BOSTON SCIENTIFIC CORP
Form 10-K
February 22, 2013
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934, or

For the fiscal year ended December 31, 2012

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

Commission File No. 1-11083
BOSTON SCIENTIFIC CORPORATION
(Exact name of registrant as specified in its charter)

DELAWARE	04-2695240
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

ONE BOSTON SCIENTIFIC PLACE, NATICK, MASSACHUSETTS 01760-1537
(Address of principal executive offices) (zip code)
(508) 650-8000
(Registrant's telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

COMMON STOCK, $.01 PAR VALUE PER SHARE	NEW YORK STOCK EXCHANGE
(Title of each class)	(Name of exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act:
NONE
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes: þ No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: o No þ
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: þ No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorted period that the registrant was required to submit and post such files). Yes: þ No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the 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 þ	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

The aggregate market value of the registrant's common stock held by non-affiliates was approximately $7.9 billion based on the closing price of the registrant's common stock on June 30, 2012, the last business day of the registrant's most recently completed second fiscal quarter.

The number of shares outstanding of the registrant's common stock as of January 31, 2013 was 1,357,426,289.

Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with its 2013 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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PART I

ITEM 1. BUSINESS

The Company

Boston Scientific Corporation is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. Our mission is to transform lives through innovative medical solutions that improve the health of patients around the world. When used in this report, the terms “we,” “us,” “our” and “the Company” mean Boston Scientific Corporation and its divisions and subsidiaries.

Our history began in the late 1960s when our co-founder, John Abele, acquired an equity interest in Medi-tech, Inc., a research and development company focused on developing alternatives to surgery. In 1969, Medi-tech introduced a family of steerable catheters used in some of the first less-invasive procedures performed. In 1979, John Abele joined with Pete Nicholas to form Boston Scientific Corporation, which indirectly acquired Medi-tech. This acquisition began a period of active and focused marketing, new product development and organizational growth. Since then, we have advanced the practice of less-invasive medicine by helping physicians and other medical professionals treat a variety of diseases and conditions and improve patients’ quality of life by providing alternatives to surgery and other medical procedures that are typically traumatic to the body.

Our net sales have increased substantially since our formation over thirty years ago. Our growth has been fueled in part by strategic acquisitions designed to improve our ability to take advantage of growth opportunities in the medical device industry. Our strategic acquisitions have helped us to add promising new technologies to our pipeline and to offer one of the broadest product portfolios in the world for use in less-invasive procedures. We believe that the depth and breadth of our product portfolio has also enabled us to compete more effectively in the current healthcare environment of cost containment, managed care, large buying groups, government contracting, hospital consolidation, and international expansion and will generally assist us in navigating through the complexities of the global healthcare market, including healthcare reform.

Business Strategy

The following are our five strategic imperatives:

- Strengthen Execution to Grow Share

We believe that our success will be driven by our ability to consistently deliver initiatives that grow profitability and market share. We are focused on improving the speed and performance of our business units by adding new capabilities, processes, and innovative technologies.

- Expand into High Growth Adjacencies

We seek to diversify our product portfolio by realigning our research and development spend and focusing our business development investment toward higher growth opportunities. We are focused on executing on our committed growth adjacencies while increasing our access to developing technologies. Through this diversification we expect to increase our opportunity for growth in areas that complement our core businesses.

- Drive Global Expansion

We are focused on expanding into the emerging markets. By expanding our global commercial presence, we seek to increase revenue and market share, and strengthen our relationships with leading physicians and their clinical research programs. We are focused on building new capabilities in countries whose economies and healthcare sectors are growing rapidly. We have local leadership teams with extensive in-country experience to help strengthen our position in these fast growing regions.

- Fund the Journey to Fuel Growth

We are driving continuous improvement to expand our profitability, optimizing our manufacturing cost structure, reducing our corporate infrastructure and re-allocating spending to support our growth initiatives.

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- Develop Key Capabilities

We intend to develop key capabilities by providing economic and customer focused solutions so that our product portfolio is aligned to the needs of the market place and by developing core internal skills to better manage our business in a dynamic and evolving environment. We are globally focused on building a culture of empowerment and engagement while improving our diversity.

We believe that our execution of these strategic imperatives will drive innovation, accelerate profitable revenue growth and increase stockholder value.

Products

During 2012, our products were offered for sale by seven core businesses - Interventional Cardiology, Cardiac Rhythm Management (CRM), Endoscopy, Peripheral Interventions, Urology/Women's Health, Neuromodulation, and Electrophysiology. In January 2011, we closed the sale of our Neurovascular business to Stryker Corporation. We continue to generate sales from the Neurovascular business pursuant to our supply and distribution agreements with Stryker; however, these sales are at significantly lower levels and at reduced gross profit margins as compared to periods prior to the divestiture.

During 2012, we derived 30 percent of our sales from our Interventional Cardiology business, 26 percent of our sales from our CRM business, 17 percent of our sales from our Endoscopy business, 11 percent of our sales from our Peripheral Interventions business, seven percent of our sales from our Urology/Women's Health business, five percent of our sales from our Neuromodulation business, and two percent of our sales from our Electrophysiology business. Approximately two percent of our 2012 sales were derived from the Neurovascular business that we sold to Stryker Corporation.

The following section describes certain of our product offerings:

Endoscopy

Gastroenterology

We market a broad range of products to diagnose, treat and ease a variety of digestive diseases, including those affecting the esophagus, stomach, liver, pancreas, duodenum, and colon. Common disease states include esophagitis, portal hypertension, peptic ulcers as well as esophageal, biliary, pancreatic and colonic cancer. We offer the Radial Jaw® 4 Single-Use Biopsy Forceps, which are designed to enable collection of large high-quality tissue specimens without the need to use large channel therapeutic endoscopes. Our exclusive line of RX Biliary System™ devices are designed to provide greater access and control for physicians to diagnose and treat challenging conditions of the bile ducts, such as removing gallstones, opening obstructed bile ducts and obtaining biopsies in suspected tumors. We also market the Spyglass® Direct Visualization System for direct imaging of the pancreatico-biliary system. The Spyglass® System is the first single-operator cholangioscopy device that offers clinicians a direct visualization of the pancreatico-biliary system and includes supporting devices for tissue acquisition, stone management and lithotripsy. Our products also include the WallFlex® family of stents, in particular, the WallFlex® Biliary line and WallFlex® Esophageal line; and in 2012, we launched our WallFlex® Biliary Transheptic stent system for treatment of biliary strictures. In addition, we continue to see growth of our hemostasis franchise on the continued adoption and utilization of our Resolution® Clip Device for gastrointestinal bleeding. In December of 2012, the first patient enrolled in our study comparing the WallFlex® Biliary RX Fully Covered self-expanding metal stent (SEMS) to plastic stents for the treatment of benign bile duct strictures caused by chronic pancreatitis. SEMS, which have a significantly larger diameter than plastic biliary stents, have long been the standard of care for palliation of malignant biliary strictures. This study is evaluating the benefits of using a SEMS in benign biliary strictures, with an objective to demonstrate stricture resolution in fewer procedures.

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Interventional Bronchoscopy

We market devices to diagnose, treat and ease pulmonary disease systems within the airway and lungs. Our products are designed to help perform biopsies, retrieve foreign bodies from the airway, open narrowings of an airway, stop internal bleeding, and ease symptoms of some types of airway cancers. Our product line includes pulmonary biopsy forceps, transbronchial aspiration needles, cytology brushes and tracheobronchial stents used to dilate narrowed airway passages or for tumor management. In October 2010, we completed our acquisition of Asthmatx, Inc., which adds to our Endoscopy portfolio a less-invasive, catheter-based bronchial thermoplasty procedure for the treatment of severe persistent asthma. The Alair® Bronchial Thermoplasty System, developed by Asthmatx, has both Conformite Europeenne (CE) Mark and U.S. Food and Drug Administration (FDA) approval and is the first device-based asthma treatment approved by the FDA. In the third quarter of 2012, the America Medical Association (AMA) Current Procedural Terminology (CPT) editorial panel assigned category I CPT codes specifically for bronchial thermoplasty beginning January 1, 2013. Once recognized, the Category I CPT procedure codes will be available for all public and private health insurance payers in the United States, which will allow physicians and hospitals to seek reimbursement for bronchial thermoplasty procedures. We believe these codes will provide greater access to treatment for patients with poorly controlled severe asthma, help facilitate claims processing and help private payers' approve coverage for this form of treatment. We continue to focus on driving commercialization and increased awareness of the Alair® System.

Peripheral Interventions (PI)

We sell various products designed to treat patients with peripheral disease (disease which appears in blood vessels other than in the heart and in the biliary tree), including a broad line of medical devices used in percutaneous transluminal angioplasty (PTA) and peripheral vascular stenting. Our peripheral product offerings include stents, balloon catheters, wires, peripheral embolization devices and vena cava filters. We launched three new peripheral angioplasty balloons in 2011, including our next-generation Mustang™ percutaneous transluminal angioplasty balloon, our Coyote™ balloon catheter, a highly deliverable and ultra-low profile balloon dilatation catheter designed for a wide range of peripheral angioplasty procedures and our Charger™ PTA Balloon Catheter, a 0.035” percutaneous transluminal angioplasty balloon catheter designed for post-stent dilatation as well as conventional balloon angioplasty to open blocked peripheral arteries. With our Coyote, Mustang and Charger devices, we offer balloons across all size platforms. In 2012, we launched our EPIC™ self-expanding nitinol stent system in the U.S. and certain international markets, the Carotid WALLSTENT® stent system in Japan, and Innova™ self-expanding bare metal stent system in Europe and certain international markets.

In February 2011, we announced the acquisitions of S.I. Therapies and ReVascular Therapeutics, Inc., which added to our PI portfolio a re-entry catheter and intraluminal chronic total occlusion (CTO) crossing device, enabling endovascular treatment in cases that typically cannot be treated with standard endovascular devices. In 2011, we commenced a limited market release of our OFFROAD™ re-entry catheter system in certain international markets, and in February 2012, we launched our TRUEPATH™ intraluminal CTO device in the U.S., EMEA, and other international markets. We believe that offering these devices will enhance our position in assisting physicians in addressing the challenges of treating complex peripheral lesions. In the fourth quarter of 2012, we acquired Vessix Vascular, Inc., a developer of catheter-based renal denervation systems for the treatment of uncontrolled hypertension. We expect to launch this platform commercially in Europe and other international markets in 2013.

