maturity at an amount below the original purchase value; (ii) intend to hold the investment to recovery and, based on a more-likely-than-not probability assessment, will not be required to sell the security before recovery; and (iii) deem that it is not probable that we will receive less than 100% of the principal and accrued interest from the issuer. Therefore, 100% of the impairment was charged to other comprehensive income (loss). Our auction rate securities are classified as long-term and are valued at \$21.4 million using significant unobservable inputs. Further, we continue to liquidate investments in auction rate securities as opportunities arise. During fiscal years 2010 and 2009, \$3.0 million and \$9.4 million, respectively, in auction rate securities were redeemed at par in connection with issuer calls.

If the issuers of the auction rate securities are unable to successfully complete future auctions and their credit ratings deteriorate, we may in the future be required to record an impairment charge to earnings on these investments. It could conceivably take until the final maturity of the underlying notes (up to 30 years) to realize the investments' carrying value.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 2. Investments (Continued)

The aggregate value of our corporate owned life insurance policies and mutual fund investments included in our deferred compensation plan as of January 1, 2011 and January 2, 2010 were as follows:

	<b>January 1, 2011</b>	<b>January 2, 2010</b>	
	(in thousands)		
Deferred compensation plan	\$3,188	\$2,436	

The investments associated with the deferred compensation plan is included in "Other long-term assets" on our consolidated balance sheets at the cash surrender value of our corporate owned life insurance policies and the fair value of the mutual fund investments. The realized gain before tax from the change in the value of the deferred compensation plan for both fiscal years 2010 and 2009 of approximately \$0.4 million and a realized loss for fiscal year 2008 of approximately \$0.9 million.

## 3. Fair Value Measurement

ASC 820, Fair Value Measurements and Disclosure, 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 used various approaches, including market, income and/or cost approaches, and each of these approaches requires certain inputs. Fair value measurement 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 and 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.

We fair value our financial and nonfinancial assets and liabilities based on the observability of inputs used in the valuation of such assets and liabilities using the following fair value hierarchy. The fair value hierarchy ranks the quality and reliability of the information used to determine fair values. Financial and nonfinancial assets and liabilities carried or disclosed at fair value were classified and disclosed in one of the following three categories:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: 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.
- Level 3: Inputs that are unobservable and significant to the overall fair value measurement.

Assets and Liabilities That Are Measured at Fair Value on a Recurring Basis

ASC 820 principally applies to financial assets and liabilities which include short-term investments, auction rate securities, foreign exchange instruments, and certain of our deferred compensation plan assets. These items are marked-to-market at each reporting period. The information in the following paragraphs and tables primarily addresses matters relative to these financial assets and liabilities.

# THORATEC CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 3. Fair Value Measurement (Continued)

The following table represents the fair value hierarchy for our financial assets and financial liabilities measured at fair value on a recurring basis:

			January 1, 2011		
	Assets and liabilities at carrying value	Total fair value	Quoted prices in active markets for identical assets	Significant other observable inputs	Significant unobservable inputs
			(Level 1)	(Level 2)	(Level 3)
			(in thousands)		
Assets					
Short-term investments:					
Municipal bonds	\$256,121	\$256,121	\$—	\$256,121	\$ —
Variable demand notes	119,080	119,080	_	119,080	
Corporate bonds	16,055	16,055	_	16,055	
Prepaid expenses and other assets—					
mark-to-market on foreign exchange					
instruments (Note 4)	172	172	_	172	_
Long-term investments—auction rate					
securities	21,379	21,379	_	_	21,379
Other long-term assets—deferred					
compensation plan	2,408	2,408	_	2,408	
			January 2, 2010		
	Assets and liabilities at carrying value	Total fair value	Quoted prices in active markets for identical assets	Significant other observable inputs	Significant unobservable inputs
	liabilities at carrying		Quoted prices in active markets for	other observable	unobservable
	liabilities at carrying		Quoted prices in active markets for identical assets	other observable inputs	unobservable inputs
Assets	liabilities at carrying		Quoted prices in active markets for identical assets  (Level 1)	other observable inputs	unobservable inputs
Assets Short-term investments:	liabilities at carrying		Quoted prices in active markets for identical assets  (Level 1)	other observable inputs	unobservable inputs
	liabilities at carrying		Quoted prices in active markets for identical assets  (Level 1)	other observable inputs	unobservable inputs
Short-term investments:  Municipal bonds	liabilities at carrying value	fair value	Quoted prices in active markets for identical assets  (Level 1)	other observable inputs (Level 2)	unobservable inputs (Level 3)
Short-term investments: Municipal bonds	liabilities at carrying value  \$198,176	\$198,176	Quoted prices in active markets for identical assets  (Level 1)	other observable inputs (Level 2)	unobservable inputs (Level 3)
Short-term investments:  Municipal bonds	\$198,176	\$198,176 66,865	Quoted prices in active markets for identical assets  (Level 1)	other observable inputs (Level 2)  \$198,176 66,865	unobservable inputs (Level 3)
Short-term investments:  Municipal bonds	\$198,176 66,865 14,133	\$198,176 66,865 14,133	Quoted prices in active markets for identical assets  (Level 1)	\$198,176 66,865 14,133	unobservable inputs (Level 3)
Short-term investments:  Municipal bonds  Variable demand notes  Corporate bonds  Prepaid expenses and other assets— mark-to-market on foreign exchange instruments (Note 4)	\$198,176	\$198,176 66,865	Quoted prices in active markets for identical assets  (Level 1)	other observable inputs (Level 2)  \$198,176 66,865	unobservable inputs (Level 3)
Short-term investments:  Municipal bonds  Variable demand notes  Corporate bonds  Prepaid expenses and other assets— mark-to-market on foreign exchange instruments (Note 4)  Long-term investments—auction rate	\$198,176 66,865 14,133	\$198,176 66,865 14,133	Quoted prices in active markets for identical assets  (Level 1)	\$198,176 66,865 14,133	\$
Short-term investments:  Municipal bonds  Variable demand notes  Corporate bonds  Prepaid expenses and other assets— mark-to-market on foreign exchange instruments (Note 4)  Long-term investments—auction rate securities	\$198,176 66,865 14,133	\$198,176 66,865 14,133	Quoted prices in active markets for identical assets  (Level 1)	\$198,176 66,865 14,133	unobservable inputs (Level 3)
Short-term investments:  Municipal bonds  Variable demand notes  Corporate bonds  Prepaid expenses and other assets— mark-to-market on foreign exchange instruments (Note 4)  Long-term investments—auction rate	\$198,176 66,865 14,133	\$198,176 66,865 14,133	Quoted prices in active markets for identical assets  (Level 1)	\$198,176 66,865 14,133	\$

## Valuation Techniques

Financial assets are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. Our Level 2 financial assets include short-term investments and certain of our deferred compensation plan securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 3. Fair Value Measurement (Continued)

Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. Level 3 financial assets include the auction rate securities for which there is limited market activity such that the determination of fair value requires significant judgment or estimation. The auction rate securities were valued using a discounted cash flow model over a five-year period based on estimated interest rates, the present value of future principal payments, and interest payments discounted at rates considered to reflect the current market conditions and the credit quality of auction rate securities.

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. We recognize transfers into and out of levels within the fair value hierarchy in which the actual event or change in circumstances that caused the transfer occurs. There were no significant transfers between Level 1 and Level 2 during fiscal years 2010 or 2009. When a determination is made to classify an asset or liability within Level 3, the determination is based upon the significance of the unobservable inputs to the overall fair value measurement. The following table provides a reconciliation of the beginning and ending balances for the assets measured at fair value using significant unobservable inputs (Level 3):

Auction

	Rate Securities
Balance as of January 3, 2009	\$29,959
Settlements at par	(9,400)
Transfer to Level 2	(100)
Unrealized holding gain on auction rate securities, included in other comprehensive	
income (loss)	4,175
Balance as of January 2, 2010	\$24,634
Settlements at par	(3,000)
income (loss)	(255)
Balance as of January 1, 2011	\$21,379

We continue to monitor the market for auction rate securities and consider its impact (if any) on the fair value of our investments. If the current market conditions deteriorate further, or the anticipated recovery in fair values does not occur, we may be required to record additional unrealized losses in other comprehensive income or other-than-temporary impairment charges to the consolidated statements of operations in future periods.

Assets and Liabilities That Are Measured at Fair Value on a Nonrecurring Basis

Non-financial assets such as goodwill, intangible assets, and property, plant, and equipment are evaluated for impairment and adjusted to fair value only when an impairment is recognized. There was no impairment recorded for fiscal year 2010 or 2009. Non-financial assets such as purchased intangibles acquired during the twelve months ended January 1, 2011, are measured at fair value using Level 3 inputs, which include discounted cash flow methodologies, or similar techniques, when there is limited market activity and the determination of fair value requires significant judgment or estimation.

## Financial Instruments Disclosed at Fair Value

Senior subordinated convertible notes measured at fair value using Level 2 inputs, including quoted prices of identical liabilities, are measured at a fair value of \$204.1 million and \$205.4 million, as of January 1, 2011 and January 2, 2010, respectively. The senior subordinated convertible notes were reclassified to current liabilities during the second quarter of 2010 due to a redemption feature which may require us to repurchase all or a portion of the senior subordinated convertible notes as early as May 16, 2011. For a detailed discussion, see Note 10 "Senior Subordinated Convertible Notes."

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. Foreign Exchange Instruments

We utilize foreign currency forward exchange contracts and options to mitigate against future movements in foreign exchange rates that affect certain existing and forecasted foreign currency denominated sales and purchase transactions. We do not use derivative financial instruments for speculative or trading purposes. We routinely hedge our exposure to certain foreign currencies with various financial institutions in an effort to minimize the impact of certain currency exchange rate fluctuations. If a financial counterparty to any of our derivative arrangements experiences financial difficulties or is otherwise unable to honor the terms of the foreign currency forward contract, we may experience material financial losses.

