THORATEC CORP
Form 10-K
February 20, 2013

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark one)

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

For the fiscal year ended December 29, 2012

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

For the transition period from to
Commission file number: 000-49798

Thoratec Corporation

(Exact Name of Registrant as Specified in Its Charter)

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

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

Securities registered pursuant to Section 12(b) of the Exchange Act:

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

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

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

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

Indicate by a check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and

(2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ý No o

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

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

Large accelerated filer ý	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller Reporting Company o

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

The aggregate market value of the voting stock held by non-affiliates computed by reference to the last sale reported of such stock on June 29, 2012, the last business day of the Registrant's second fiscal quarter, was $1,958,277,875.

As of February 8, 2013, the Registrant had 57,605,296 shares of common stock outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE

Designated portions of Thoratec's definitive proxy statement for its 2013 annual meeting of shareholders are incorporated by reference into Part III of this Form 10-K.

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PART I

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.

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, company compliance program, audit 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

We develop, manufacture and market proprietary medical devices used for mechanical circulatory support ("MCS") for the treatment of heart failure ("HF") patients. For chronic circulatory support for HF patients, our primary product lines are our ventricular assist devices ("VADs"): HeartMate Left Ventricular Assist System ("HeartMate XVE"), HeartMate II Left Ventricular Assist System ("HeartMate II"), Thoratec Paracorporeal Ventricular Assist Device ("PVAD"), and Thoratec Implantable Ventricular Assist Device ("IVAD"). We refer to HeartMate XVE and HeartMate II collectively as the "HeartMate product line" and PVAD and IVAD collectively as the "Thoratec product line." For acute circulatory support, our product lines are CentriMag Acute Circulatory System ("CentriMag") and for pediatric patients PediMag/PediVAS Acute Circulatory System ("PediMag/PediVAS"). HeartMate XVE, HeartMate II, PVAD, IVAD, CentriMag and PediMag/PediVAS are approved by the U.S. Food and Drug Administration ("FDA"), and have received Conformité Européene ("CE") Mark approval in Europe.

MCS devices supplement the pumping function of the heart in patients with 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 MCS devices. Some of our devices can also provide support for the right side of the heart.

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

HeartMate II

HeartMate II is an implantable, electrically powered, continuous flow, left ventricular assist device ("LVAD") consisting of a rotary blood pump designed to provide intermediate and long-term MCS. HeartMate II is designed to improve survival and quality of life for a broad range of advanced HF patients. Significantly smaller than HeartMate XVE and with only one moving part, HeartMate II is simpler and designed to operate more quietly than pulsatile devices.

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, HeartMate II received CE Mark approval. HeartMate II is the most widely used and standard LVAD.

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HeartMate XVE

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. We discontinued the sale of HeartMate XVE at the end of fiscal 2011.

HeartMate XVE received FDA approval for BTT in December 2001 and for DT in April 2003. In June 2003, HeartMate XVE received CE Mark approval.

CentriMag

CentriMag is an extracorporeal full-flow acute surgical support platform incorporating a polycarbonate pump, based on magnetically levitated bearingless motor technology. CentriMag is cleared 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 ("HDE") 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. We have an ongoing study to evaluate the effectiveness of the CentriMag for periods of support up to thirty days. CentriMag has CE Mark approval to provide support for up to thirty days for both cardiac and respiratory failure.

On August 3, 2011, we completed the acquisition of the medical business of Levitronix LLC ("Levitronix Medical"). Prior to the acquisition, we provided distribution and clinical support to Levitronix Medical in the U.S. for CentriMag under an agreement that would have expired at the end of 2011.

PediMag/PediVAS

PediMag and PediVAS are identical, extracorporeal full-flow acute surgical support platforms incorporating a polycarbonate pump, based on magnetically levitated bearingless motor technology, designed to provide acute surgical support to pediatric patients. The brand names differ according to indication for use, duration of support, and regulatory approval. PediMag is cleared by the FDA for use, in conjunction with the CentriMag console and motor, for support periods of up to six hours. Outside the U.S., the device is branded as PediVAS. This device has CE Mark to provide support for up to 30 days for both cardiac and respiratory failure.