We also sell products designed to treat patients with non-vascular disease (disease that appears outside the blood system). Our non-vascular suite of products includes biliary stents, drainage catheters and micro-puncture sets designed to treat, diagnose and ease various forms of benign and malignant tumors. We continue to market our extensive line of Interventional Oncology product solutions, including the recently launched Renegade® HI-FLO™ Fathom® microcatheter and guidewire system and Interlock™ - 35 Fibered IDC™ Occlusion System for peripheral embolization.

Neuromodulation

Within our Neuromodulation business, we market the Precision® Spinal Cord Stimulation (SCS) system, used for the management of chronic pain. This system delivers pain management by applying an electrical signal to mask pain signals traveling from the spinal cord to the brain. In addition, during the fourth quarter of 2012 we received CE Mark

approval for the Precision Spectra™ Spinal Cord Stimulator System and began a European market launch of this technology. The Precision Spectra system is the world's first and only SCS system with 32 contacts and 32 dedicated power sources and is designed to provide improved pain relief to a wide range of patients who suffer from chronic pain. In 2011, we launched our Clik™ Anchor for our Precision® Plus™ SCS System, the world's first rechargeable SCS device for chronic pain management. In the fourth quarter of 2011, we received FDA approval for and launched the Infinion™ 16 Percutaneous Lead, the world's first and only 16-contact percutaneous lead. We also market the Linear™ 3-4 and Linear 3-6 Percutaneous Leads for use with our SCS systems, which are designed to provide physicians more treatment options for their chronic pain patients. These leads provide the broadest range of percutaneous lead configurations in the industry.

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We believe that we continue to have a technology advantage compared to our competitors with proprietary features such as Multiple Independent Current Control, which is intended to allow the physician to target specific areas of pain more precisely. We are looking to strengthen the clinical evidence with spinal cord stimulation and are committed to studies designed to demonstrate cost effectiveness or demonstrate the value of proprietary features in our SCS system.

In January 2011, we completed the acquisition of Intelect Medical, Inc., a development-stage company developing advanced visualization and programming for the Vercise™ system. We believe this acquisition leverages the core architecture of our Vercise™ platform and will advance our technology in the field of deep-brain stimulation. During the third quarter of 2012, we received CE Mark approval for the use of our Vercise™ Deep Brain Stimulation (DBS) System for the treatment of Parkinson's disease in Europe. We believe we have an exciting opportunity in DBS with our ability to customize the field designed to precisely stimulate the target without extraneous stimulation of adjacent areas that may cause unwanted side effects.

Urology/Women’s Health

Our Urology/Women’s Health division develops, manufactures and sells devices to treat various urological and gynecological disorders. Within our Urology business, we sell a variety of products designed to treat patients with urinary stone disease and benign prostatic hyperplasia (BPH). We offer a full line of stone management products, including ureteral stents, wires, lithotripsy devices, stone retrieval devices, sheaths, balloons and catheters. Within our Women's health business, we market a range of devices for the treatment of conditions such as female urinary incontinence, pelvic floor reconstruction (rebuilding of the anatomy to its original state), and menorrhagia (excessive menstrual bleeding). We offer a full breadth of mid-urethral sling products, sling materials, graft materials, pelvic floor reconstruction kits, and suturing devices. We market our Genesys Hydro ThermAblator® (HTA) system, a next-generation endometrial ablation system designed to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia. The Genesys HTA System features a smaller and lighter console, simplified set-up requirements, and an enhanced graphic user interface and is designed to improve operating performance.

Electrophysiology

Within our Electrophysiology business, we develop less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart. Included in our product offerings are radio frequency (RF) generators, steerable RF ablation catheters, intracardiac ultrasound catheters, diagnostic catheters, delivery sheaths, and other accessories. Our leading products include the Blazer® and Blazer Prime® line of temperature ablation catheters, designed to deliver enhanced performance, responsiveness, and durability. Our cooled ablation portfolio includes the only closed-loop irrigated catheter on the market, the Chilli II® cooled ablation catheter, and the newly launched Blazer™ Open-Irrigated ablation catheter with a unique Total Tip Cooling™ Design. In 2012, we received Health Canada and CE Mark approval of the Blazer™ Open-Irrigated Catheter, our latest radiofrequency ablation (RFA) catheter designed to treat a variety of arrhythmias such as atrial fibrillation, atrial flutter, ventricular tachycardia and other supraventricular tachycardias.

Additionally, on October 9, 2012, we acquired Rhythmia Medical, Inc., a developer of next-generation mapping and navigation solutions for use in cardiac catheter ablations and other electrophysiology procedures, including atrial fibrillation and atrial flutter. We believe that this acquisition, as well as the recent and expected product launches, will help to position us to competitively participate in the fast-growing Electrophysiology market.

Cardiac Rhythm Management

We develop, manufacture and market a variety of implantable devices that monitor the heart and deliver electricity to treat cardiac abnormalities, including:

- Implantable cardioverter defibrillator (ICD) systems used to detect and treat abnormally fast heart rhythms (tachycardia) that could result in sudden cardiac death, including the world's first and only commercially available subcutaneous implantable cardioverter defibrillator - the S-ICD® System, and implantable cardiac resynchronization therapy defibrillator (CRT-D) systems used to treat heart failure; and
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Implantable pacemaker systems used to manage slow or irregular heart rhythms (bradycardia), including implantable cardiac resynchronization therapy pacemaker (CRT-P) systems used to treat heart failure.

A key component of many of our implantable device systems is our remote LATITUDE® Patient Management System, which enables physicians to monitor device performance remotely while patients are in their homes, allowing for more frequent monitoring in order to guide treatment decisions.

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In the first half of 2012, we launched our INGENIO™ family of pacemaker systems in the U.S. and EMEA, and in the third quarter of 2012, we received CE Mark approval for use of our INGENIO™ and ADVANTIO™ pacemakers in patients in need of a magnetic resonance imaging (MRI) scan, which we believe represents a significant advancement to our family of pacemaker devices. In the second quarter of 2012, we received FDA approval for our INVIVE™ cardiac resynchronization therapy pacemakers (CRT-Ps). INVIVE™ is built on the same platform as our high voltage cardiac resynchronization therapy defibrillator (CRT-Ds), is enabled for remote patient monitoring, and includes features that promote ease of use. Also during the first half of 2012, we completed the acquisition of Cameron Health, Inc. (Cameron). Cameron developed the world's first and only commercially available subcutaneous implantable cardioverter defibrillator - the S-ICD® System, which we believe is a differentiated technology that will provide us the opportunity to both increase our market share in the existing ICD market and expand that market over time. The S-ICD® system has CE Mark approval and is available in EMEA. In addition, during the third quarter of 2012 we received FDA approval for the S-ICD® system and commenced a limited commercial launch in the U.S. With this approval, we are now able to offer our U.S. physician customers an entirely new option to treat their patients who are at risk for sudden cardiac arrest. We believe the recent product developments noted above will help to better position us within the CRM market.

Interventional Cardiology

Coronary Stent Systems

Our broad, innovative product offerings have enabled us to become a leader in the interventional cardiology market. This leadership is due in large part to our coronary stent product offerings. Coronary stents are tiny, mesh tubes used in the treatment of coronary artery disease, which are implanted in patients to prop open arteries and facilitate blood flow to and from the heart. We believe we have further enhanced the outcomes associated with the use of coronary stents, particularly the processes that lead to restenosis (the growth of neointimal tissue within an artery after angioplasty and stenting), through dedicated internal and external product development, strategic alliances and scientific research of drug-eluting stent systems. We market our internally-developed and self-manufactured PROMUS® Element™ everolimus-eluting stent platform in all major markets worldwide, as well as our TAXUS® paclitaxel-eluting stent line, including our third-generation TAXUS® Element™ stent system. We are the only company in the industry to offer a two-drug platform strategy with our paclitaxel-eluting and everolimus-eluting stent system offerings, and we offer a broad range of stent sizes. In addition, during the fourth quarter of 2012, we received CE Mark approval for the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System featuring an ultra-thin abluminal (outer) bioabsorbable polymer coating. The SYNERGY Stent is unique in that its proprietary polymer and everolimus drug coating dissipate by three months. This innovation has the potential to improve post-implant vessel healing and will eliminate long-term polymer exposure, a possible cause of late adverse events. In the first quarter of 2013, we also received CE Mark approval and launched our next-generation Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System in Europe and other select geographies.

Core Coronary Technology

We market a broad line of products used to treat patients with atherosclerosis, a principal cause of coronary artery obstructive disease which is characterized by a thickening of the walls of the coronary arteries and a narrowing of arterial openings caused by the progressive development of deposits of plaque. Our product offerings include balloon catheters, rotational atherectomy systems, guide wires, guide catheters, embolic protection devices, and diagnostic catheters used in percutaneous transluminal coronary angioplasty (PTCA) procedures, as well as intravascular ultrasound (IVUS) imaging system. In addition, in October 2012, we completed the acquisition of BridgePoint Medical, Inc., a developer of proprietary, catheter-based systems to treat coronary chronic total occlusions (CTOs). Through this acquisition we expect to augment our current portfolio of Interventional Cardiology products, which we believe will enable us to be a single-source supplier for complex PCI procedures. During 2012 we received FDA clearance for our Emerge™ Percutaneous Transluminal Coronary Angioplasty (PTCA) Balloon Dilatation Catheter and began marketing the device in the United States. The Emerge Catheter is a next-generation pre-dilatation balloon catheter designed specifically to offer exceptional deliverability for physicians to address challenging lesions in coronary arteries. Both the Monorail® and Over-The-Wire (OTW) options are available. The Emerge Catheter has been commercially available in CE Mark countries since the second quarter of 2012.