On January 4, 2009, we adopted the accounting pronouncement that requires the disclosure about our objective of using derivative instruments for our forward foreign currency contracts that qualify as derivatives which is incorporated in ASC 815, *Derivatives and Hedging*, and do not qualify for hedge accounting. The notional amount of foreign currency contracts with a maximum maturity of four months which do not qualify for hedge accounting, were as follows:

	<b>Notional Amounts</b>	
	Fiscal Years	
	2010	2009
	(in thou	sands)
Contracts to sell foreign currency	\$23,552	\$2,707

Effective January 3, 2010, we changed our functional currency for our U.K. subsidiary from U.K. pounds to euros. This change did not have a material impact on our consolidated financial statements. As of January 1, 2011, we had forward contracts to sell euros to U.S. dollars with a notional value of  $\xi$ 1.4 million, to sell U.S. dollars to euros with a notional value of  $\xi$ 1.9 million. As of January 2, 2010, we had forward contracts to sell euros to U.S. dollars with a notional value of  $\xi$ 1.6 million and to sell U.K. pounds to U.S. dollars with a notional value of  $\xi$ 1.0 million. As of January 1, 2011, our forward contracts to sell had an average exchange rate of one U.S. dollar to 1.3372 euros and one euro to 1.1690 U.K. pounds.

The following represents our realized fair value of the forward currency contracts and offsets to the foreign currency exchange gains and losses which were included in "Interest income and other" in the consolidated statements of operations:

	Fiscal Years		
	2010	2009	2008
	(iı	n thousan	ds)
Foreign currency exchange gain (loss) on foreign currency contracts	\$ 744	\$ 334	\$(1,984)
Foreign currency exchange (loss) gain on foreign currency transaction			
adjustments	(761)	(961)	2,057

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 5. Inventories

Inventories consisted of the following:

	January 1, 2011	<b>January 2, 2010</b>
	(in thousands)	
Finished goods	\$ 8,439	\$12,920
Work-in-process	14,971	7,350
Raw materials		24,365
Total	\$59,790	\$44,635

## 6. Property, Plant and Equipment, Net

Property, plant and equipment, net consisted of the following:

	January 1, 2011	January 2, 2010
	(in thousands)	
Land, building and improvements	\$ 18,498	\$ 18,134
Equipment and capitalized software	40,887	38,281
Furniture and leasehold improvements	22,070	20,655
Total	81,455	77,070
Less accumulated depreciation	(43,378)	(39,955)
Total	\$ 38,077	\$ 37,115

Depreciation expense in fiscal years 2010, 2009 and 2008 was \$6.7 million, \$7.5 million and \$6.8 million, respectively.

## 7. Purchased Intangible Assets and Goodwill

The carrying amount of goodwill was \$95.0 million as of January 1, 2011 and January 2, 2010.

In January 2010, we purchased patents at a fair value of \$1.4 million, which we capitalized under ASC 350, *Intangibles—Goodwill and Other*. These patents have an estimated useful life of approximately ten years.

In October 2009, we purchased patents at a fair value of \$1.9 million, which we capitalized under ASC 350. These patents have an estimated useful life of nine years.

In February 2001, we merged with Thermo Cardiosystems, Inc. ("TCA"). Prior to the merger with TCA, TCA was a subsidiary of Thermo Electron Corporation. The components of identifiable intangible assets related to the merger include: patents and trademarks, core technology (Thoralon, our proprietary bio material), and developed technology (patented technology, other than core technology, acquired in the merger).

The purchased intangibles on the consolidated balance sheets are summarized as follows:

	Fiscal Year 2010		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
		(in thousands)	
Patents and trademarks	\$ 40,832	\$ (30,672)	\$10,160
Core technology	37,180	(17,502)	19,678
Developed technology	121,805	(63,125)	58,680
Total purchased intangible assets	\$199,817	\$(111,299)	\$88,518

# THORATEC CORPORATION NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 7. Purchased Intangible Assets and Goodwill (Continued)

	Fiscal Year 2009		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
		(in thousands)	
Patents and trademarks	\$ 39,418	\$ (29,625)	\$ 9,793
Core technology	37,180	(15,558)	21,622
Developed technology	121,805	(56,344)	65,461
Total purchased intangible assets	\$198,403	\$(101,527)	\$96,876

Amortization expense related to identifiable intangible assets for fiscal 2010, 2009 and 2008 was \$9.8 million, \$9.8 million and \$12.3 million, respectively.

Patents and trademarks have remaining useful lives ranging from eight to eleven years, and core and developed technology assets have remaining useful lives ranging from one to eleven years.

Estimated amortization expense for the next five fiscal years and all years thereafter are as follows:

	(in thousands)
Fiscal year:	
2011	\$ 8,892
2012	8,787
2013	8,787
2014	
2015	8,786
Thereafter	44,480
Total	\$88,518

## 8. Other Assets

Levitronix Convertible Debenture:

On August 23, 2006, we purchased a \$5.0 million convertible debenture from Levitronix, a company with which we have a distribution arrangement to sell Levitronix products. The convertible debenture is a long-term note receivable with an annual interest rate of 5.7%, to be accrued monthly and at the option of Levitronix, paid in cash or in-kind semi-annually on February 23 and August 23 until its maturity on August 23, 2013. We may convert the debenture at any time at our option into membership interests of Levitronix at a conversion price of \$4.2857, which may be adjusted as a result of certain corporate events. This conversion feature is not an embedded derivative because the membership interests of the issuer are not readily convertible to cash.

During the fourth quarter of 2009, we received a principal payment of \$3.0 million. As of January 2, 2010, the convertible debenture of \$2.0 million plus accrued interest of \$0.8 million and was included in "Other long-term assets" on our consolidated balance sheets. If we had converted the debenture as of January 2, 2010, our ownership in Levitronix would have been less than 5%. We received the remaining principal plus unpaid accrued interest of \$2.9 million during the third quarter of 2010. As of January 1, 2011, the balance was zero.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 8. Other Assets (Continued)

## HeartWare Loan Agreement:

On February 12, 2009, we entered into a definitive merger agreement with HeartWare International Inc. ("HeartWare"), pursuant to which we intended to acquire HeartWare. The Company and HeartWare mutually agreed effective July 31, 2009 to terminate the definitive merger agreement pursuant to which we would have acquired HeartWare. As announced on July 29, 2009, the Federal Trade Commission ("FTC") informed HeartWare and us that it would file a complaint in U.S. Federal District Court to challenge our proposed acquisition of HeartWare. HeartWare and our decision to terminate the definitive merger agreement was in response to the FTC's determination to challenge the proposed acquisition.

Pursuant to the definitive merger agreement with HeartWare, we deposited \$20.0 million (the "Loan Amount") into an escrow account on February 13, 2009 and agreed to loan such funds to HeartWare. Despite the mutual termination of the definitive merger agreement, the Loan Amount continued to remain available for borrowing by HeartWare under certain circumstances. On August 5, 2009, HeartWare borrowed \$4.0 million from the escrow account leaving a balance of \$16.0 million. In November, HeartWare repaid the \$4.0 million and in December 2009, HeartWare borrowed and repaid \$16.0 million, extinguishing the escrow facility and eliminating any further obligations with respect to the Loan Amount. Also in the fourth quarter, the conversion option gain of \$5.2 million, recorded in the third quarter of 2009, was reversed and there was no option value as of the fiscal year ended January 2, 2010.

#### 9. Commitments and Contingencies

## Legal Proceedings

From time to time we are involved in litigation arising out of claims in the normal course of business. Based on the information presently available, management believes that there are no claims or actions pending or threatened against us, the ultimate resolution of which will have a material adverse effect on our financial position, liquidity or results of operations, although the results of litigation are inherently uncertain and adverse outcomes are possible.

#### Leases

We lease manufacturing, office and research facilities and equipment under various operating lease agreements. Future minimum lease payments for the next five years and thereafter are as follows:

	(in thousands)
Fiscal year ended:	
2011	\$ 2,452
2012	2,349
2013	2,324
2014	1,796
2015	1,548
Thereafter	10,609
Total	\$21,078

Rent expense for all operating leases for fiscal 2010, 2009 and 2008 was \$1.9 million, \$1.6 million and \$1.6 million, respectively.

## Commitments

We had purchase order commitments, including both supply and inventory related agreements, totaling approximately \$112.3 million and \$70.5 million as of the end of fiscal 2010 and 2009, respectively.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

#### 10. Senior Subordinated Convertible Notes

In 2004, we completed the sale of \$143.8 million initial principal amount of senior subordinated convertible notes due in 2034. The convertible notes were sold to "qualified institutional buyers" pursuant to the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Rule 144A thereunder.

The senior subordinated convertible notes were issued at an issue price of \$580.98 per note, which is 58.098% of the principal amount at maturity of the notes. The senior subordinated convertible notes bear interest at a rate of 1.3798% per year on the principal amount at maturity, payable semi-annually in arrears in cash on May 16 and November 16 of each year, from November 16, 2004 until May 16, 2011. Beginning on May 16, 2011, the original issue discount will accrue daily at a rate of 2.375% per year on a semi-annual bond equivalent basis and, on the maturity date, a holder will receive \$1,000 per note. As a result, the aggregate principal amount of the notes at maturity will be \$243.4 million.