PVAD

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

A pneumatic power source drives PVAD. It is designed for short-to-intermediate duration for post-cardiotomy myocardial recovery following cardiac surgery and BTT. PVAD and IVAD, described below, offer left, right or biventricular support for use for BTT. This characteristic is significant because the vast majority of BTT patients treated with PVAD and IVAD require right as well as left-side ventricular assistance. PVAD and IVAD are also the only devices approved for both BTT and recovery following cardiac surgery. PVAD incorporates our proprietary biomaterial, Thoralon, which has excellent tissue and blood compatibility and is resistant to blood clots.

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

IVAD

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

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.

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DISCONTINUED OPERATIONS

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 our consolidated financial statements.

PRODUCT SEGMENTS

Following the sale of ITC in 2010, the Company has one operating segment (Cardiovascular group). This segment is organized and operates to develop and manufacture mechanical circulatory products to support the cardiovascular systems of humans and to provide product-related services. Information concerning revenues set forth in Note 13 in the Notes to Consolidated Financial Statements, which is included elsewhere in this Annual Report on Form 10-K.

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, 6.6 million people suffer from HF in the U.S. and approximately 600,000 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 approximately 2,169 hearts became available for transplant in the U.S. during the twelve months reported to December 2012, the most recent period for which data is available. At February 12, 2013, approximately 3,423 patients were on the U.S. national transplant waiting list, and we believe a comparable number of patients are currently waiting in each of the U.S. and 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: for DT 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

On January 20, 2010, we received approval to market HeartMate II for DT in patients with New York Heart Association Class III B 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. In 2012, we completed the FDA-required post-market study of 247 patients who received the HeartMate II for DT.

The National Institute for Health estimated that the DT 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.

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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 bridge-to-transplant patients will continue to increase as surgeons' level of comfort with the technology increases, particularly for longer-term support cases. We currently have three devices that are commercially marketed and approved in the U.S. for BTT support in adults.

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 is to maintain and expand our leadership position through execution of the following market and product development initiatives:

Expand the utilization of MCS therapy worldwide in patients with advanced heart failure

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

Clinician education and outreach. We continue to expand awareness of MCS through education and outreach programs, both at implanting centers and within the referring cardiology community. We are building upon our existing relationships with cardiac surgeons and heart failure cardiologists in both transplant and open heart centers and using our existing sales channels 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 about the benefits of MCS through our team of over 40 Market Development Managers in the U.S. as well as through clinical symposia, on-line education programs, and other outreach efforts.

Center expansion. We ended 2012 with 323 HeartMate II centers globally, including 164 in the U.S. and 159 internationally, an increase of 30 centers during the year. In addition, there are now 118 U.S. centers with Joint Commission certification for reimbursement for DT.

Geographic expansion. We are focused on increased worldwide adoption of MCS by developing MCS therapy in important emerging markets through obtaining regulatory approval, developing centers of excellence, and increasing awareness.

Patient education and awareness. We also continue to expand awareness and education for patients and their care givers about the benefits of MCS therapy that include improved survival and quality of life.

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Offer a broad range of products. We currently offer the widest range of MCS devices to cover indications for use ranging from acute to long-term support. We believe that the breadth of our product offering represents an important competitive advantage because it allows us to address the various preferences of clinicians, the 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 pumps.

As part of our ongoing evolution of the HeartMate product line, in 2009 we launched our external peripherals, Go Gear, including new batteries, charger and power module. That improved quality of life to patients by offering them additional freedom and mobility. We also launched sealed inflow and outflow grafts for HeartMate II during 2011, which improved ease of implant. Additionally, during 2013, we plan to launch the Pocket Controller for the HeartMate II system. This device is designed to be smaller, lighter, and easier to use than previous controllers, and it incorporates a backup battery for enhanced patient safety.

Our cross platform technologies in development include remote monitoring, a fully implantable system and improved surgical and automated anastomotic tools. We have not yet entered human clinical testing with these cross platform technologies.

We also continue to invest in next-generation pump platforms, including HeartMate III, Percutaneous Heart Pump ("PHP"), and HeartMate X. HeartMate III is a fully magnetically levitated, centrifugal, continuous flow pump. The full magnetic levitation allows for wide blood gaps and pulsatility, which we believe will result in a lower rate of adverse events. We are also developing the PHP, which is a catheter based axial flow heart pump for application in an unstable HF patient population. The device features a collapsible elastomeric impeller and nitinol cannula that expand to nearly double its size upon insertion. PHP is designed to deliver four to five liters per minute of average blood flow. Lastly, we are developing a miniaturized pump called HeartMate X. The HeartMate III LVAS is designed to remove the external driveline continuing to improve a patient's quality of life.