Intraluminal Ultrasound Imaging

We market a family of intraluminal catheter-directed ultrasound imaging catheters and systems for use in coronary arteries and heart chambers as well as certain peripheral vessels. The iLab® Ultrasound Imaging System continues as our flagship console and is compatible with our full line of imaging catheters. This system is designed to enhance the diagnosis and treatment of blocked vessels and heart disorders. Further, iLab systems have been placed in cardiology labs worldwide which provide an installed base through which we expect to launch new products, including an improved line of coronary Intravascular Vessel Imaging catheters and an integrated Fractional Flow Reserve (FFR) device. Following regulatory approval, these Imaging products would provide our cardiology sales force with a differentiated product offering in one of the fastest growing segments of interventional cardiology.

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Structural Heart Therapy

In January 2011, we completed the acquisition of Sadra Medical, Inc. (Sadra). Through the acquisition of Sadra, we are developing a fully repositionable and retrievable device for transcatheter aortic valve replacement (TAVR) to treat through patients with severe aortic stenosis. The Lotus™ Valve System consists of a stent-mounted tissue valve prosthesis and catheter delivery system for guidance and placement of the valve. The low-profile delivery system and introducer sheath are designed to enable accurate positioning, repositioning and retrieval at any time prior to release of the aortic valve implant. We believe TAVR is one of the fastest growing medical device markets.

In March 2011, we completed the acquisition of Atritech, Inc. (Atritech). Atritech developed a novel device designed to close the left atrial appendage in patients with atrial fibrillation (AF) who are at risk for ischemic stroke. The WATCHMAN® Left Atrial Appendage Closure Technology (WATCHMAN® LAA), developed by Atritech, is the first device proven in a randomized clinical trial to offer an alternative to anticoagulant drugs, and is approved for use in CE Mark countries. Additionally in August 2012, European regulators approved an expanded indication for the WATCHMAN® LAA Closure Device. The new indication offers patients with AF, and a contraindication to warfarin and the newer oral anticoagulants, a new treatment option for stroke reduction.

Innovation

Our approach to innovation combines internally-developed products and technologies with those we may obtain externally through strategic acquisitions and alliances. Our research and development efforts are focused largely on the development of next-generation and novel technology offerings across multiple programs and divisions. In addition, we have undertaken strategic acquisitions to help enable us to continue to be a leader in the medical device industry. We expect to continue to invest in our core franchises, and also investigate opportunities to further expand our presence in, and diversify into, strategic growth adjacencies. We have closed several acquisitions targeting many of these areas. In 2011, we completed the acquisitions of Sadra Medical, Inc., Intelect Medical, Inc., and Atritech, Inc., and in 2012, we completed the acquisitions of Cameron Health Inc., BridgePoint Medical, Inc., Rhythmia Medical Inc., and Vessix Vascular Inc., all discussed above. There can be no assurance that technologies developed internally or acquired through acquisitions and alliances will achieve technological feasibility, obtain regulatory approvals or gain market acceptance, and any delay in the development or approval of these technologies may adversely impact our ability to drive future growth.

Research and Development

Our investment in research and development is critical to driving our future growth. We expended $886 million on research and development in 2012, $895 million in 2011 and $939 million in 2010, representing approximately 12 percent of our net sales each year. Our investment in research and development reflects:

- regulatory compliance, clinical science, and internal research and development programs, as well as other programs obtained through our strategic acquisitions and alliances; and

- engineering efforts which incorporate customer feedback into continuous improvement efforts for currently marketed and next-generation products.

We have directed our development efforts toward regulatory compliance and innovative technologies designed to expand current markets or enter adjacent markets. We are transforming the way we conduct research and development and are scrutinizing our cost structure, which we expect will enhance our overall efficiency and effectiveness. Our approach to new product design and development is through focused, cross-functional teams. We believe that our formal process for technology and product development aids in our ability to offer innovative and manufacturable products in a consistent and timely manner. Involvement of the research and development, clinical, quality, regulatory, manufacturing and marketing teams early in the process is the cornerstone of our product development cycle. This collaboration allows these teams to concentrate resources on the most viable and clinically relevant new products and technologies, and focus on bringing them to market in a timely and cost-effective manner. In addition to internal development, we work with hundreds of leading research institutions, universities and clinicians around the

world to develop, evaluate and clinically test our products. We believe our future success will depend upon the strength of these development efforts.

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Marketing and Sales

During 2012, we marketed our products to over 13,000 hospitals, clinics, outpatient facilities and medical offices in nearly 100 countries worldwide. The majority of our net sales are derived from countries in which we have direct sales organizations. We also have a network of distributors and dealers who offer our products in certain countries and markets, which accounts for our remaining sales. We expect to continue to leverage our infrastructure in markets where commercially appropriate and use third parties in those markets where it is not economical or strategic to establish or maintain a direct presence. We are not dependent on any single institution and no single institution accounted for more than ten percent of our net sales in 2012 or 2011; however, large group purchasing organizations, hospital networks and other buying groups have become increasingly important to our business and represent a substantial portion of our U.S. net sales. We have a dedicated corporate sales organization in the U.S. focused principally on selling to major buying groups and integrated healthcare networks. We consistently strive to understand and exceed the expectations of our customers. Each of our businesses maintains dedicated sales forces and marketing teams focusing on physicians who specialize in the diagnosis and treatment of different medical conditions. We believe that this focused disease state management enables us to develop highly knowledgeable and dedicated sales representatives and to foster collaborative relationships with physicians. We believe that we have positive working relationships with physicians and others in the medical industry, which enable us to gain a detailed understanding of new therapeutic and diagnostic alternatives and to respond quickly to the changing needs of physicians and their patients.

International Operations

International net sales accounted for approximately 50 percent of our net sales in 2012. Net sales and operating income attributable to our 2012 geographic regions are presented in Note O – Segment Reporting to our 2012 consolidated financial statements included in Item 8 of this Annual Report, incorporated by reference herein. Our international structure operates through three international business units: EMEA, consisting of Europe, the Middle East and Africa; Japan; and Inter-Continental, consisting of our Asia Pacific and the Americas reporting units. Maintaining and expanding our international presence is an important component of our long-term growth plan. Through our international presence, we seek to increase net sales and market share, leverage our relationships with leading physicians and their clinical research programs, accelerate the time to bring new products to market, and gain access to worldwide technological developments that we can implement across our product lines. We are investing in infrastructure in emerging markets in order to introduce new products and strengthen our sales capabilities in these countries. A discussion of the risks associated with our international operations is included in Item 1A of this Annual Report.

As of December 31, 2012, we had six international manufacturing facilities, including three in Ireland, two in Costa Rica and one in Puerto Rico. Approximately 59 percent of our products sold worldwide during 2012 were manufactured at these facilities. Additionally, we maintain international research and development capabilities in Ireland, as well as physician training centers in France and Japan.

Manufacturing and Raw Materials

We are focused on continuously improving our supply chain effectiveness, strengthening our manufacturing processes and increasing operational efficiencies within our organization. By shifting global manufacturing along product lines, we are able to leverage our existing resources and concentrate on the development and commercial launch of new products and the enhancement of existing products. We continue to implement new systems designed to provide improved quality and reliability, service, greater efficiency and lower supply chain costs, and have substantially increased our focus on process controls and validations, supplier controls, distribution controls and providing our operations teams with the training and tools necessary to drive continuous improvement in product quality. In addition, we remain focused on examining our operations and general business activities to identify cost-improvement opportunities in order to enhance our operational effectiveness.

Our products are designed and manufactured in technology centers around the world, either by us or third parties. In most cases, the manufacturing of our products is concentrated in one or a few locations. We consistently monitor our inventory levels, manufacturing and distribution capabilities, and maintain recovery plans to address potential disruptions that we may encounter. However, significant interruptions in our manufacture of products for an extended

duration may result in loss of market share, which could adversely affect our results of operations and financial condition.

Many components used in the manufacture of our products are readily fabricated from commonly available raw materials or off-the-shelf items available from multiple supply sources; however, certain items are custom made to meet our specifications. We believe that in most cases, redundant capacity exists at our suppliers and that alternative sources of supply are available or could be developed within a reasonable period of time. We also have an on-going program to identify single-source components and to develop alternative back-up supplies and we regularly re-address the adequacy and abilities of our suppliers to meet our needs.

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In certain cases, we may not be able to quickly establish additional or replacement suppliers for specific materials, components or products, largely due to the regulatory approval system and the complex nature of our manufacturing processes and those of our suppliers. A reduction or interruption in supply, an inability to develop and validate alternative sources if required, or a significant increase in the price of raw materials, components or products could adversely affect our operations and financial condition, particularly materials or components related to our CRM products and drug-eluting stent systems. In addition, our products require sterilization prior to sale and we utilize a mix of internal resources and third-party vendors to perform this service. We believe we have capabilities sufficient to sterilize our products; however, to the extent we or our third-party sterilizers are unable to sterilize our products, whether due to capacity, regulatory or other constraints, we may be unable to transition to other providers in a timely manner, which could have an adverse impact on our operations.

Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act, the Securities and Exchange Commission (SEC) promulgated final rules regarding disclosure of the use of certain minerals, known as conflict minerals, which are mined from the Democratic Republic of the Congo and adjoining countries. These rules may impose additional costs on us, including for diligence as to the sources of any conflict minerals used in our products, as well as for any resulting changes we make to products, processes, or sources of supply. In addition, these rules could have an adverse effect on the sourcing, supply, and pricing of materials used in our products.

Quality Assurance

We are committed to providing high quality products to our customers. To meet this commitment, we have implemented updated quality systems and concepts throughout our organization. Our quality system starts with the initial product specification and continues through the design of the product, component specification process and the manufacturing, sale and servicing of the product. Our quality system is intended to build in quality and process control and to utilize continuous improvement concepts throughout the product life. These systems are designed to enable us to satisfy the various international quality system regulations, including those of the FDA with respect to products sold in the U.S. All of our manufacturing facilities, including our U.S. and European distribution centers, are certified under the ISO13485 quality system standard, established by the International Standards Organization, for medical devices, which requires, among other items, an implemented quality system that applies to component quality, supplier control, product design and manufacturing operations. This certification can be obtained only after a complete audit of a company’s quality system by an independent outside auditor. Maintenance of the certification requires that these facilities undergo periodic re-examination.