Holders of the senior subordinated convertible notes may convert their convertible notes into shares of our common stock at a conversion rate of 29.4652 shares per \$1,000 principal amount of senior subordinated convertible notes, which represents a conversion price of \$19.72 per share, subject to adjustments upon the occurrence of certain events as set forth in the indenture. Holders have been and are able to convert their convertible notes at any point after the close of business on October 30, 2004 if, as of the last day of the preceding calendar quarter, the closing price of our common stock for at least 20 trading days in a period of 30 consecutive trading days ending on the last trading day of such preceding calendar quarter is more than 120% of the accreted conversion price per share of our common stock. Commencing October 1, 2008, this market price conversion feature was satisfied, such that holders of the senior subordinated convertible notes may convert their notes through the final maturity date of the notes into shares of the Company's common stock at a conversion rate of 29.4652 shares per \$1,000 principal amount of senior subordinated convertible notes, subject to adjustments as provided in the indenture. If holders elect conversion, we may, at our option, deliver shares of common stock, pay a holder in cash, or deliver a combination of shares and cash, as determined pursuant to the terms of the notes. As of January 1, 2011, 4,045 bonds of the 247,427 bonds originally issued have been submitted to be converted and we have elected to pay cash in lieu of shares for these bonds.

Holders may require us to repurchase all or a portion of their senior subordinated convertible notes on each of May 16, 2011, 2014, 2019, 2024 and 2029 at a repurchase price equal to 100% of the issue price, plus accrued original issue discount, if any. Based on this redemption feature, we reclassified the net carrying amount of the senior subordinated convertible notes to current liabilities during 2010.

The senior subordinated convertible notes are subordinated to all of our senior indebtedness and structurally subordinated to all indebtedness of our subsidiary. Therefore, in the event of a bankruptcy, liquidation or dissolution of the Company or our subsidiary and acceleration of or payment default on our senior indebtedness, holders of the convertible notes will not receive any payment until holders of any senior indebtedness we may have outstanding have been paid in full.

In accordance with ASC 470-20, *Debt*, which applies to certain convertible debt instruments that may be settled in cash or other assets, or partially in cash, upon conversion, we recorded the long-term debt and equity components on the senior subordinated convertible notes separately. This accounting pronouncement increased interest expense associated with our senior subordinated convertible notes by adding a non-cash component to amortize a debt discount calculated based on the difference between the cash coupon rate (2.375% per year) of the senior subordinated convertible notes and the effective interest rate on debt borrowing (9% per year). The discount, which represents the non-cash interest expense, classified as interest expense on the statements of operations, is being amortized to interest expense over a seven-year period ending May 16, 2011 (the expected life of the liability component) using the effective interest method. Additionally, we allocated transaction costs on the same percentage as the liability and equity component, such that a portion of the deferred debt issuance costs is allocated to the liability component to be amortized using the effective interest method until May 16, 2011, and the equity component to be included in additional paid-in capital.

### 10. Senior Subordinated Convertible Notes (Continued)

Interest expense primarily includes the payment of interest and amortization of discount related to senior subordinated convertible notes as follows:

	]	S	
	2010	2009	2008
	(iı	n thousand	ls)
Interest expense—cash component	\$3,379	\$3,414	\$3,414
Interest expense—non-cash component	8,842	8,224	7,566

The debt and equity component (recorded in additional paid-in-capital, net of income tax benefit) consisted of the following:

	January 1, 2011	January 2, 2010
	(in tho	usands)
Senior subordinated convertible notes		
Principal amount	\$141,400	\$143,750
Unamortized discount	(3,235)	(11,821)
Net carrying amount	\$138,165	\$131,929
Equity component, net of income tax benefit	\$ 25,340	\$ 28,462

We may redeem either in whole or in part any of the senior subordinated convertible notes at any time beginning May 16, 2011, by giving the holders at least 30 days notice, at a redemption price equal to the sum of the issue price and the accrued original issue discount. If the holders converted the senior subordinated convertible notes into shares of our stock as of January 1, 2011, the if-converted value would be \$203.1 million, based on our stock price of \$28.32 per share on December 30, 2010, which amount exceeds the original value of \$141.4 million by \$61.7 million. This if-converted value is \$40.3 million less than the \$243.4 million face amount at maturity in 2034.

The aggregate fair value of the senior subordinated convertible notes at January 1, 2011 was \$204.1 million.

### 11. Share-Based Compensation

Share-based compensation expense is measured based on the grant-date fair value of the share-based awards. We recognize share-based compensation expense for the portion of the awards that will ultimately be expected to vest, on a straight-line basis over the requisite service period for those awards with graded vesting and service conditions. We develop an estimate of the number of share-based awards, which will ultimately vest primarily based on historical experience. The estimated forfeiture rate is reassessed periodically throughout the requisite service period. Such estimates are revised if they differ materially from actual forfeitures. As required, the forfeiture estimates will be adjusted to reflect actual forfeitures when an award vests.

Share-based compensation expense and related stock option award activity is presented on a consolidated basis, unless otherwise presented as continuing or discontinued operations.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 11. Share-Based Compensation (Continued)

Share-based compensation expense included in the consolidated statements of operations consists of the following:

	Fiscal Years		
	2010	2009	2008
	(iı	n thousands	)
Cost of product sales	\$ 1,262	\$ 1,045	\$ 971
Selling, general and administrative	8,064	6,670	5,048
Research and development	3,328	2,575	1,945
Total share-based compensation expense before taxes	12,654	10,290	7,964
Tax benefit for share-based compensation expense	4,649	2,396	3,160
Total share-based compensation expense—continuing operations			
(net of taxes)	\$ 8,005	\$ 7,894	\$4,804
Total share-based compensation expense—discontinued operations			
(net of taxes)	\$ 2,203	\$ 2,153	\$1,724

Share-based compensation expense of \$0.3 million and \$0.3 million was capitalized to inventory as of January 1, 2011 and January 2, 2010, respectively.

We receive a tax deduction for certain stock option exercises during the period the options are exercised, generally for the excess of the fair market value of the options at the date of exercise over the exercise prices of the options. Our consolidated statements of cash flows presentation reports the excess tax benefits (i.e., windfalls only for tax deductions in excess of the share-based compensation expense recognized) as financing cash flows of \$9.5 million, \$3.2 million and \$4.5 million for fiscal years 2010, 2009 and 2008, respectively.

Cash proceeds from the exercise of stock options were \$22.8 million, \$9.2 million and \$22.9 million for fiscal years 2010, 2009 and 2008, respectively. Cash proceeds from our employee stock purchase plan were \$3.4 million, \$2.9 million and \$2.1 million for fiscal years 2010, 2009 and 2008, respectively. The actual income tax benefit realized from stock option exercises was \$11.2 million, \$3.9 million and \$6.9 million for fiscal years 2010, 2009 and 2008, respectively.

### **Equity Plans**

In 1997, the Board of Directors adopted the 1997 Stock Option Plan ("1997 SOP"). The 1997 SOP was amended by approval of our shareholders in February 2001, amended by the Board of Directors in December 2001, amended again by approval of our shareholders in May 2003, and amended again by the Board of Directors in March 2006. The 1997 SOP allowed us to grant up to a total of 13.7 million shares of common stock in the form of stock options, restricted stock awards and stock bonuses. This plan expired in May 2006 and no options were granted under the 1997 SOP in 2010.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 11. Share-Based Compensation (Continued)

In April 2006, the Board of Directors approved the 2006 Incentive Stock Plan ("2006 Plan") and in May 2006 the 2006 Plan was approved by our shareholders. In May 2006 and April 2008 the 2006 Plan was amended by the Board of Directors and in May 2008 the 2006 Plan as amended was approved by our shareholders. In May 2008 and March 2010, the 2006 Plan was further amended by the Board of Directors and approved by our shareholders in May 2008 and May 2010, respectively. The 2006 Plan allows us to grant to employees and directors of, and consultants to, the Company up to a total of 8.6 million shares of stock awards. Each share issued from and after May 20, 2008 through May 18, 2010 as restricted stock bonuses, restricted stock units, phantom stock units, performance share bonuses, or performance share units reduces the number of shares available for issuance under the 2006 Plan by one and seventy-four hundredths (1.74) shares, and each share issued as stock options, restricted stock purchases or stock appreciation rights reduces the shares available for issuance under the 2006 Plan on a share-for-share basis. Each share issued from and after May 19, 2010 as restricted stock bonuses, restricted stock units, phantom stock units, performance share bonuses or performance share units reduces the number of shares available for issuance under the 2006 Plan by one and seven-tenths (1.7) shares, and each share issued as stock options, restricted stock purchases or stock appreciation rights reduces the shares available for issuance under the 2006 Plan on a share-for-share basis. During the fiscal year ended January 1, 2011, approximately 482,000 options were granted under the 2006 Plan at an exercise price equal to the fair market value on the date of grant, and approximately 718,000 shares of restricted stock units were granted under the 2006 Plan. As of January 1, 2011, 4.3 million shares remained available for grant under the 2006 Plan.

### Stock Options

Upon approval in May 2006, the 2006 Plan replaced our previous common stock option plans and equity incentive plans. As of January 1, 2011, we had 2.7 million options outstanding under the 2006 Plan and the replaced plans. Options under the 2006 Plan may be granted by the Board of Directors at the fair market value on the date of grant and generally become fully exercisable within four years after the grant date and expire between five and ten years from the date of grant. The vesting of outstanding options held by certain officers was accelerated as a result of the sale of ITC and resulted in a charge to discontinued operations.

The fair value of each option is estimated at the date of grant using the Black-Scholes option pricing model with the following assumptions:

		Fiscal Years	
	2010	2009	2008
Risk-free interest rate	2.95%	2.34%	3.25%
Expected volatility	40%	53%	40%
Expected option life	4.87 - 5.89 years	4.89 - 6.03 years	5.08 - 6.07 years
Dividends	None	None	None

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 11. Share-Based Compensation (Continued)

The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The expected term of options represents the period of time that options are expected to be outstanding. We use separate assumptions for groups of employees (for example, officers) that have similar historical exercise behavior. The range above reflects the expected option impact of these separate groups. Prior to fiscal 2010, our estimated volatility was based solely on the historical volatility of our common stock and beginning in fiscal 2010 we base our expected volatility on a combination of historical volatility trends and market-based implied volatility because we have determined that this combination of historical volatility trends and market-based implied trends are reflective of market conditions. The decision to incorporate implied volatility was based on our assessment that implied volatility of publicly traded options in Thoratec common stock is reflective of market conditions and is generally reflective of both historical volatility and expectations of how future volatility will differ from historical volatility. In determining the extent of use of implied volatility, we considered: (i) the volume of market activity of traded options; (ii) the ability to reasonably match the input variables of traded options to those of stock options granted by us, including the date of grant; (iii) the similarity of the exercise prices; and (iv) the length of term of traded options.