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. We work closely with VAD centers to continue to improve patient selection, reduce adverse events, and enhance the efficiency of follow-up care, 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. For instance, we acquired the intellectual property assets of PHP from Getinge AB in the first quarter of 2010 and Levitronix Medical in the third quarter of 2011.

SALES AND MARKETING

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 sales and marketing initiatives include education seminars, symposia, journal advertisements, and direct consumers marketing, all common initiatives in the cardiovascular device market. We partner with universities, experienced clinicians and opinion leaders to assist with expanding clinical educational needs. Our Market Development Managers work with our leading VAD centers to generate referrals through increasing 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.

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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. 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.

COMPETITION

Competition from medical device companies 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., CircuLite, Aachen Innovative Solutions GmbH, Maquet Cardiovascular, LLC (a division of Getinge AB), and Berlin Heart GmbH.

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, trademark, 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 about twenty years from the date a patent application is filed. The remaining durations on our patents range from less than one year to up to twenty 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 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 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, license rights and policies with regard to confidential information, trade secrets and inventions, we may be subject to challenges to the validity of our patents, claims that our products allegedly infringe the patent rights of others and the disclosure of our confidential information or trade secrets. These and other related risks are described more fully under the heading "*Our inability to protect our proprietary technologies or an infringement of others' patents could harm our competitive position*" in the "Risk Factors" section of this Annual Report on Form 10-K.

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

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GOVERNMENT REGULATIONS

Regulation by governmental authorities in the 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.

FDA 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 are regulated as medical devices. To obtain FDA approval to market MCS systems 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 on www.clinicaltrials.gov (none of the information available at this website 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 a premarket approval ("PMA") application, a PMA Supplement or a 510(k) premarket notification. There are substantial user fees that must be paid upon submission of the PMA application, PMA Supplement or 510(k) premarket notification 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. For high risk devices such as our MCS systems, the FDA may assemble an expert scientific advisory panel to review the clinical trial data submitted in a PMA before making its decision about whether the device is safe and effective and/or whether to approve the PMA.

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 many devices are never cleared for marketing. This is a lengthy and expensive process and there can be no assurance that FDA approval will be obtained.

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.

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) premarket notification 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, and in October 2012, MDUFMA was reauthorized for fiscal years 2012-2017. 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.

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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 healthcare regulation. This includes the federal Anti-Kickback Law and similar state anti-kickback laws, the federal False Claims Act, the Physician Payment Sunshine Act, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health ("HITECH") Act of 2009, 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, recent health care reform legislation has strengthened these laws. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, collectively, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. 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 are 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").

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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.

The Physician Payment Sunshine Act ("PPSA"), which was included in the PPACA, also imposes new reporting and disclosure requirements on device and drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. In addition, device and drug manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Manufacturers will be required to begin data collection on August 1, 2013 and report such data to CMS by March 31, 2014.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

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.

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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.

The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, signed into law on February 17, 2009, included the HITECH Act and 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. HIPAA and HITECH are enforced by regulations promulgated by the U.S. Department of Health and Human Services, including a final omnibus rule published on January 25, 2013. We believe that we are in compliance with all of the applicable HIPAA and HITECH standards, rules and regulations, except possibly the January 25, 2013 final omnibus rule, with which we expect to be in compliance by the required date of September 23, 2013. 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 and HITECH, some states have enacted privacy and security statutes or regulations that, in some cases, are more stringent than those issued under HIPAA and HITECH. 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. With the CE Mark, 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 of our devices in commercial distribution, including 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.

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Other Regulations

We are also subject to various international, 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 these and other laws or regulations in the future.

The Dodd-Frank Wall Street Reform and Consumer Protection Act includes certain disclosure requirements regarding the use of "conflict minerals" originating from the Democratic Republic of Congo and adjoining countries and procedures regarding a manufacturer's efforts to prevent the sourcing of "conflict minerals."

The Dodd-Frank Wall Street Reform and Consumer Protection Act impose new disclosure requirements regarding the use of "Conflict Minerals" mined from the Democratic Republic of Congo and adjoining countries in products, whether or not these products are manufactured by third parties. The conflict minerals include tin, tantalum, tungsten and gold, and their derivatives. These new requirements could affect the pricing, sourcing and availability of minerals used in the manufacture of our products. There will be additional costs associated with complying with the disclosure requirements, such as costs related to determining the source of any conflict minerals used in our products. Our supply chain is complex and we may be unable to verify the origins for all metals used in our products. We may also encounter challenges with our customers and stockholders if we are unable to certify that our products are conflict free.