In addition, we maintain an on-going initiative to seek ISO14001 certification at our plants around the world. ISO14001 is a globally recognized standard for Environmental Management Systems, established by the International Standards Organization, which provides a voluntary framework to identify key environmental aspects associated with our business. We engage in continuous environmental performance improvement efforts, and at present, as it relates to our major manufacturing and Tier 1 distribution facilities, 13 of our 14 facilities have attained ISO14001 certification. We are committed to achieving ISO14001 certification at all of our major manufacturing facilities and Tier I distribution centers worldwide.

Competition

We encounter significant competition across our product lines and in each market in which we sell our products from various companies, some of which may have greater financial and marketing resources than we do. Our primary competitors include Abbott Laboratories; Medtronic, Inc.; and St. Jude Medical, Inc. as well as a wide range of medical device companies that sell a single or limited number of competitive products or participate in only a specific market segment. We also face competition from non-medical device companies, such as pharmaceutical companies, which may offer alternative therapies for disease states intended to be treated using our products.

We believe that our products compete primarily on their ability to safely and effectively perform diagnostic and therapeutic procedures in a less-invasive manner, as well as clinical outcomes, ease of use, comparative effectiveness, reliability and physician familiarity. In the current environment of managed care, economically-motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price, value, reliability and efficiency. We believe the current global economic conditions and healthcare reform measures could put additional competitive pressure on us, including on

our average selling prices, overall procedure rates and market sizes. We recognize that our continued competitive success will depend upon our ability to offer products with differentiated clinical outcomes; create or acquire innovative, scientifically advanced technology; apply our technology cost-effectively and with superior quality across product lines and markets; develop or acquire proprietary products; attract and retain skilled personnel; obtain patent or other protection for our products; obtain required regulatory and reimbursement approvals; continually enhance our quality systems; manufacture and successfully market our products either directly or through outside parties; and supply sufficient inventory to meet customer demand.

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Regulatory Environment

The medical devices that we manufacture and market are subject to regulation by numerous worldwide regulatory bodies, including the FDA and comparable international regulatory agencies. These agencies require manufacturers of medical devices to comply with applicable laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of medical devices. Devices are generally subject to varying levels of regulatory control, based on the risk level of the device.

In the U.S., authorization to commercially distribute a new device generally can be met in one of three ways. The first process requires that a premarket notification (510(k)) be made to the FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device, the "predicate" device. Applicants must submit performance data to establish substantial equivalence. In some instances, data from human clinical trials must also be submitted in support of a 510(k) premarket notification. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption (IDE) regulations. The FDA must issue a decision finding substantial equivalence before commercial distribution can occur. Changes to cleared devices that could not significantly affect the safety or effectiveness of the device can generally be made without additional 510(k) premarket notifications; otherwise, a new 510(k) is required.

The second process requires the submission of a premarket approval (PMA) application to the FDA to demonstrate that the device is safe and effective for its intended use. This approval process applies to most Class III devices, and generally requires clinical data to support the safety and effectiveness of the device, obtained in adherence with IDE requirements. The FDA will approve the PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose, and that the proposed manufacturing is in compliance with the Quality System Regulation (QSR). This process is generally more detailed, lengthier and more expensive than the 510(k) process.

The third process requires that an application for a Humanitarian Device Exemption (HDE) be made to the FDA for the use of a Humanitarian Use Device (HUD). An HUD is intended to benefit patients by treating or diagnosing a disease or condition that affects, or is manifested in, fewer than 4,000 individuals in the U.S. per year. The application submitted to the FDA for an HDE is similar in both form and content to a PMA application, but is exempt from the effectiveness requirements of a PMA. The HUD provision of the regulation provides an incentive for the development of devices for use in the treatment or diagnosis of diseases affecting smaller patient populations.

In the European Union, we are required to comply with applicable medical device directives (including the Medical Devices Directive and the Active Implantable Medical Devices Directive) and obtain CE Mark certification in order to market medical devices. The CE Mark is applied following approval from an independent notified body or declaration of conformity. It is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. We are also required to comply with the regulations of each other country where we commercialize products, such as the requirement that we obtain approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) before we can launch new products in Japan.

The FDA and other worldwide regulatory agencies actively monitor compliance to local laws and regulations through review and inspection of design and manufacturing practices, record keeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices; detain or seize adulterated or misbranded medical devices; order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin first. Most countries outside of the U.S. require that product approvals be recertified on a regular

basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

Our global regulatory environment is becoming increasingly stringent, and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded on existing regulations. Certain regulators are exhibiting less flexibility and are requiring local data in addition to global data.

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While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact our ability to obtain future approvals for our products, or could increase the cost and time to obtain such approvals in the future.
We are also subject to various environmental laws, directives and regulations both in the U.S. and abroad. Our operations, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We do not believe that compliance with environmental laws will have a material impact on our capital expenditures, earnings or competitive position. However, given the scope and nature of these laws, there can be no assurance that environmental laws will not have a material impact on our results of operations. We assess potential environmental contingent liabilities on a regular basis. At present, we are not aware of any such liabilities that would have a material impact on our business.
We believe that sound environmental, health and safety performance contributes to our competitive strength while benefiting our customers, shareholders and employees. We are committed to continuous improvement in these areas by reducing pollution, the depletion of natural resources, and our overall environmental footprint. Specifically, we are working to optimize energy and resource usage, ultimately reducing greenhouse gas emissions and waste. We are certified to the FTSE4Good Corporate Social Responsibility Index, managed by The Financial Times and the London Stock Exchange, which measures the performance of companies that meet globally recognized standards of corporate responsibility. This certification recognizes our dedication to those standards, and it places us in a select group of companies with a demonstrated commitment to responsible business practices and sound environmental policies.

Government Affairs

We maintain a global Government Affairs presence, headquartered in Washington D.C., to actively monitor and advocate on a myriad of legislation and policies impacting us, both on a domestic and an international front. The Government Affairs office works closely with members of Congress and committee staff, the White House and Administration office, state legislatures and regulatory agencies, and governments overseas on issues affecting our business. Our proactive approach and depth of political and policy expertise are aimed at having our positions heard by federal, state and global decision-makers, while also advancing our business objectives by educating policymakers on our positions, key priorities and the value of our technologies. The Government Affairs office also manages our political action committee and works closely with trade groups on issues affecting our industry and healthcare in general.

Healthcare Reform

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives related to limiting the growth of healthcare costs (including price regulation); competitive pricing; coverage and payment policies; comparative effectiveness of therapies; technology assessments; and health care delivery structure reforms, are continuing in many countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. Although we believe our less-invasive products and technologies generate favorable clinical outcomes, value and cost efficiency, the resources necessary to demonstrate value to our customers, patients, payors, and other stakeholders may be significant. In addition, uncertainty remains regarding the continued implementation of the Patient Protection and Affordable Care Act (ACA) and its impact to our business.
Further, the federal government, as part of the ACA, and certain state governments have enacted laws aimed at increasing transparency in relationships between medical device, biologics and pharmaceutical companies and healthcare professionals (HCPs). As a result, we are required by law to report many types of payments made and items of value provided to HCPs licensed by certain states. On the federal level, we are required to begin tracking financial relationships in August 2013 and reporting by the end of the first quarter of 2014. We have devoted substantial time and financial resources in order to develop and implement enhanced structure, policies, systems and processes in order to comply with these U.S. federal and state legal and regulatory requirements. In addition, certain foreign jurisdictions are currently acting to implement similar laws. Failure to adhere to our policies, comply with required laws or implement adequate policies and practices to address changes to legal and regulatory requirements could have a negative impact on our results of operations. Additionally, new legislation imposes a 2.3 percent excise tax on medical

device manufacturers on U.S. sales of Class I, II and III medical devices beginning in January 2013.

Third-Party Coverage and Reimbursement

Our products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third-party payors, including governmental programs (e.g., Medicare and Medicaid in the United States), private insurance plans and managed care programs, for the healthcare services provided to their patients.

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We expect that pricing of medical devices will remain under pressure as alternative payment models such as bundling, value-based purchasing and accountable care organizations (ACOs) begin to take shape in the United States. Initiatives to limit the growth of healthcare costs, including price regulation, are also underway in many countries in which we do business. Implementation of cost containment initiatives and healthcare reforms in significant markets such as the U.S., Japan, Europe and other markets may limit the price of, or the level at which reimbursement is provided for, our products and may influence a physician's selection of products used to treat patients.

In addition, patients and clinicians are becoming more informed on the risks and benefits of alternative treatments as comparative effectiveness research findings are beginning to be disseminated. Therefore, we believe that compelling clinical and economic data will become increasingly important to demonstrate efficacy and justify the economic benefits of technology purchases.

Third-party payors and governments may provide or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Reimbursement by payors for these services is based on a wide range of methodologies that may reflect the services' assessed resource costs, clinical outcomes and economic value. These reimbursement methodologies confer different, and sometimes conflicting, levels of financial risk and incentives to healthcare providers and patients, and these methodologies are subject to frequent refinements.

Third-party payors are also increasingly adjusting reimbursement rates, often downwards, and challenging the prices charged for medical products and services. There can be no assurance that our products will be automatically covered by third-party payors, that reimbursement will be available or, if available, that the third-party payors' coverage policies will not adversely affect our ability to sell our products profitably.

Proprietary Rights and Patent Litigation

We rely on a combination of patents, trademarks, trade secrets and non-disclosure agreements to protect our intellectual property. We generally file patent applications in the U.S. and foreign countries where patent protection for our technology is appropriate and available. As of December 31, 2012, we held more than 15,000 patents, and had approximately 7,300 patent applications pending worldwide that cover various aspects of our technology. In addition, we hold exclusive and non-exclusive licenses to a variety of third-party technologies covered by patents and patent applications. There can be no assurance that pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage. In the aggregate, these intellectual property assets and licenses are of material importance to our business; however, we believe that no single patent, technology, trademark, intellectual property asset or license, except for those relating to our drug-eluting coronary stent systems, is material in relation to our business as a whole.