As of January 1, 2011, there was \$3.8 million of unrecognized compensation expense, net of estimated forfeitures, related to stock options which expense we expect to recognize over a weighted average period of 1.24 years. The aggregate intrinsic value of in-the-money options outstanding was \$23.8 million, based on the closing price of our common stock on December 30, 2010, the last trading day in the fiscal year ended January 1, 2011, of \$28.32. As of January 1, 2011, the intrinsic value of options currently exercisable was \$20.2 million and the intrinsic value of options vested and expected to vest was \$23.7 million.

The total intrinsic value of options exercised for the fiscal years 2010, 2009, 2008 was \$33.1 million, \$9.2 million and \$20.7 million, respectively.

### 11. Share-Based Compensation (Continued)

Stock option activity is summarized as follows:

	Number of Options (in thousands)	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contract Life (years)
Outstanding as of December 29, 2007 (3,940 exercisable at \$13.72 weighted average price per share)	5,748	\$15.46	6.19
Granted	383 (104) (1,768)	14.98 18.76 12.96	0.12
Outstanding as of January 3, 2009 (2,775 exercisable at \$15.23 weighted average price per share)	4,259	\$16.37	5.98
Granted	345 (95) (652)	24.03 22.44 14.08	
Outstanding as of January 2, 2010 (2,687 exercisable at \$16.17 weighted average price per share)	3,857	\$17.29	5.60
Granted	482 (215) (1,430)	30.47 24.10 15.97	
Outstanding as of January 1, 2011 (1,883 exercisable at \$17.60 weighted average price per share)	2,694	\$19.81	5.05
Outstanding options vested at fiscal year end 2010 and expected to vest	2,608	\$19.56	4.93

The weighted average remaining contract life for options exercisable was 1.24 years.

The weighted average grant-date fair value of options granted during the fiscal years 2010, 2009 and 2008 was \$12.80 per share, \$12.07 per share and \$6.44 per share, respectively.

### 11. Share-Based Compensation (Continued)

Options outstanding as of January 1, 2011 are summarized as follows:

	Options Outstanding		Options 1	Exercisable	
	(in thousands, except contractual life and exercise price)				
Exercise Price Range	Number	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
\$5.60 - \$10.56	111	1.91	\$ 9.48	111	\$ 9.48
10.60 - 12.45	321	2.65	12.43	321	12.43
12.61 - 14.97	385	4.95	14.55	240	14.30
15.01 - 17.84	245	2.31	16.20	243	16.20
17.91 - 17.91	280	5.23	17.91	200	17.91
18.56 - 20.34	289	3.43	20.27	287	20.28
20.60 - 22.69	34	3.63	21.04	31	20.89
23.62 - 23.62	375	5.04	23.62	375	23.62
23.64 - 29.00	264	7.67	24.15	72	24.11
29.81 - 44.79	390	9.17	30.66	3	29.81
	2,694	5.05	19.81	1,883	17.60

#### Restricted Stock Awards and Units

The 2006 Plan allows for the issuance of restricted stock awards and restricted stock units, which awards or units may not be sold or otherwise transferred until certain restrictions have lapsed. The unearned share-based compensation related to these awards is being amortized to compensation expense over the period of the restrictions, generally four years. The expense for these awards was determined based on the market price of our shares on the date of grant applied to the total number of shares that were granted.

### Restricted Stock Awards

Share-based compensation expense from continuing operations related to restricted stock awards was \$2.9 million for the fiscal year ended January 1, 2011. As of January 1, 2011, we had \$1.5 million of unrecognized compensation expense, net of estimated forfeitures, related to restricted stock awards, which amount we expect to recognize over 0.85 years. There were no restricted stock awards granted during fiscal year 2010.

### 11. Share-Based Compensation (Continued)

Restricted stock award activity is summarized as follows:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value
Outstanding unvested restricted stock as of December 29,		
2007	768	18.29
Granted	496	15.41
Vested	(231)	18.40
Forfeited or expired	(50)	17.90
Outstanding unvested restricted stock as of January 3, 2009	983	16.83
Granted	_	_
Vested	(326)	17.12
Forfeited or expired	_(48)	17.36
Outstanding unvested restricted stock as of January 2, 2010	609	16.63
Granted		_
Vested	(289)	17.20
Forfeited or expired	(86)	16.14
Outstanding unvested restricted stock as of January 1, 2011	234	16.11

### Restricted Stock Units

Share-based compensation expense from continuing operations related to restricted stock units was \$5.2 million for the fiscal year ended January 1, 2011. As of January 1, 2011, we had \$13.3 million of unrecognized compensation expense, net of estimated forfeitures, related to restricted stock units, which amount we expect to recognize over 2.85 years. The aggregate intrinsic value of the units outstanding, based on our stock price on January 1, 2011 was \$19.5 million. The vesting of outstanding restricted stock units held by certain officers and non officers was accelerated as a result of the sale of ITC and resulted in a charge to discontinued operations.

Restricted stock units activity is summarized as follows:

	Number of Units (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contract (in Years)
Outstanding units as of December 29, 2007	21	18.58	2.82
Granted	15	15.00	
Released	(7)	18.68	
Forfeited or expired	(1)	18.05	
Outstanding units as of January 3, 2009	28	16.66	2.46
Granted	498	24.63	
Released	(49)	24.70	
Forfeited or expired	(14)	23.93	
Outstanding units as of January 2, 2010	463	24.17	3.12
Granted	718	31.47	
Released	(250)	28.89	
Forfeited or expired	(243)	27.61	
Outstanding units as of January 1, 2011	688	28.86	1.53

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 11. Share-Based Compensation (Continued)

### Employee Stock Purchase Plan

In May 2002, our shareholders approved the Company's Employee Stock Purchase Plan ("ESPP") under which 500,000 shares of common stock were reserved for issuance. In addition, the ESPP provides for an annual, automatic increase of up to 250,000 shares in the total number of shares available for issuance thereunder on March 1 of each year, unless our Board of Directors specifies a smaller increase or no increase. Under this provision, an additional 250,000 shares were reserved for issuance under the ESPP on each of March 1, 2006, March 1, 2008 and March 1, 2009; our Board of Directors specified no increase as of each other year. Eligible employees may purchase a limited number of shares, over a six month period, of our common stock at 85% of the lower of the market value on the offering date or the market value on the purchase date. During the fiscal year ended January 1, 2011, approximately 140,000 shares of common stock were issued under the ESPP. As of January 1, 2011, approximately 160,000 shares remained available for issuance under this plan.

The estimated subscription date fair value of the offering under the ESPP for fiscal years 2010, 2009 and 2008 was approximately \$0.6 million, \$0.6 million and \$0.5 million respectively, using the Black-Scholes option pricing model and the following assumptions:

	Fiscal Years			
	2010	2009	2008	
Risk-free interest rate	0.16%	0.17%	1.07%	
Expected volatility	46%	40%	60%	
Expected option life		0.50 years	0.50 years	
Dividends	None	None	None	

At January 1, 2011, there was approximately \$0.4 million of unrecognized compensation expense related to ESPP subscriptions that began on November 1, 2010, which amount we expect to recognize during the first four months of 2011.

### 12. Common and Preferred Stock

We have authorized 100 million shares of no par common stock, and 2.5 million shares of no par preferred stock, of which 540,541 shares have been designated Series A, 500,000 shares have been designated Series B and 100,000 shares have been designated Series RP.

Our share repurchase programs, which authorized us to repurchase up to a total of \$130 million of our common stock, 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. No shares of our common stock were repurchased under our publicly announced repurchase programs during the fiscal years ended January 1, 2011 and January 2, 2010. All repurchased shares have been retired and are not included in net income per common share. As of January 1, 2011, we had \$10.1 million remaining on our share repurchase programs.

The Series A preferred stock is entitled to cumulative annual dividends of \$1.30 per share and has a liquidation preference of \$9.25 per share plus cumulative unpaid dividends. We may redeem the Series A preferred stock at any time for its liquidation preference. Each share of Series A preferred stock is convertible into one-third of a share of common stock, after adjusting for earned but unpaid dividends. As of January 1, 2011, no shares of Series A preferred stock were outstanding.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 12. Common and Preferred Stock (Continued)

The Series B preferred stock is senior to the Series A in all preferences. The Series B preferred stock is entitled to cumulative annual dividends of \$0.96 per share and has a liquidation preference of \$8.00 per share plus cumulative unpaid dividends. The Series B preferred stock is redeemable by us five years after its issuance for its liquidation preference. Each share of Series B preferred stock is convertible at any time into three and one-third shares of common stock and has certain anti-dilution provisions. Series B preferred shares vote on an as-converted basis. As of January 1, 2011, no shares of Series B preferred stock were outstanding.

On May 2, 2002, we adopted a shareholder rights plan, which we call the Rights Plan. Under the Rights Plan, we distributed one purchase right for each share of common stock outstanding at the close of business on May 17, 2002. If a person or group acquires 15% or more of our common stock in a transaction not pre-approved by our Board of Directors, each right will entitle its holder, other than the acquirer, to buy our common stock at 50% of its market value for the right's then current exercise price (initially \$70.00). In addition, if an unapproved party acquires more than 15% of our common stock, and our Company or our business is later acquired by the unapproved party or in a transaction in which all shareholders are not treated alike, shareholders with unexercised rights, other than the unapproved party, will be entitled to purchase common stock of the acquirer with a value of twice the exercise price of the rights. Each right also becomes exercisable for one one-thousandth of a share of our Series RP preferred stock at the right's then current exercise price ten days after an unapproved third party makes, or announces an intention to make, a tender offer or exchange offer that, if completed, would result in the unapproved party acquiring 15% or more of our common stock. Our Board of Directors may redeem the rights for a nominal amount at any time before an event that causes the rights to become exercisable. The rights will expire on May 2, 2012.