In addition, compliance with complex international and U.S. laws and regulations that apply to our international operations increases our cost of doing business. These numerous and sometimes conflicting laws and regulations include U.S. laws such as the Foreign Corrupt Practices Act, the U. K. Bribery Act, and similar worldwide anti-bribery laws in non-U.S. jurisdictions, which generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business, among others. Violations of these laws and regulations could result in fines and penalties, criminal sanctions against us, our officers, or our employees, prohibitions on the conduct of our business and damage to our reputation. Although we have implemented policies and procedures designed to ensure compliance with these laws and regulations as well as training on such policies and procedures, there can be no assurance that our employees, contractors, distributors and agents will not violate our policies.

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. As of December 31, 2012, approximately 118 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.

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Healthcare laws in the U.S. are subject to ongoing changes, including changes to the amount of reimbursement for hospital services and the manner in which such services are paid. Federal legislation in particular can substantially change the way healthcare is financed by both governmental and private insurers and may negatively impact payment rates for our products. For example, in March 2010, the PPACA was passed, which imposes significant new measures and responsibilities on the U.S. pharmaceutical and medical device industries. The PPACA, among other things, establishes annual fees and taxes on manufacturers of certain medical devices, including our devices, and promotes programs that increase the federal government's comparative effectiveness research, which may be used to evaluate the selection of medical services by clinicians and others. PPACA also implements payment system reforms such as a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, and creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projections of such spending exceed a specified growth rate.

In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

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 are manufactured at our facilities located in Pleasanton, California and Zurich, Switzerland. These facilities have been inspected, approved and licensed by the FDA and/or European Unified Body for the manufacture of medical devices, and have received the ISO 13485 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 demand expectations for HeartMate II. As of December 29, 2012, the renovated facility has the necessary capacity to meet the requirements for our VAD products for the next four to six years.

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 2012, 2011, and 2010 was not significant.

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RESEARCH AND DEVELOPMENT

Our research and development expenses in fiscal years 2012, 2011 and 2010 totaled $87.7 million, $66.3 million and $58.8 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 PHP pump. 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 2012, 2011 and 2010.

Sales originating outside of the U.S. and U.S. export sales accounted for approximately 19%, 18% and 17% of our total product sales in 2012, 2011 and 2010, respectively. No individual foreign country accounted for more than 10% of our net sales in any of the last three fiscal years.

EMPLOYEES

As of December 29, 2012, we had a total of 934 employees, consisting of 855 full-time employees and 79 temporary employees. Of our total employees, 867 are employed in the U.S. and 67 are employed outside the U.S. None of our employees is 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, acquisitions, 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 U.S. 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 occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline significantly. Investors should consider the following risks, as well as the other information included in this Annual Report on Form 10-K, and other documents we file from time-to-time with the SEC, such as our quarterly reports on Form 10-Q, our current reports on Form 8-K and any public announcements we make from time-to-time.

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 if 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., clearance from the FDA of a 510(k) pre-market notification or approval of a more extensive submission known as a PMA application is required. If the FDA concludes that any of our products does not meet the requirements to obtain clearance under Section 510(k) of the FDCA, then we will be required to file a PMA application for that product. The process for a PMA application is lengthy, expensive and typically requires extensive pre-clinical and clinical trial data.

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

In addition, our medical device products and operations are subject to extensive regulation by the FDA pursuant to the 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, and 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. For example, the FDA has issued and could in the future issue warning letters or other communications to the Company. If the Company fails to satisfy or remediate the matters discussed in any such warning letters or communications, the FDA could take further enforcement action, including prohibiting the sale or marketing of the affected product. 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;

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

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

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

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

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

Competition from medical device companies and medical device divisions of 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 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., CircuLite, Aachen Innovative Solutions GmbH, Maquet Cardiovascular, LLC (a division of Getinge AB) and Berlin Heart GmbH.

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 currently available in clinical trials or in development could prove to be clinically superior, easier to implant, and/or less expensive than current commercialized devices, thereby impacting our market share.

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

We depend on a number of custom designed components and materials supplied by other companies including, in some cases, single source suppliers for components, instruments and materials used in our VAD products. For example, a single source supplier currently manufactures and supplies components used to manufacture the ruby bearings used in the HeartMate II pump. 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