We rely on non-disclosure and non-competition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop equivalent proprietary information or that third parties will not otherwise gain access to our trade secrets and proprietary knowledge.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, particularly in the areas in which we compete. We continue to defend ourselves against claims and legal actions alleging infringement of the patent rights of others. Adverse determinations in any patent litigation could subject us to significant liabilities to third parties, require us to seek licenses from third parties, and, if licenses are not available, prevent us from manufacturing, selling or using certain of our products, which could have a material adverse effect on our business. Additionally, we may find it necessary to initiate litigation to enforce our patent rights, to protect our trade secrets or know-how and to determine the scope and validity of the proprietary rights of others. Patent litigation can be costly and time-consuming, and there can be no assurance that our litigation expenses will not be significant in the future or that the outcome of litigation will be favorable to us. Accordingly, we may seek to settle some or all of our pending litigation, particularly to manage risk over time. Settlement may include cross licensing of the patents that are the subject of the litigation as well as our other intellectual property and may involve monetary payments to or from third parties.

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We maintain an insurance policy providing limited coverage against securities claims, and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims or adverse decisions. See Item 3 and Note K – Commitments and Contingencies to our 2012 consolidated financial statements included in Item 8 of this Annual Report for a discussion of intellectual property and other litigation and proceedings in which we are involved. In management's opinion, we are not currently involved in any legal proceeding other than those specifically identified in Note K, which, individually or in the aggregate, could have a material effect on our financial condition, operations and/or cash flows.

Risk Management

We have an Enterprise Risk Management (ERM) program in which we provide coordinated oversight, control and continuous improvement of processes and tools used to identify and manage business risk. On an annual basis, we reassess our risks based on the Committee of Sponsoring Organizations of the Treadway Commission (COSO) ERM framework in the areas of strategic risk, financial risk, external risk, operational risk and compliance risk with the goal of achieving our business strategies and objectives. This assessment, which engages key individuals from our Board of Directors and management, provides increased visibility into the risks we face, highlights risk interdependencies, and seeks to improve overall risk management effectiveness.

Current Economic Climate

Our results of operations could be substantially affected by global economic factors and local operating and economic conditions. Our customers may experience financial difficulties or be unable to borrow money to fund their operations which may adversely impact their ability or decision to purchase our products, particularly capital equipment, or to pay for our products they do purchase on a timely basis, if at all. We cannot predict to what extent global economic conditions, including the increased focus on healthcare systems and costs in the U.S. and abroad may negatively impact our average selling prices, our net sales and profit margins, procedural volumes and reimbursement rates from third-party payors.

Employees

As of December 31, 2012, we had approximately 24,000 employees, including approximately 12,000 in operations; 6,000 in selling, marketing and distribution; 4,000 in clinical, regulatory and research and development; and 2,000 in administration. Of these employees, we employed approximately 10,000 outside the U.S., approximately 7,000 of whom are in the manufacturing operations function. We believe that the continued success of our business will depend, in part, on our ability to attract and retain qualified personnel, and we are committed to developing our people and providing them with opportunities to contribute to our growth and success.

Community Outreach

We are committed to making more possible in the communities where we live and work. We bring this commitment to life by supporting global, national and local health and education initiatives, striving to improve patient advocacy, adhering to strong ethical standards that deliver on our commitments, and minimizing our impact on the environment.

A prominent example of our ongoing commitment to patients is our Close the Gap program, which aims to eliminate cardiovascular care disparities by helping to ensure all patients - regardless of age, gender, race, ethnicity or primary language - receive access to optimal cardiac care.

To achieve this goal, Close the Gap provides awareness to the community about cardiovascular risk factors, teaches healthcare providers about cultural beliefs and barriers to treatment, and advocates for measures that help ensure all patients receive the cardiovascular care they need. By sponsoring programs and working via partnerships in the community, our Close the Gap program has helped these messages reach over one million people.

Through the Boston Scientific Foundation, established in 2001, we fund non-profit organizations in our local communities. Community grants focus on increasing access to quality healthcare and improving educational opportunities, particularly with regards to science, technology, engineering and math (STEM) education. Boston Scientific has committed to contributing $15 million to our Close the Gap program and STEM education.

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Seasonality

Our worldwide sales do not reflect any significant degree of seasonality; however, customer purchases have historically been lighter in the third quarter of the year, as compared to other quarters. This reflects, among other factors, lower demand during summer months in the northern hemisphere, particularly in European countries.

Available Information

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website (www.bostonscientific.com) as soon as reasonably practicable after we electronically file the material with or furnish it to the U.S. Securities and Exchange Commission (SEC). Printed copies of these posted materials are also available free of charge to shareholders who request them in writing from Investor Relations, One Boston Scientific Place, Natick, MA 01760-1537. Information on our website or linked to our website is not incorporated by reference into this Annual Report.

Safe Harbor for Forward-Looking Statements

Certain statements that we may make from time to time, including statements contained in this Annual Report and information incorporated by reference into this Annual Report, constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements may be identified by words like “anticipate,” “expect,” “project,” “believe,” “plan,” “may,” “estimate,” “intend” and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our financial performance; our business and results of operations; our business strategy and related financial returns; our growth initiatives, including our emerging markets strategy and investments; acquisitions and related payments, and the integration and impact of acquired businesses and technologies; finalizing the separation of our Neurovascular business; the timing and impact of our restructuring and plant network optimization initiatives, including expected costs and cost savings; our intention not to pay dividends; use of our cash flow; our outstanding accounts receivable in Europe; our estimates for the U.S. and worldwide CRM markets; our estimates for the worldwide coronary stent market; changes in the market and our market share for our other businesses; procedural volumes and pricing pressures; competitive pressures facing our businesses; our royalty and other expenses; clinical trials, including timing and results; our product portfolio; product development and iterations; new and existing product launches, including their timing and acceptance, and their impact on the market and our business; competitive product launches; product performance and our ability to gain a competitive advantage; the strength of our technologies and pipeline; timing of regulatory approvals; our regulatory and quality compliance; expected research and development efforts and the allocation of research and development expenditures; our sales and marketing strategy; reimbursement practices; the ability of our suppliers and sterilizers to meet our requirements; our ability to meet customer demand; goodwill and other intangible asset impairment analysis and charges; the effect of new accounting pronouncements on our financial results; the impact of healthcare reform legislation, including compliance with the Affordable Care Act; the effect of new and proposed tax laws, including the medical devise excise tax; the outcome and timing of matters before taxing authorities; our tax position and income tax reserves, and our ability to realize all our deferred tax assets; the outcome and impact of intellectual property, qui tam actions, governmental investigations and proceedings and litigation matters; adequacy of our reserves; the drivers and impact of our investment ratings; anticipated expenses and capital expenditures and our ability to finance them; and our ability to meet the financial covenants required by our credit facilities, or to renegotiate the terms of or obtain waivers for compliance with those covenants. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements. Except as required by law, we do not intend to update any forward-looking statements even if new information becomes available or other events occur in the future.

The forward-looking statements in this Annual Report are based on certain risks and uncertainties, including the risk factors described in Item 1A under the heading “Risk Factors” and the specific risk factors discussed below and in connection with forward-looking statements throughout this Annual Report, which could cause actual results to vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the forward-looking statements. These additional factors include, among other things, future political, economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation and governmental investigations; financial market conditions; and future business decisions made by us and our competitors, all of which are difficult or impossible to predict accurately and many of which are beyond our control. We caution each reader of this Annual Report to consider carefully these factors.

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The following are some of the important risk factors that could cause our actual results to differ materially from our expectations in any forward-looking statements. For further discussion of these and other risk factors, see Item 1A - Risk Factors.

Our Businesses

- Our ability to increase CRM net sales, including for both new and replacement units, expand the market and capture market share;

- The volatility of the coronary stent market and our ability to increase our drug-eluting stent systems net sales, including with respect to our SYNERGY™, PROMUS® Element™ and Promus PREMIER™ stent systems, and capture market share;

- The on-going impact on our business, including CRM and coronary stent businesses, of physician alignment to hospitals, governmental investigations and audits of hospitals, and other market and economic conditions on the overall number of procedures performed, including with respect to the drug-eluting coronary stent market the average number of stents used per procedure, and average selling prices;

- Competitive offerings and related declines in average selling prices for our products, particularly our drug-eluting coronary stent systems and our CRM products;

- The performance of, and physician and patient confidence in, our products and technologies, including our coronary drug-eluting stent systems and CRM products, or those of our competitors;

- The impact and outcome of ongoing and future clinical trials, including coronary stent and CRM clinical trials, and market studies undertaken by us, our competitors or other third parties;

- Our ability to timely and successfully launch new or next-generation products and technology features worldwide and across our businesses in line with our commercialization strategies, including our S-ICD® system;

- The effect of consolidation and competition in the markets in which we do business, or plan to do business;

- Disruption in the manufacture or supply of certain components, materials or products, or the failure to timely secure alternative manufacturing or additional or replacement components, materials or products;

- Our ability to retain and attract key personnel, including in our cardiology and CRM sales force and other key cardiology and CRM personnel;

- The impact of enhanced requirements to obtain regulatory approval in the U.S. and around the world, including the associated timing and cost of product approval; and

- The impact of increased pressure on the availability and rate of third-party reimbursement for our products and procedures in the U.S and around the world, including with respect to the timing and costs of creating and expanding markets for new products and technologies.

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Regulatory Compliance and Litigation

- The impact of healthcare policy changes and legislative or regulatory efforts in the U.S. and around the world to modify product approval or reimbursement processes, including a trend toward demonstrating clinical outcomes, comparative effectiveness and cost efficiency, as well as the impact of other healthcare reform legislation;

- Risks associated with our regulatory compliance and quality systems and activities in the U.S. and around the world, including meeting regulatory standards applicable to manufacturing and quality processes;

- Our ability to minimize or avoid future field actions or FDA warning letters relating to our products and processes and the on-going inherent risk of potential physician advisories related to medical devices;

- The impact of increased scrutiny of and heightened global regulatory enforcement facing the medical device industry arising from political and regulatory changes as well as economic pressures;

- The effect of our litigation and risk management practices, including self-insurance, and compliance activities on our loss contingencies, legal provision and cash flows;

- The impact of, diversion of management attention as a result of, and costs to cooperate with, litigate and/or resolve, governmental investigations and our class action, product liability, contract and other legal proceedings; and

- Risks associated with a failure to protect our intellectual property rights and the outcome of patent litigation.