In connection with the Rights Plan, we designated 100,000 no par shares of Series RP preferred stock. These shares, if issued, will be entitled to receive quarterly dividends and liquidation preferences. There are no shares of Series RP preferred stock issued and outstanding and we do not anticipate issuing any shares of Series RP preferred stock except as may be required under the Rights Plan.

### 13. Retirement Savings Plans

Substantially all of our full-time employees are eligible to participate in a 401(k) retirement savings plan (the "Retirement Plan"). Under the Retirement Plan, employees may elect to contribute up to 100% of their eligible compensation to the Retirement Plan with Thoratec making discretionary matching contributions, subject to certain IRS limitations. In each of fiscal 2010, 2009 and 2008, our matching contribution was 50%, up to the first 6% of eligible employee plan contribution. Employees vest in our matching contribution to the Retirement Plan at the rate of 25% per year, with full vesting after four years of service with us. In fiscal 2010, 2009 and 2008, we made contributions to the Retirement Plan of approximately \$1.4 million, \$1.2 million and \$1.0 million, respectively.

In 2004, we established a non-qualified, unfunded deferred compensation plan for certain management employees and our Board of Directors. Amounts deferred and contributed under the deferred compensation plan are credited or charged with the performance of investment options offered under the plan and elected by the participants. The liability for compensation deferred under this plan was \$3.3 million and \$2.8 million at January 1, 2011 and January 2, 2010, respectively, and is included in "Other long-term liability" on our consolidated balance sheets. We manage the risk of changes in the fair value of the liability for deferred compensation by electing to match our liability under the plan with investments that offset a substantial portion of the Company's exposure. The cash surrender value of our corporate owned life insurance policies and the fair value of the mutual fund investments was \$3.2 million as of January 1, 2011 and \$2.4 million as of January 2, 2010, and is included in "Other long-term assets" on our consolidated balance sheets.

### 14. Taxes on Income

Significant components of income taxes are as follows:

	Fiscal Years		
	2010	2009	2008
	(i	n thousands	(s)
Continuing operations:			
Current: Federal	\$ 35,122	\$18,636	\$ 9,980
State	7,501 2,516	3,480 415	2,837 2,122
Deferred:	45,139	22,531	14,939
Federal	(10,326) (1,347)	(5,615) (3,006)	(7,911) (2,082)
Foreign	76 (11,597)	(219) (8,840)	$\frac{(207)}{(10,200)}$
Total income tax expense—continuing operations	\$ 33,542	\$13,691	\$ 4,739
Discontinued operations: Current:			
Federal	\$ (4,431)	\$ 85	\$ 1,598
State	634	156	355
	(3,797)	241	1,953
Deferred: Federal	(950)	(1,395)	(932)
State	(449) 18	(368)	(199)
	(1,381)	(1,763)	(1,131)
Total income tax expense (benefit)—discontinued operations	\$ (5,178)	\$(1,522)	\$ 822
Income before taxes generated from geographic areas are as follows:			
		Fiscal Years	i
	2010	2009	2008
	(i	in thousand	s)
Continuing operations:  Domestic	\$ 89,386	¢40.020	¢15 220
Foreign	3,161	\$40,028 2,568	\$15,229 5,903
Total—continuing operations	\$ 92,547	\$42,596	\$21,132
Discontinued operations:			
Domestic	\$(11,017)	<u>\$(1,843)</u>	\$ 2,760

### 14. Taxes on Income (Continued)

The income tax expense in the accompanying statements of operations differs from the provision calculated by applying the U.S. federal statutory income tax rate of 35% to income before taxes due to the following:

	Fiscal Years					
	2010	)	2009		2008	3
		(in thou	sands, exce	pt percer	itages)	
Continuing operations:						
U.S. federal statutory income tax expense	\$32,391	35.0%	\$14,908	35.0%	\$ 7,396	35.0%
State income tax expense/(benefit), net of federal tax						
expense or benefit	2,638	2.9	853	2.0	(296)	(1.4)
Share-based compensation	(283)	(0.3)	172	0.4	11	0.1
Non-deductible expenses	199	0.2	286	0.7	473	2.2
Research and development credits	(1,077)	(1.2)	(736)	(1.7)	(573)	(2.7)
Foreign earnings permanently reinvested	(39)	(0.1)	(138)	(0.3)	(99)	(0.5)
Tax advantaged investment income	(1,472)	(1.6)	(1,599)	(3.8)	(2,575)	(12.2)
Return-to-provision true-up	1,169	1.3	592	1.4	(417)	(2.0)
CA rate change	_	_	(927)	(2.2)	_	_
Revaluation of combined state deferred	575	0.6	_	_	_	_
Purchased intangible rate change	_	_	(973)	(2.3)	_	_
Section 162(m) write-down	700	0.8	1,424	3.3	_	_
Domestic production activities	(2,530)	(2.7)	(1,291)	(3.0)	(304)	(1.4)
Valuation allowance	821	0.9		·—	-	-
Other	_	_	121	0.3	(36)	(0.2)
Tax reserves	450	0.4	999	2.3	1,159	5.5
Total income tax benefit (expense) from continuing						
operations	\$33,542	36.2%	\$13,691	32.1%	\$ 4,739	22.4%

Deferred income taxes reflect the net tax effects of: (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating loss and tax credit carryforwards.

### 14. Taxes on Income (Continued)

Significant components of deferred tax assets and liabilities for continuing operations are as follows:

	January 1, 2011	January 2, 2010	
	(in thousands)		
Deferred tax assets:			
Write-off of acquired technology	\$ 124	\$ 247	
Reserves and accruals	3,403	2,984	
Depreciation and amortization	4,610	2,246	
Inventory basis difference	5,752	4,669	
Share-based compensation	5,028	4,356	
Research and development and other credit carryforwards	4,174	2,753	
Capital loss carryovers	5,072	_	
Other, net	1,225	497	
Total deferred tax assets	29,388	17,752	
Valuation allowance	(5,072)	_	
	24,316	17,752	
Deferred tax liabilities:			
Purchased intangibles	(32,709)	(35,800)	
Interest expense	(1,267)	(4,430)	
Other, net	(35)	(46)	
Total deferred tax liabilities	(34,011)	(40,276)	
Net deferred tax liabilities	\$ (9,695)	\$(22,524)	
Reported As:			
Net current deferred tax assets	\$ 9,677	\$ 8,846	
Net long-term deferred tax assets (included in "Other	727	720	
long-term assets")	737	729	
Net long-term deferred tax liabilities	(20,109)	(32,099)	
Net deferred tax liabilities	\$ (9,695)	\$(22,524)	

At the end of 2010, we had approximately \$13.3 million of federal and state capital losses, of which \$11.3 million relates to the sale of ITC, which may generally be carried back three years for federal purposes and carried forward five years up to 2015 for both federal and California purposes.

At the end of 2010, we had research and development tax credit carryovers for state purposes of approximately \$7.6 million. These state credits generally may be carried forward indefinitely.

The valuation allowance for deferred tax assets as of January 1, 2011 and January 2, 2010 was approximately \$5.1 million and none, respectively. The valuation allowance of \$5.1 million, as of January 1, 2011 is related to capital loss carryforwards that, in the judgment of management, are not more likely than not to be realized, of which \$4.3 million relates to the sale of ITC and \$0.8 million relates to continuing operations. In assessing the recoverability of deferred tax assets, management considers whether it is more likely than not that some or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the periods in which those temporary differences are deductible. We do not currently anticipate that we will recognize capital gains which will enable us to utilize our capital loss carryforwards and, as such, we have recorded a full valuation allowance against this deferred tax asset. We believe realization of all of our remaining net deferred tax assets as of January 1, 2011 is more likely than not based on the future reversal of temporary tax differences and upon future taxable earnings exclusive of reversing temporary differences.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 14. Taxes on Income (Continued)

We have utilized the "short-cut" method for purposes of determining our hypothetical stock option pool of excess tax benefits. As of January 1, 2011 the stock option pool of excess tax benefits was \$24.3 million.

The federal, state and foreign provisions do not reflect certain tax savings resulting from tax benefits associated with our various stock option plans. The savings were credited to additional paid-in-capital for \$11.3 million, \$3.9 million and \$6.9 million in fiscal 2010, 2009 and 2008, respectively.

We provide U.S. income taxes on the earnings of foreign subsidiaries unless such earnings are considered permanently reinvested in their respective foreign jurisdictions. As of January 1, 2011 the cumulative earnings on which U.S. income taxes have not been provided were approximately \$12.8 million. A determination of the potential deferred tax liability which would result from these earnings is not practicable at this time. Foreign earnings were considered to be permanently reinvested in operations outside the U.S.

We evaluate tax positions for recognition using a more-likely-than-not recognition threshold, and those tax positions eligible for recognition are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon the effective settlement with a taxing authority that has full knowledge of all relevant information.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits from continuing operations is as follows:

	Fiscal Years		
	2010	2009	2008
	(in thousands)		s)
Balance at beginning of fiscal year	\$ 9,561	\$8,389	\$6,440
Gross increases based on tax positions related to the current year	1,518	732	725
Gross increases for tax positions, related to prior years	3,723	738	1,348
Gross decreases for tax positions, related to prior years	(271)	(145)	(29)
Settlements	_	(9)	(9)
Lapse of statute of limitations	(3,751)	(144)	(86)
Balance at end of fiscal year	\$10,780	\$9,561	\$8,389

Included in the unrecognized tax benefits balance at January 1, 2011, January 2, 2010 and January 3, 2009 was \$8.4 million, \$4.8 million and \$3.8 million, respectively, which, if recognized, would impact our effective tax rate.