Innovation and Certain Growth Initiatives

- The timing, size and nature of our strategic growth initiatives and market opportunities, including with respect to our internal research and development platforms and externally available research and development platforms and technologies, and the ultimate cost and success of those initiatives and opportunities;

- Our ability to complete planned clinical trials successfully, obtain regulatory approvals and launch new and next generation products in a timely manner consistent with cost estimates, including the successful completion of in-process projects from purchased research and development;

- Our ability to identify and prioritize our internal research and development project portfolio and our external investment portfolio on profitable revenue growth opportunities as well as to keep them in line with the estimated timing and costs of such projects and expected revenue levels for the resulting products and technologies;

- Our ability to successfully develop, manufacture and market new products and technologies in a timely manner and the ability of our competitors and other third parties to develop products or technologies that render our products or technologies noncompetitive or obsolete;

- The impact of our failure to succeed at or our decision to discontinue, write-down or reduce the funding of any of our research and development projects, including in-process projects from purchased research and development, in our growth adjacencies or otherwise;

- Dependence on acquisitions, alliances or investments to introduce new products or technologies and to enter new or adjacent growth markets, and our ability to fund them or to fund contingent payments with respect to those acquisitions, alliances and investments; and

- The failure to successfully integrate and realize the expected benefits from the strategic acquisitions, alliances and investments we have consummated or may consummate in the future.

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International Markets

- Our dependency on international net sales to achieve growth, including in emerging markets;
- The impact of changes in our international structure and leadership;
- Risks associated with international operations and investments, including political and economic conditions, protection of our intellectual property, compliance with established and developing local legal and regulatory requirements as well as changes in reimbursement practices and policies;
- Our ability to maintain or expand our worldwide market positions in the various markets in which we compete or seek to compete, including through investments in product diversification and emerging markets such as Brazil, Russia, India and China;
- Our ability to execute and realize anticipated benefits from our investments in emerging markets; and
- The potential effect of foreign currency fluctuations and interest rate fluctuations on our net sales, expenses and resulting margins.

Liquidity

- Our ability to generate sufficient cash flow to fund operations, capital expenditures, global expansion initiatives, litigation settlements, share repurchases and strategic investments and acquisitions as well as maintaining our investment grade ratings and managing our debt levels and covenant compliance;
- Our ability to access the public and private capital markets when desired and to issue debt or equity securities on terms reasonably acceptable to us;
- The unfavorable resolution of open tax matters, exposure to additional tax liabilities and the impact of changes in U.S. and international tax laws;
- The impact of examinations and assessments by domestic and international taxing authorities on our tax provision, financial condition or results of operations;
- The impact of goodwill and other intangible asset impairment charges, including on our results of operations; and
- The impact of the European sovereign debt crisis on our ability to collect outstanding and future receivables and/or sell receivables under our factoring programs.

Cost Reduction and Optimization Initiatives

- Risks associated with significant changes made or expected to be made to our organizational and operational structure, pursuant to our 2011 Restructuring plan as expanded and as a result of our 2010 Restructuring plan and Plant Network Optimization program; and
- Business disruption and employee distraction as we execute our global compliance program, restructuring plans and divestitures of assets or businesses and implementing strategic and restructuring initiatives.

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ITEM 1A. RISK FACTORS

In addition to the other information contained in this Annual Report and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition, cash flows or results of operations could be materially adversely affected by any of these risks. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements set forth at the end of Item 1 of this Annual Report. Additional risks not presently known to us or that we currently deem immaterial may also adversely affect our business, financial condition, cash flows or results of operations.

Declines in average selling prices for our products, particularly our drug-eluting coronary stent systems, may materially adversely affect our results of operations.

We have experienced pricing pressures across many of our businesses due to competitive activity, increased market power of our customers as the healthcare industry consolidates, economic pressures experienced by our customers, and the impact of managed care organizations and other third-party payors. Competitive pricing pressures have particularly affected our drug-eluting coronary stent system offerings. We estimate that the average selling price of our drug-eluting stent systems in the U.S. decreased seven percent in 2012 as compared to the prior year. Continued declines in average selling prices of our products due to pricing pressures may have an adverse impact on our results of operations.

We derive a significant portion of our net sales from the sale of drug-eluting coronary stent systems and CRM products. Declines in market size, average selling prices, procedural volumes, and our share of the markets in which we compete; increased competition; market perceptions of studies published by third parties; or product launch delays may materially adversely affect our results of operations and financial condition, including potential future write-offs of our goodwill and other intangible assets balances.

Net sales from drug-eluting coronary stent systems represented approximately 18 percent of our consolidated net sales during 2012. In 2012, lower average selling prices driven by competitive and other pricing pressures and declines in procedural volumes resulted in a decline in our share of the U.S. drug-eluting stent market, as well as an overall decrease in the size of the market. There can be no assurance that these and other factors will not further impact our share of the U.S. or worldwide drug-eluting stent markets, that we will regain or gain share of the U.S. or worldwide drug-eluting stent markets, or that the size of the U.S. drug-eluting stent market will reach previous levels or will not decline further, all of which could materially adversely affect our results of operations or financial condition. In addition, a delay in the timing of the launch of next-generation products, the overall performance of, and continued physician confidence in, those products may result in a further decline in our market share and have an adverse impact on our results of operations.

Net sales from our CRM group represented approximately 26 percent of our consolidated net sales in 2012. Our CRM net sales declined in 2012 primarily due to the impact of average selling price pressures driven by governmental, competitive and other pricing pressures, and lower procedural volumes as a result of continued contraction in the U.S. ICD market. Further, physician reaction to study results published by the Journal of the American Medical Association regarding evidence-based guidelines for ICD implants, the U.S. Department of Justice investigation into hospitals' ICD implant practices, the expansion of Medicare recovery audits and ongoing physician alignment to hospitals have had, and may continue to have, a negative impact on the size of the CRM market. Our U.S. ICD sales represented approximately 45 percent of our worldwide CRM net sales in 2012, and any changes in this market could have a material adverse effect on our financial condition or results of operations. There can be no assurance that the size of the CRM market will increase above existing levels or that we will be able to increase CRM market share or increase net sales in a timely manner, if at all. Decreases in market size or our share of the CRM market and decreases in net sales from our CRM products could have a significant impact on our financial condition or results of operations. In addition, our inability to increase our worldwide CRM net sales could result in future goodwill and other intangible asset impairment charges. Further, variability in the timing of the launch of next-generation products may result in excess or expired inventory positions and future inventory charges, or may result in a loss of market share and adversely impact our results of operations.

Consolidation in the healthcare industry could lead to increased demands for price concessions or the exclusion of some suppliers from certain of our significant market segments, which could have an adverse effect on our business, financial condition or results of operations.

The cost of healthcare has risen significantly over the past decade and numerous initiatives and reforms by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry, including hospitals.

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This consolidation has resulted in greater pricing pressures, decreased average selling prices, and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some of our hospital customers. There can be no assurance that measures we may take to address these trends will succeed. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors, which may continue to exert further downward pressure on the prices of our products and adversely impact our business, financial condition or results of operations.

We face intense competition and may not be able to keep pace with the rapid technological changes in the medical devices industry, which could have an adverse effect on our business, financial condition or results of operations.

The medical device markets in which we primarily participate are highly competitive. We encounter significant competition across our product lines and in each market in which our products are sold from various medical device companies, some of which may have greater financial and marketing resources than we do. Our primary competitors include Abbott Laboratories; Medtronic, Inc.; and St. Jude Medical, Inc., as well as a wide range of medical device companies that sell a single or limited number of competitive products or which participate in only a specific market segment. We also face competition from non-medical device companies, including pharmaceutical companies, which may offer alternative therapies for disease states intended to be treated using our products.

Additionally, the medical device markets in which we primarily participate are characterized by extensive research and development, and rapid technological change. Developments by other companies of new or improved products, processes or technologies may make our products or proposed products obsolete or less competitive and may negatively impact our net sales. We are required to devote continued efforts and financial resources to develop or acquire scientifically advanced technologies and products, apply our technologies cost-effectively across product lines and markets, obtain patent and other protection for our technologies and products, obtain required regulatory and reimbursement approvals and successfully manufacture and market our products consistent with our quality standards. If we fail to develop new products or enhance existing products, it could have a material adverse effect on our business, financial condition or results of operations.

Because we derive a significant amount of our net sales from international operations and a significant percentage of our future growth is expected to come from international operations, including from emerging markets, changes in international economic or regulatory conditions could have a material impact on our business, financial condition or results of operations.

Sales outside the U.S. accounted for approximately 50 percent of our net sales in 2012. Additionally, a significant percentage of our future growth is expected to come from international operations, including from our increased sales presence and other investments in emerging markets such as Brazil, Russia, China and India. We recently created a new Asia-Pacific regional organization under new leadership to further increase our capabilities and strengthen our position in this fast growing region. Sales practices in certain international markets, however, may be inconsistent with our desired business practices and U.S. legal requirements, which may impact our ability to expand as planned. In addition, we continue to invest in infrastructure in Brazil, China and India, including the development of a world class training center for healthcare providers and invest in local research and development and clinical studies. However, risks and uncertainties related to political and economic conditions in these regions, traditional business practices, foreign currency fluctuations, interest rate fluctuations, regulatory and reimbursement approvals, competitive offerings, infrastructure development complications and intellectual property protection may adversely impact our ability to implement our business strategy in these markets and, as a result, our sales growth and operating profits from our international operations may be adversely affected.

Further, international markets are increasingly being affected by economic pressure to contain reimbursement levels and healthcare costs; and certain international markets may also be impacted by foreign government efforts to understand healthcare practices and pricing in other countries, which could result in increased pricing transparency across geographies and pressure to harmonize reimbursement and ultimately reduce the selling prices of our products. Most international jurisdictions have regulatory approval and periodic renewal requirements for medical devices, and countries that previously did not have regulatory requirements for medical devices may adopt such requirements; we

must comply with these requirements in order to market our products in these jurisdictions. In addition, the trend in countries around the world toward more stringent regulatory requirements for product clearance, changing reimbursement models and more rigorous inspection and enforcement activities has generally caused or may cause us and other medical device manufacturers to experience more uncertainty, delay, risk and expense. We expect the international regulatory environment will continue to evolve, which could impact our ability to obtain approvals for our products in those jurisdictions, which may have a material impact on our business.

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Further, any significant changes in the competitive, political, legal, regulatory, reimbursement or economic environment where we conduct international operations may have a material impact on our business, financial condition or results of operations.

If we are unable to manage our debt levels, maintain investment grade credit ratings at the three ratings agencies, or experience a disruption in our cash flows it could have an adverse effect on our cost of borrowing, financial condition or results of operations.

As part of our strategy to maximize stockholder value we use financial leverage to reduce our cost of capital. Our outstanding debt balance was at $4.256 billion as of December 31, 2012 and $4.261 billion as of December 31, 2011. In February 2012, Moody's Investors Service upgraded our corporate credit rating to Baa3, an investment-grade rating, and in July 2011, Fitch Ratings upgraded our corporate credit rating to BBB-, an investment-grade rating. In addition, Standard & Poor's Ratings Services has maintained an investment-grade corporate credit rating for us since 2009. We believe these ratings reflect the strength of our product portfolio and cash flows, the reduction of our debt, and our improved financial fundamentals. Our inability to maintain investment grade credit ratings at the three ratings agencies, however, could increase our cost of borrowing funds in the future. Delays in our product development and new product launches, disruption in our cash flow or our ability to continue to effectively manage our debt levels could have an adverse effect on our cost of borrowing, financial condition or results of operations. In addition, our credit facilities contain financial covenants that require us to maintain specified financial ratios. If we are unable to satisfy these covenants, we may be required to obtain waivers from our lenders and no assurance can be made that our lenders would grant such waivers on favorable terms or at all, and we could be required to repay any borrowings on demand.

We may record future goodwill impairment charges or other asset impairment charges related to one or more of our business or regional reporting units, which could materially adversely impact our results of operations.

We test our goodwill balances during the second quarter of each year for impairment, or more frequently if indicators are present or changes in circumstances suggest that impairment may exist. We assess goodwill for impairment at the reporting unit level and, in evaluating the potential for impairment of goodwill, we make assumptions regarding estimated revenue projections, growth rates, cash flows and discount rates. As a result of revised estimates developed during our annual strategic planning process and analysis performed in conjunction with our annual goodwill impairment test in the second quarter of 2012, we concluded that the revenue growth rates projected for our Europe, Middle East and Africa (EMEA) reporting unit would be slightly lower than our previous estimates primarily driven by macro-economic factors, and our performance in the European market. We concluded that the goodwill within the EMEA reporting unit was impaired and recorded a non-cash $3.602 billion ($3.579 billion after-tax) charge in the second quarter of 2012. In the third quarter of 2012, we performed an interim goodwill impairment test and recorded a non-cash $748 million (pre- and after-tax) charge associated with our U.S. Cardiac Rhythm Management (U.S. CRM) reporting unit, primarily driven by the reduction in the estimated size of the U.S. CRM market, related adjustments to our business and other competitive factors, which led to lower projected U.S. CRM results compared to prior forecasts.

We continue to identify three reporting units with goodwill that is at higher risk of potential failure of the first step of the goodwill impairment test in future reporting periods. These reporting units include our U.S. CRM reporting unit, which holds $216 million of remaining allocated goodwill; our U.S. Cardiovascular reporting unit, which holds $2.380 billion of allocated goodwill; and our U.S. Neuromodulation reporting unit, which holds $1.266 billion of allocated goodwill, each as of December 31, 2012. As of December 31, 2012, the level of excess fair value over carrying value for these reporting units identified as being at higher risk (with the exception of the U.S. CRM reporting unit, whose carrying value continues to exceed its fair value) was approximately seven to 11 percent. During the fourth quarter of 2012, the level of excess fair value over carrying value of our U.S. Cardiovascular reporting unit declined as a result of our performance, declines in our market share due to competitive launches, and continued average selling price declines in the U.S. drug-eluting stent (DES) market as a result of continued competitive pressures and declines in procedural volumes.

Based on the remaining book value of our U.S. CRM reporting unit following the goodwill impairment charge recorded during the third quarter of 2012, the carrying value of our U.S. CRM reporting unit continues to exceed its

fair value, due primarily to the value of amortizable intangible assets allocated to this reporting unit. The remaining book value of the amortizable intangible assets allocated to the U.S. CRM reporting unit was approximately $3.303 billion as of December 31, 2012. In accordance with ASC Topic 350, we tested the amortizable intangible assets as of September 30, 2012, in conjunction with the interim goodwill impairment test of our U.S. CRM reporting unit. We performed the impairment analysis of the amortizable intangible assets on an undiscounted cash flow basis, and concluded that these assets were not impaired. However, following the recent declines in our CRM projections, the recoverability of our CRM-related amortizable intangibles ($4.636 billion globally as of December 31, 2012) are sensitive to changes in future cash flow assumptions and our CRM business performance. The $4.636 billion of CRM-related amortizable intangibles are at higher risk of potential failure of the first step of the amortizable intangible recoverability test in future reporting periods. An impairment of a material portion of our CRM-related amortizable intangibles carrying value would occur if the second step of the amortizable intangible test is required in a future reporting period.

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On a quarterly basis, we monitor the key drivers of fair value for our reporting units to detect events or other changes that would warrant an interim impairment test of our goodwill. We also monitor quarterly for events or other potential indicators of impairment that would warrant an interim impairment test of our intangible assets. For each of these assets, relatively small declines in the future performance and cash flows of the reporting unit or asset group, changes in our reporting units or in the structure of our business as a result of future reorganizations or divestitures of assets or businesses, or small changes in other key assumptions, may result in the recognition of significant asset impairment charges, which could have a material adverse impact on our results of operations.

Failure to integrate acquired businesses into our operations successfully, or effectively manage the separation activities relating to the divestiture of our Neurovascular business, could adversely affect our business, financial condition and operating results.

As part of our strategy to realign our business portfolio, we completed several acquisitions in 2012 and 2011 in our strategic growth areas and may pursue additional acquisitions in the future. Our integration of the operations of acquired businesses requires significant efforts, including the coordination of information technologies, research and development, sales and marketing, operations, manufacturing and finance. These efforts result in additional expenses and involve significant amounts of management's time. Some of the factors that could affect the success of our acquisitions include, among others, the strength of the acquired companies' underlying technology and ability to execute, results of clinical trials, regulatory approvals and reimbursement levels of the acquired products and related procedures, our ability to adequately fund acquired in-process research and development projects and retain key employees, and our ability to achieve synergies with our acquired companies, such as increasing sales of our products, achieving cost savings and effectively combining technologies to develop new products. Our failure to manage successfully and coordinate the growth of the combined acquired companies could have an adverse impact on our business and our future growth. In addition, we cannot be certain that the businesses we acquire will become profitable or remain so and if our acquisitions are not successful, we may record related asset impairment charges in the future.

In addition, we closed the sale of our Neurovascular business to Stryker Corporation in January 2011. The divestiture of this business continues to involve a number of risks, including the diversion of management and employee attention and unexpected costs and delays, including with respect to the transfer of certain manufacturing facilities that we expect to occur during 2013. In addition, we are providing post-closing services through a transition services agreement, and are also manufacturing and supplying products to Stryker. These transition services and supply arrangements are expected to end in 2013. Our inability to effectively manage the separation activities and events could adversely affect our business, financial condition and results of operations.

We may not be successful in our strategy relating to future strategic acquisitions of, investments in, or alliances with, other companies and businesses, which have been a significant source of historical growth for us, and will be key to our diversification into new markets and technologies.

Our strategic acquisitions, investments and alliances are intended to further expand our ability to offer customers effective, high quality medical devices that satisfy their interventional needs. If we are unsuccessful in our acquisitions, investments and alliances, we may be unable to grow our business. These acquisitions, investments and alliances have been a significant source of our growth. The success of our strategy relating to future acquisitions, investments or alliances will depend on a number of factors, including:

- our ability to identify suitable opportunities for acquisition, investment or alliance, if at all;
- our ability to finance any future acquisition, investment or alliance on terms acceptable to us, if at all;
- whether we are able to complete an acquisition, investment or alliance on terms that are satisfactory to us, if at all; and
- intellectual property and litigation related to newly acquired technologies.

Any potential future acquisitions we consummate may be dilutive to our earnings and may require additional debt or equity financing, depending on their size or nature.

We may not realize the expected benefits from our restructuring and optimization initiatives; our long-term expense reduction programs may result in an increase in short-term expense; and our efforts may lead to additional unintended consequences.

In January 2013, we announced an expansion of our 2011 Restructuring plan (the Expansion), which is intended to further strengthen our operational effectiveness and efficiencies and support new investments, which we expect to increase stockholder value. Key activities under the Expansion include further initiatives to: standardize and automate certain processes and activities; relocate select administrative and functional activities; rationalize organizational reporting structures; expand shared services; and align expenses to revenues within certain divisions and geographic regions. In addition, they include further efforts to streamline various corporate functions, eliminate bureaucracy, increase productivity and better align corporate resources to our key business strategies.

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Further, in February 2010, we announced a 2010 Restructuring plan designed to strengthen and position us for long-term success. Key activities under the 2010 Restructuring plan included the integration of our Cardiovascular and CRM businesses, as well as the restructuring of certain other businesses and corporate functions; the realignment of our international structure; and the reprioritization and diversification of our product portfolio. Additionally, in January 2009, we announced our Plant Network Optimization program, aimed at simplifying our plant network, reducing our manufacturing costs and improving gross margins. Activities under our 2010 Restructuring plan were completed in 2012, and our Plant Network Optimization program was substantially completed in 2012. Cost reduction initiatives under these collective plans include various cost and efficiency improvement measures, which may include headcount reductions; the relocation of certain resources as well as administrative and functional activities; the closure of certain facilities; the transfer of certain production lines; the sale of certain non-strategic assets and other efforts to streamline our business, among other actions. These measures could yield unintended consequences, such as distraction of our management and employees, business disruption, attrition beyond our planned reduction in workforce and reduced employee productivity. We may be unable to attract or retain key personnel. Attrition beyond our planned reduction in workforce or a material decrease in employee morale or productivity could negatively affect our business, sales, financial condition and results of operations. In addition, headcount reductions may subject us to the risk of litigation, which could result in substantial cost. Moreover, our expense reduction programs result in charges and expenses that impact our operating results. We cannot guarantee that these measures, or other expense reduction measures we take in the future, will result in the expected cost savings.