Our policy for classifying interest and penalties associated with unrecognized income tax benefits is to include the following items in income tax expense from continuing operations:

	Fiscal Years		S
	2010	2009	2008
	(in	thousand	ls)
Interest	\$(365)	\$140	\$125
Penalties	(27)	(4)	1

We accrued the following interest and penalties in our balance sheets from continuing operations:

	January 1, 2011	January 2, 2010	January 3, 2009
		(in thousands)	
Interest	\$238	\$605	\$465
Penalties	11	37	41

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 14. Taxes on Income (Continued)

We file tax returns in the U.S. for federal purposes, the U.K., state tax returns in California and New Jersey and tax returns in other domestic and foreign jurisdictions. The years 2006 through 2009 remain open to examination for U.S. purposes, 2007 through 2009 for U.K. purposes, 2007 through 2009 for New Jersey purposes, and 2005 through 2009 for California purposes. In 2011, it is reasonably possible that we will settle existing audits or close certain years to examination under the relevant statute of limitations. This may further decrease our liability for unrecognized tax benefits by approximately \$3.8 million.

We are under audit by the State of California for the tax years from 2003 to 2007. Although the ultimate outcome and the timing of the conclusion of this examination is unknown, we believe that adequate amounts have been provided for any adjustments that may result from the current examination and that the final outcome will not have a material adverse effect on our consolidated statements of operations.

### 15. Geographic Information

Our functional entities operate in two segments: Cardiovascular and ITC. Due to the sale of ITC, segment disclosure is no longer presented. For a discussion of our ITC segment, which is classified as discontinued operations, refer to Note 16, "Discontinued Operations." Our Cardiovascular segment is classified as continuing operations.

Our geographic information for our product revenue sold by our continuing operations to the domestic and international markets is discussed below.

Revenue attributed to a country or region includes product sales to hospitals, physicians and distributors and is based on final destination where the products are sold. During fiscal years 2010, 2009 and 2008, no customer or international country represented individually greater than 10% of our total product sales. The geographic composition of our product sales from continuing operations was as follows:

	Fiscal Years		
	2010	2009	2008
		in thousands	
Product sales:			
Domestic	\$317,380	\$225,110	\$167,764
International	65,593	54,858	47,211
Total	\$382,973	\$279,968	\$214,975

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

### 16. Discontinued Operations

On April 25, 2010, our board of directors made a decision to sell our wholly-owned subsidiary, International Technidyne Corporation ("ITC") and on November 4, 2010, we sold ITC to ITC Nexus Holding Company, Inc. ("Nexus") for \$55 million in cash pursuant to a Stock Purchase Agreement ("Purchase Agreement"), dated as of November 4, 2010, by and between the Company and Nexus. We accounted for the transaction as a sale of discontinued operations, and, accordingly, we have reclassified the results of operations and any losses resulting from the disposition for all periods presented to reflect them as such.

The results of the ITC business are included in discontinued operations on our consolidated statement of operations for the years ended January 1, 2011, January 2, 2010 and January 3, 2009 as follows:

	I	iscal Years	
	2010	2009	2008
	(in	thousands	
Product sales	\$ 76,038	\$93,969	\$98,589
Cost of product sales(1)	51,427	58,548	56,997
Gross profit	24,611	35,421	41,592
Operating expenses(1):			
Selling, general and administrative	24,332	25,848	25,194
Research and development	10,478	11,484	12,946
Amortization of purchased intangible assets	269	829	837
Total operating expenses	35,079	38,161	38,977
Loss from operations	(10,468)	(2,740)	2,615
Other income:			
Other income	40	897	145
Loss before income taxes	(10,428)	(1,843)	2,760
Income tax benefit (expense)	5,178	1,522	(822)
Loss on sale of discontinued operations	(589)		
Net income (loss) from discontinued operations	\$ (5,839)	\$ (321)	\$ 1,938

<sup>(1)</sup> As a result of the sale of ITC, the vesting of outstanding options and restricted stock units held by certain officers and non officers was accelerated and the related share-based compensation charge of \$3.2 million was recorded to cost of product sales or operating expenses for fiscal year 2010.

### 16. Discontinued Operations (Continued)

The assets and liabilities of ITC are classified as held for sale as of January 2, 2010. Such amounts are comprised of the following:

	$\frac{\text{January 2, 2010(1)}}{(\text{in thousands})}$
ASSETS	,
Current assets:	
Receivables, net of allowances of \$522	\$18,030
Inventories	22,300
Deferred tax asset	3,415
Prepaid expenses and other assets	881
Total current assets	44,626
Property, plant and equipment, net	14,737
Goodwill	4,271
Purchased intangible assets, net	2,984
Other long-term assets	1,026
Total assets held for sale	\$67,644
LIABILITIES	
Current liabilities:	
Bank overdraft	\$ 1,326
Accounts payable	2,310
Accrued compensation	4,990
Other accrued liabilities	2,970
Total current liabilities	11,596
Other long-term liabilities	1,067
Total liabilities related to assets held for sale	<u>\$12,663</u>

<sup>(1)</sup> Management has elected to classify the assets and liabilities of ITC as held for sale as of January 2, 2010 and allows for comparative presentation on the consolidated balance sheets.

The Company is providing indemnification to Nexus for (a) breaches of certain representations and warranties, (b) covenant breaches, (c) specified U.S. Food and Drug Administration matters and (d) customary matters, subject to limitations set forth in the Purchase Agreement, including a \$5.5 million and \$7.0 million indemnification under (a) and (c) above, respectively.

There are no remaining assets or liabilities recorded as of January 1, 2011 related to ITC's operations.

### 17. Net Income (Loss) Per Share

We adopted authoritative accounting guidance that requires participating securities to be included in the calculation of the net income per share using the two-class method. Our restricted shares awards subject to repurchase and settled in shares of common stock upon vesting have non-forfeitable rights to receive dividends on an equal basis with common stock and therefore are considered participating securities. Under the two-class method, basic and diluted net income per common share is determined by calculating net income per share for common stock and participating securities based on participation rights in undistributed earnings. Dilutive net income per common share also considers the dilutive effect of the in-the-money stock options and restricted stock units, calculated using the treasury stock method. Under the treasury stock method, the amount of assumed proceeds from unexercised stock options and restricted stock units includes the amount of unrecognized compensation cost attributable to future services, assumed proceeds from the exercise of the options, and the incremental income tax benefit or liability that would be recorded in additional-paid-in capital when the award becomes deductible.

### 17. Net Income (Loss) Per Share (Continued)

Basic and diluted net income (loss) per common share attributable to common shareholders under the two-class method were calculated as follows:

	I	iscal Years	6
	2010	2009	2008
		thousand per share	
Basic net income per common share calculation	<b>****</b>	***	
Net income from continuing operations	\$59,005 (363)	\$28,905 (360)	\$16,393 (283)
Net income from continuing operations attributable to common shareholders	\$58,642	\$28,545	\$16,110
Net income (loss) from discontinued operations	\$(5,839) 37	\$ (321) 4	\$ 1,938 (34)
Net income (loss) from discontinued operations attributable to common shareholders	\$(5,802)	\$ (317)	\$ 1,904
Net income	\$53,166 (326)	\$28,584 (356)	\$18,331 (317)
Net income attributable to common shareholders	\$52,840	\$28,228	\$18,014
Weighted average number of common shares used to compute basic net income (loss) per			
common share	57,670	55,910	54,144
Basic net income (loss) per common share from Continuing operations	\$ 1.02	\$ 0.51	\$ 0.30
Discontinued operations	\$ (0.10)	\$ (0.01)	\$ 0.03
Total	\$ 0.92	\$ 0.50	\$ 0.33
Diluted net income per common share calculation			
Net income from continuing operations	\$59,005 (358)	\$28,905 (351)	\$16,393 (277)
Net income from continuing operations attributable to common shareholders	\$58,647	\$28,554	\$16,116
Net income (loss) from discontinued operations	\$(5,839) 38	\$ (321) 4	\$ 1,938 (34)
Net income (loss) from discontinued operations attributable to common shareholders	\$(5,801)	\$ (317)	\$ 1,904
Net income	\$53,166 (320)	\$28,584 (347)	\$18,331 (311)
Net income attributable to common shareholders	\$52,846	\$28,237	\$18,020
Weighted average number of common shares used to compute basic net income (loss) per			
common share attributable to common shares	57,670 1,401	55,910 1,412	54,144 1,099
Weighted average number of common shares used to compute diluted net income (loss) per common share	59,071	57,322	55,243
Diluted net income (loss) per common share from			
Continuing operations	\$ 0.99	\$ 0.50	\$ 0.30
Discontinued operations	\$ (0.10)	\$ (0.01)	\$ 0.03
Total	\$ 0.89	\$ 0.49	\$ 0.33

The weighted average unvested restricted stock awards outstanding were 356,966, 704,673, and 952,784 for the fiscal years 2010, 2009 and 2008, respectively.

### 17. Net Income (Loss) Per Share (Continued)

Potential common share equivalents have been excluded where the inclusion would be anti-dilutive are as follows:

F	iscal Yea	ars
2010	2009	2008
(in	thousar	ıds)

Options to purchase shares not included in the computation of diluted net income per common share because their inclusion would be antidilutive.

363 294 1,284

The computation of diluted net income (loss) per common share for fiscal years 2010, 2009 and 2008 excludes the effect of assuming the conversion of our senior subordinated convertible notes, which are convertible at \$19.72 per share into 7.2 million, 7.3 million and 7.3 million shares of common stock, respectively, because the effect would have been antidilutive.

### 18. Quarterly Results of Operations (Unaudited)

The following is a summary of our unaudited quarterly results of operations for the fiscal years 2010 and 2009:

	First	Second	Third	Fourth
	(in thousands, except per share data)			data)
Fiscal Year 2010:				
Product sales from continuing operations	\$99,272	\$95,098	\$90,996	\$97,607
Gross profit from continuing operations	67,701	64,519	62,375	64,669
Net income from continuing operations	13,364	17,537	15,480	12,624
Net loss from discontinued operations	(931)	(1,583)	(1,183)	(2,142)
Net income	12,433	15,954	14,297	10,482
Basic net income (loss) per common share from:				
Continuing operations	\$ 0.23	\$ 0.30	\$ 0.26	\$ 0.22
Discontinued operations(2)	\$ (0.01)	\$ (0.02)	\$ (0.02)	\$ (0.04)
Net income	\$ 0.22	\$ 0.28	\$ 0.24	\$ 0.18
Diluted net income (loss) per common share from:				
Continuing operations	\$ 0.23	\$ 0.29	\$ 0.26	\$ 0.21
Discontinued operations(2)	\$ (0.02)	\$ (0.02)	\$ (0.02)	\$ (0.04)
Net income	\$ 0.21	\$ 0.27	\$ 0.24	\$ 0.17
Fiscal Year 2009:				
Product sales from continuing operations	\$64,629	\$69,222	\$65,114	\$81,003
Gross profit from continuing operations	44,358	42,442	45,138	52,475
Net income from continuing operations	6,170	2,886	11,776(1)	8,073(1)
Net income (loss) from discontinued operations	(542)	(1,054)	1	1,274
Net income	5,628	1,832	11,777(1)	9,347(1)
Basic net income (loss) per common share from:				
Continuing operations	\$ 0.11	\$ 0.05	\$ 0.21	\$ 0.14
Discontinued operations(2)	\$ (0.01)	\$ (0.02)	\$ —	\$ 0.02
Net income	\$ 0.10	\$ 0.03	\$ 0.21	\$ 0.16
Diluted net income (loss) per common share from:				
Continuing operations	\$ 0.11	\$ 0.05	\$ 0.20	\$ 0.14
Discontinued operations(2)	\$ (0.01)	\$ (0.02)	\$ —	\$ 0.02
Net income	\$ 0.10	\$ 0.03	\$ 0.20	\$ 0.16

<sup>(1)</sup> Net income (loss) per share in the third quarter of 2009 includes the fair value of a conversion option gain of \$5.2 million (\$3.1 million, net of tax) related to the intended HeartWare agreement, which was reversed in the fourth quarter of 2009, upon the extinguishment of the HeartWare loan agreement. For further details related to the termination of the merger agreement with HeartWare and the extinguishment of the loan agreement, please refer to Note 8, "Other Assets."

### 19. Subsequent Event

On February 14, 2011, we announced that our Board of Directors has authorized the repurchase of up to \$100 million shares of our common stock under a new program effective through February 14, 2012.

<sup>(2)</sup> During fiscal year 2010, we completed the sale of ITC. We accounted for the transaction as a sale of discontinued operations, and, accordingly, we have reclassified the results of operations and any losses resulting from the disposition for all periods presented to reflect them as such. Loss on discontinued operations in fiscal 2010 included a loss on disposal of \$0.6 million as described in Note 16, "Discontinued Operations."

#### Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

#### Item 9A. Controls and Procedures

Attached as exhibits to this Annual Report on Form 10-K are certifications of our Chief Executive Officer and Chief Financial Officer, which are required in accordance with Rule 13a-14 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This "Controls and Procedures" section includes information concerning the controls and controls evaluation referred to in the certifications.

#### Disclosure Controls and Procedures

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, as of January 1, 2011. The evaluation of our disclosure controls and procedures included a review of our processes and implementation and the effect on the information generated for use in this Annual Report on Form 10-K. In the course of this evaluation, we sought to identify any significant deficiencies or material weaknesses in our disclosure controls and procedures, to determine whether we had identified any acts of fraud involving personnel who have a significant role in our disclosure controls and procedures, and to confirm that any necessary corrective action, including process improvements, was taken. This type of evaluation is done quarterly so that our conclusions concerning the effectiveness of these controls can be reported in our periodic reports filed with the SEC. The overall goals of these evaluation activities are to monitor our disclosure controls and procedures, modifying them as circumstances warrant.

Based on that evaluation, our management, including the Chief Executive Officer and Chief Financial Officer, concluded that as of January 1, 2011 the Company's disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and to provide reasonable assurance that such information is accumulated and communicated to our management, including our principal executive officer, as appropriate to allow for timely decisions regarding required disclosures.

### Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Management assessed our internal control over financial reporting as of January 1, 2011, the end of our fiscal year. Management based its assessment on criteria established in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. This assessment is supported by testing and monitoring performed by our internal accounting and finance organization.

Based on our assessment, management has concluded that our internal control over financial reporting was effective as of January 1, 2011. The results of management's assessment were reviewed with the Audit Committee.

Our independent registered public accounting firm, Deloitte & Touche LLP, has issued a report on our internal control over financial reporting, which is included in Item 8 of this Annual Report on Form 10-K.

### Changes to Internal Controls

There have been no changes in our internal controls over financial reporting during the quarter ended January 1, 2011 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

#### Inherent Limitations on Controls and Procedures

Our management, including the Chief Executive Officer and the Chief Financial Officer, does not expect that our disclosure controls and procedures and our internal controls will prevent all error and all fraud. A control system, no matter how well designed and operated, can only provide reasonable assurances that the objectives of the control system are met. The design of a control system reflects resource constraints; the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been or will be detected. As these inherent limitations are known features of the financial reporting process, it is possible to design into the process safeguards to reduce, though not eliminate, these risks. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns occur because of simple error or mistake. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events. While our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, there can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

We intend to review and evaluate the design and effectiveness of our disclosure controls and procedures on an ongoing basis and to improve our controls and procedures over time and to correct any deficiencies that we may discover in the future. While our Chief Executive Officer and Chief Financial Officer have concluded that, as of January 1, 2011, the design of our disclosure controls and procedures, as defined in Rule 13a-15(e) under the Exchange Act, was effective, future events affecting our business may cause us to significantly modify our disclosure controls and procedures.

### Item 9B. Other Information

None.

### PART III

### Item 10. Directors, Executive Officers and Corporate Governance

Certain information regarding our executive officers is included in Part I of this Annual Report on Form 10-K under the caption "Our Executive Officers." All other information regarding directors, executive officers and corporate governance required by Item 10 is incorporated herein by reference from the information under the captions "Board of Directors Structure and Compensation," "Election of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance," "Code of Ethics and Corporate Governance," and in other applicable sections in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2011 annual meeting of shareholders.

### Item 11. Executive Compensation

The information required by Item 11 is incorporated herein by reference from the information under the captions "Board of Directors Structure and Compensation," "Compensation Discussion and Analysis," "Report of the Compensation and Option Committee of the Board of Directors" and "Executive Compensation" in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2011 annual meeting of shareholders.

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

The information required by Item 12 is incorporated herein by reference from the information under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance Under Equity Compensation Plans" in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2011 annual meeting of shareholders.

### Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by Item 13 is incorporated herein by reference from the information under the caption "Certain Transactions" in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2011 annual meeting of shareholders.

### Item 14. Principal Accounting Fees and Services

The information required by Item 14 is incorporated herein by reference from the information under the caption "Fees Paid to Accountants for Services Rendered During Fiscal Years 2010 and 2009" in the definitive proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A for our 2011 annual meeting of shareholders.

### PART IV

### Item 15. Exhibit and Financial Statement Schedules

- (a) List of documents filed as part of this report:
  - 1. Financial Statements and Reports of Independent Registered Public Accounting Firm.

Reference is made to the Index to Financial Statements under Item 8 of Part II of this Annual Report on Form 10-K, where these documents are included.

### 2. Financial Statement Schedules

Schedule II—Valuation and Qualifying Accounts and Reserves for each of the three fiscal years ended January 1, 2011, January 2, 2010 and January 3, 2009. Other financial statement schedules are not included either because they are not required or the information is otherwise shown in our audited consolidated financial statements or the notes thereto.

### 3. Exhibits

Reference is made to the Exhibit Index on page 99 of this Annual Report on Form 10-K, where these documents are included.

### SCHEDULE II—VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

### For Each of the Three Fiscal Years:

	Balance Beginning of Year	Additions (charges to expense)	Deductions	Balance End of Year
		(in thou	sands)	
Year Ended January 1, 2011(2):				
Allowance for doubtful accounts	\$322	\$1,012	\$ —	\$1,334
Valuation allowance	\$ —	\$5,072	\$ —	\$5,072
Year Ended January 2, 2010(2):				
Allowance for doubtful accounts	\$314	\$ 418	\$(410)(1)	\$ 322
Valuation allowance	\$ —	\$ —	\$ —	\$ —
Year Ended January 3, 2009(2):				
Allowance for doubtful accounts	\$138	\$ 298	\$(122)(1)	\$ 314
Valuation allowance	\$ —	\$ —	\$	\$ —

Accounts written off or fully reserved.
 The valuation and qualifying accounts and reserves.

### EXHIBIT INDEX

Exhibit Number	Exhibit
2.1	Stock Purchase Agreement, dated as of November 4, 2010, by and between Thoratec Corporation and ITC Nexus Holding Company, Inc.(1)
3.1	Thoratec's Articles of Incorporation, as amended.(2)
3.2	Thoratec's By-Laws, as amended February 25, 2005.(3)
4.1	Rights Agreement between Thoratec Corporation and Computershare Trust Company, Inc. as Rights Agent dated as of May 2, 2002.(4)
4.2	Indenture, dated as of May 24, 2004, by and between Thoratec Corporation and U.S. Bank, National Association, as Trustee.(5)
4.3	Form of Senior Subordinated Convertible Note due 2034.(6)
4.4	Pledge Agreement, dated as of May 24, 2004, between Thoratec Corporation and U.S. Bank, National Association, and Pledge Agreement Supplement, dated as of June 7, 2004.(5)
4.5	Control Agreement, dated as of May 24, 2004, between Thoratec Corporation and U.S. Bank, National Association, and Control Agreement Amendment, dated as of June 7, 2004.(5)
4.6	Registration Rights Agreement, dated May 24, 2004, by and among Thoratec Corporation and Merrill Lynch Pierce Fenner & Smith Incorporated as Initial Purchaser of the Senior Subordinated Convertible Notes due 2034.(5)
10.1	Form of Indemnification Agreement between Thoratec Cardiosystems and its officers and directors.(7)
10.2	Lease Agreement dated July 25, 1996, between Main Street Associates and Thoratec, as amended.(9)
10.3	First Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(10)
10.4	Second Amendment to Lease Agreement originally between Main Street Associates and Thoratec dated July 25, 1996.(11)
10.5	Thoratec's 1997 Stock Option Plan, as amended.(12)
10.6	Thoratec's 2002 Employee Stock Purchase Plan.(13)
10.7	Grantor Trust Agreement between Thoratec and Wachovia Bank, National Association effective as of November 21, 2003.(8)
10.8	Description of the Executive Disability Income Protection Program.(14)
10.9	Amended and Restated Thoratec Corporation 2006 Incentive Stock Plan.(15)
10.10	Amended and Restated Employment Agreement by and between Thoratec and Gerhard F. Burbach, dated April 23, 2007.(16)*
10.11	Amended and Restated Separation Benefits Agreement by and between Thoratec and David A. Lehman, dated April 23, 2007.(16)*
10.12	Amended and Restated Separation Benefits Agreement by and between Thoratec and David V. Smith, dated April 23, 2007.(16)*
10.13	Thoratec Corporation Amended and Restated Deferred Compensation Plan Effective January 1, 2005.(17)
10.14	Description of Director Compensation Program.(18)
10.15	Thoratec Corporation Corporate Executive Incentive Plan FY 2010, effective for certain executive officer of the Company.(19)*

Exhibit Number	Exhibit
10.16	Amendment to the Amended and Restated Employment Agreement by and between Thoratec and Gerhard F. Burbach, dated November 16, 2009.(21)*
10.17	Amendment to the Amended and Restated Separation Benefits Agreement by and between Thoratec and David A. Lehman, dated November 16, 2009.(21)*
10.18	Amendment to the Amended and Restated Separation Benefits Agreement by and between Thoratec and David V. Smith, dated November 16, 2009.(21)*
10.19	Amendment No. 1 to the Thoratec Corporation Nonqualified Deferred Compensation Plan.*
21	Subsidiaries of Thoratec.(20)
23.1	Consent of Independent Registered Public Accounting Firm.
24	Power of Attorney—Reference is made to page 103 hereof.
31.1	Section 302 Certification of Chief Executive Officer
31.2	Section 302 Certification of Chief Financial Officer
32.1	Section 906 Certification of Chief Executive Officer
32.2	Section 906 Certification of Chief Financial Officer

<sup>(1)</sup> Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended October 2, 2010 filed with the SEC on November 4, 2010 and incorporated herein by reference.

- (2) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended December 28, 2002 filed with the SEC on March 20, 2003 and incorporated herein by reference.
- (3) Filed as an Exhibit to Thoratec's Form 8-K filed with the SEC on March 3, 2005 and incorporated herein by reference.
- (4) Filed as an Exhibit to Thoratec's Form 8-A12G filed with the SEC on May 3, 2002 (Registration No. 000-49798), and incorporated herein by reference.
- (5) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended July 3, 2004 filed with the SEC on August 12, 2004, and incorporated herein by reference.
- (6) Included as an exhibit to Exhibit 4.2 and incorporated herein by reference.
- (7) Filed as an Exhibit to Thoratec Cardiosystems' Registration Statement on Form S-1 (Registration No. 33-25144) and incorporated herein by reference.
- (8) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended January 3, 2004 filed with the SEC on March 17, 2004 and incorporated herein by reference.
- (9) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended June 29, 1996, filed with the SEC on August 13, 1996, and incorporated herein by reference.
- (10) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended June 28, 1997, filed with the SEC on July 30, 1997, and incorporated herein by reference.
- (11) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended September 27, 1997 filed with the SEC on November 12, 1997, and incorporated herein by reference.
- (12) Filed as an Exhibit to Thoratec's Registration Statement on Form S-8 filed with the SEC on June 18, 2003 (Registration No. 333-106238), and incorporated herein by reference.
- (13) Filed as an Exhibit to Thoratec's Form S-8 POS filed with the SEC on July 1, 2002 (Registration No. 333-90768), and incorporated herein by reference.
- (14) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended January 1, 2005 filed with the SEC on March 16, 2005 and incorporated herein by reference.
- (15) Filed as an Exhibit to Thoratec's Form 8-K filed with the SEC on May 25, 2010.
- (16) Filed as an Exhibit to Thoratec's Form 8-K filed with the SEC on April 27, 2007.
- (17) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2007 filed with the SEC on August 9, 2007 and incorporated herein by reference.
- (18) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended January 3, 2009 filed with the SEC on February 27, 2009 and incorporated herein by reference.
- (19) Filed as an Exhibit to Thoratec's Quarterly Report on Form 10-Q for the fiscal quarter ended April 3, 2010 filed with the SEC on May 5, 2010 and incorporated herein by reference.
- (20) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended December 29, 2001 filed with the SEC on March 15, 2002 and incorporated herein by reference.

- (21) Filed as an Exhibit to Thoratec's Annual Report on Form 10-K for the fiscal year ended January 2, 2010 filed with the SEC on February 24, 2010 and incorporated herein by reference.
- \* Indicates a management contract or compensatory plan.

101\*\*\* The following materials from Registrant's Annual Report on Form 10-K for the year ended January 1, 2011, formatted in Extensible Business Reporting Language (XBRL) includes: (i) Consolidated Balance Sheets as of January 1, 2011 and January 2, 2010, (ii) Consolidated Statements of Operations for the years ended January 1, 2011, January 2, 2010, and January 3, 2009, (iii) Consolidated Statements of Cash Flows for the years ended January 1, 2011, January 2, 2010, and January 3, 2009, and (iv) Notes to Consolidated Financial Statements, tagged as blocks of text.

### **SIGNATURES**

In accordance with Section 13 or Section 15(d) of the Exchange Act, as amended, the Registrant has duly caused this Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on this 23rd day of February 2011.

### THORATEC CORPORATION

By: /s/ GERHARD F. BURBACH

Gerhard F. Burbach President and Chief Executive Officer

Date: February 23, 2011

### POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS that each person whose signature appears below constitutes and appoints Gerhard F. Burbach and David Lehman, and each of them, his or her true and lawful attorney-in-fact, with full power of substitution and resubstitution, to act for him or her and in his or her name, place and stead, in any and all capacities to sign any and all amendments to this annual report on Form 10-K and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing which they, or any of them, may deem necessary or advisable to be done in connection with this annual report as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or any substitute or substitutes for any or all of them, may lawfully do or cause to be done by virtue hereof.

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the Thoratec Corporation and in the capacities and on the dates indicated.

Signature	<u>Title</u>	Date
/s/ GERHARD F. BURBACH Gerhard F. Burbach	Chief Executive Officer, President and Director (Principal Executive Officer)	February 23, 2011
/s/ DAVID V. SMITH David V. Smith	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 23, 2011
/s/ NEIL F. DIMICK Neil F. Dimick	Director and Chairman of the Board of Directors	February 23, 2011
/s/ J. DANIEL COLE  J. Daniel Cole	——— Director	February 23, 2011
/s/ STEVEN H. COLLIS Steven H. Collis	——— Director	February 23, 2011
/s/ ELISHA W. FINNEY Elisha W. Finney	——— Director	February 23, 2011
/s/ D. KEITH GROSSMAN D. Keith Grossman	——— Director	February 23, 2011
/s/ PAUL A. LAVIOLETTE Paul A. LaViolette	——— Director	February 23, 2011
/s/ DANIEL M. MULVENA Daniel M. Mulvena	——— Director	February 23, 2011

### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statements on Form S-3 (No. 333-167287, No. 333-97783, No. 333-72128, No. 333-61136, and No. 333-32684), Registration Statements on Form S-8 (No. 333-158860, No. 333-150527, No. 333-135047, No. 333-106238, No. 333-90768, No. 333-80807, No. 333-56212, No. 333-32223, No. 333-11883, No. 33-35549 and No. 33-72502), Post-Effective Amendment No. 1 to Registration Statement No. 333-90768, Post-Effective Amendment No. 1 to Registration Statement No. 1 to Registration Statement No. 2-78926, and Post-Effective Amendment No. 3 to Registration Statement No. 2-78925, of our reports dated February 23, 2011 relating to the consolidated financial statements and financial statement schedule of Thoratec Corporation and to the effectiveness of Thoratec Corporation's internal control over financial reporting, appearing in this Annual Report on Form 10-K of Thoratec Corporation for the year ended January 1, 2011.

/s/ DELOITTE & TOUCHE LLP

San Francisco, California February 23, 2011

## CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

### I, Gerhard F. Burbach, certify that:

- 1. I have reviewed this annual report on Form 10-K of Thoratec Corporation;
- 2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
  - d) disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ GERHARD F. BURBACH

Gerhard F. Burbach Chief Executive Officer

## CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

### I, David V. Smith, certify that:

- 1. I have reviewed this annual report on Form 10-K of Thoratec Corporation;
- 2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this annual report based on such evaluation; and
  - d) disclosed in this annual report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ DAVID V. SMITH

David V. Smith Chief Financial Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Thoratec Corporation (the "Company") for the period ending January 1, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Gerhard F. Burbach, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ GERHARD F. BURBACH

Gerhard F. Burbach Chief Executive Officer

# CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Thoratec Corporation (the "Company") for the period ending January 1, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David V. Smith, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ David V. Smith

David V. Smith Chief Financial Officer