Current domestic and international economic conditions could adversely affect our results of operations.

The continued global financial uncertainty, including the European sovereign debt crisis, has caused disruption in the financial markets, including diminished liquidity and credit availability. There can be no assurance that there will not be further deterioration in the global economy and the strength and timing of economic recovery remains uncertain. We cannot predict to what extent the global economic slowdown and European sovereign debt crisis may negatively impact our average selling prices, our net sales and profit margins, procedural volumes and reimbursement rates from third party payors. In addition, current economic conditions may adversely affect our suppliers, leading them to experience financial difficulties or to be unable to borrow money to fund their operations, which could cause disruptions in our ability to produce our products. Further, our customers may experience financial difficulties or be unable to borrow money to fund their operations which may adversely impact their ability or decision to purchase our products, particularly capital equipment, or to pay for our products they do purchase on a timely basis, if at all. For example, our net sales have been adversely impacted by reductions in procedural volumes due to unemployment levels and other economic factors, and these reductions may continue. In addition, the European sovereign debt crisis may impact our future ability to transfer receivables to third parties in certain Southern European countries. Third parties such as banks offering factoring programs in these countries are looking to reduce their exposure levels to government owned or supported debt. This could result in terminations of, or changes to the costs or credit limits of our existing factoring programs. Such terminations or changes could have a negative impact on our cash flow and days sales outstanding. Within Italy, Spain, and Portugal the number of days our receivables are outstanding has increased above historical levels. While we are pursuing alternative factoring providers and financing arrangements to mitigate our credit exposure to receivables in this region, there can be no assurances that we will be able to mitigate our risk of further reductions in cash flow in this region. In addition, conditions in the financial markets and other factors beyond our control may also adversely affect our ability to borrow money in the credit markets and to obtain financing for acquisitions or other general corporate and commercial purposes.

Healthcare policy changes, including recently passed healthcare reform legislation, may have a material adverse effect on our business, financial condition, results of operations and cash flows.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives to limit the growth

of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and alternative payment models, are continuing in many countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. Our strategic initiatives include measures to address this trend; however, there can be no assurance that any of our strategic measures will successfully address this trend.

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010 were enacted into law in the U.S. in March 2010. As a U.S. headquartered company with significant sales in the U.S., this healthcare reform law will materially impact us. Certain provisions of the law will not be effective until 2014 and 2015 and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood. However, on June 28, 2012, the United States Supreme Court upheld the constitutionality of the law's mandate requiring individuals to purchase health insurance but rejected specific provisions that would have penalized states that did not expand their current Medicaid programs. As a result of this ruling and other factors, we expect implementation of most of the major provisions of the law to continue. As currently enacted, the law imposes on medical device manufacturers a 2.3 percent excise tax on U.S. sales of

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Class I, II and III medical devices beginning in 2013. U.S. net sales represented approximately 50 percent of our worldwide net sales in 2012 and, therefore, this tax burden may have a material, negative impact on our results of operations and our cash flows. Other provisions of this law as currently enacted, including comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered, and may adversely affect our business and results of operations. Further, we cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation in the U.S. or internationally. However, any changes that lower reimbursements for our products, reduce medical procedure volumes or increase cost containment pressures on us or other participants in the healthcare industry could adversely affect our business and results of operations.

Healthcare cost containment pressures and legislative or administrative reforms resulting in restrictive reimbursement practices of third-party payors or preferences for alternate therapies could decrease the demand for our products, the prices which customers are willing to pay for those products and the number of procedures performed using our devices, which could have an adverse effect on our business, financial condition or results of operations.

Our products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third-party payors, including governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care programs, for the healthcare services provided to their patients. The ability of customers to obtain appropriate reimbursement for their products and services from private and governmental third-party payors is critical to the success of medical technology companies. The availability of reimbursement affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact the acceptance of new products and services. Even if we develop a promising new product, we may find limited demand for the product unless reimbursement approval is obtained from private and governmental third-party payors. Further legislative or administrative reforms to the reimbursement systems in the U.S., Japan, or other international countries in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for those procedures, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements, could have a material adverse effect on our business, financial condition or results of operations.

Major third-party payors for hospital services in the U.S. and abroad continue to work to contain healthcare costs. The introduction of cost containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed, has led to increased physician employment by hospitals in the U.S., and has shifted services between inpatient and outpatient settings. Initiatives to limit the increase of healthcare costs, including price regulation, are also underway in several countries in which we do business. Hospitals or physicians may respond to these cost-containment pressures by substituting lower cost products or other therapies for our products.

We are subject to extensive and dynamic medical device regulation, which may impede or hinder the approval or sale of our products and, in some cases, may ultimately result in an inability to obtain approval of certain products or may result in the recall or seizure of previously approved products.

Our products, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act (FDC Act), by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDC Act, medical devices must receive FDA clearance or approval before they can be commercially marketed in the U.S. In the European Union, we are required to comply with applicable medical device directives (including the Medical Devices Directive and the Active Implantable Medical Devices Directive) and obtain CE Mark certification in order to market medical devices. The CE Mark is applied following approval from an independent notified body or declaration of conformity. The process of obtaining marketing approval or clearance from the FDA or by comparable agencies in foreign countries for new products, or with respect to enhancements or modifications to existing products, could:

- take a significant period of time;

- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing, as well as increased post-market surveillance;
- require changes to products; and
- result in limitations on the indicated uses of products.

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In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin first. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries. There can be no assurance that we will receive the required approvals for new products, recertifications or modifications to existing products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements.

Our global regulatory environment is becoming increasingly stringent, and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products, as well as the clinical and regulatory costs of supporting those approvals. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded on existing regulations. Certain regulators are exhibiting less flexibility and are requiring local data in addition to global data. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. We expect this global regulatory environment will continue to evolve, which could impact our ability to obtain future approvals for our products, or could increase the cost and time to obtain such approvals in the future.

The FDA and other worldwide regulatory agencies actively monitor compliance with local laws and regulations through review and inspection of design and manufacturing practices, recordkeeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices; detain or seize adulterated or misbranded medical devices; order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the FDC Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations. International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements.

Regulations regarding the development, manufacture and sale of medical devices are evolving and subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances, seizures or recalls of products, physician advisories or other field actions, operating restrictions and/or criminal prosecution. We may also initiate field actions as a result of a failure to strictly comply with our internal quality policies. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products, physician advisories or other field actions, or the withdrawal of product approval by the FDA or by comparable agencies in foreign countries could have a material adverse effect on our business, financial condition or results of operations.

Our products, including those of our cardiovascular businesses, are continually subject to clinical trials conducted by us, our competitors or other third parties, the results of which may be unfavorable, or perceived as unfavorable by the market, and could have a material adverse effect on our business, financial condition or results of operations.

As a part of the regulatory process of obtaining marketing clearance for new products, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, by our competitors or by third parties, or the market's perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects.

Our future growth is dependent upon the development of new products, which requires significant research and development, clinical trials and regulatory approvals, all of which are very expensive and time-consuming and may not result in commercially viable products.

In order to develop new products and improve current product offerings, we focus our research and development programs largely on the development of next-generation and novel technology offerings across multiple programs and businesses. If we are unable to develop and launch products as anticipated, our ability to maintain or expand our market position in the markets in which we participate may be materially adversely impacted. Further, we are continuing to investigate, and have completed several acquisitions involving, opportunities to further expand our presence in, and diversify into priority growth areas. Expanding our focus beyond our current businesses is expensive and time-consuming. Further, there can be no assurance that we will be able to access these

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technologies on terms favorable to us, or that these technologies will achieve commercial feasibility, obtain regulatory approval or gain market acceptance. A delay in the development or approval of these technologies or our decision to reduce our investments may adversely impact the contribution of these technologies to our future growth.

The medical device industry is experiencing greater scrutiny and regulation by governmental authorities and is the subject of numerous investigations, often involving marketing and other business practices. These investigations could result in the commencement of civil and criminal proceedings; substantial fines, penalties and administrative remedies; divert the attention of our management; impose administrative costs and have an adverse effect on our financial condition, results of operations and liquidity; and may lead to greater governmental regulation in the future.

The medical devices we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. These authorities have been increasing their scrutiny of our industry. We have received subpoenas and other requests for information from Congress and other state and federal governmental agencies, including, among others, the U.S. Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services (HHS), and the Department of Defense. We have also received subpoenas and other requests for information from comparable international governmental agencies. These investigations relate primarily to financial arrangements with healthcare providers, regulatory compliance and product promotional practices. We have cooperated with these investigations and responded to these requests, and expect to continue to do so in the future. We cannot predict when the investigations will be resolved, the outcome of these investigations or their impact on us, and cooperation may involve significant costs, including document production costs. An adverse outcome in one or more of these investigations could include the commencement of civil and criminal proceedings; substantial fines, penalties and administrative remedies, including exclusion from government reimbursement programs, entry into Corporate Integrity Agreements (CIAs) with governmental agencies and amendments to existing CIAs. In addition, resolution of any of these matters could involve the imposition of additional and costly compliance obligations. For example, in 2009, we entered into a civil settlement with the DOJ regarding the DOJ's investigation relating to certain post-market surveys conducted by Guidant Corporation before we acquired Guidant in 2006. As part of the settlement, we entered into a CIA with the Office of Inspector General for HHS. The CIA requires enhancements to certain compliance procedures related to financial arrangements with healthcare providers. The obligations imposed upon us by the CIA and cooperation with ongoing investigations involve employee resource costs and diversion of employee focus. We may incur additional future costs to fulfill the obligations imposed upon us by the CIA. Further, the CIA, and if any of the ongoing investigations continue over a long period of time, could further divert the attention of management from the day-to-day operations of our business and impose significant additional administrative burdens on us. These potential consequences, as well as any adverse outcome from these investigations, could have a material adverse effect on our financial condition, results of operations and liquidity.

In addition, certain state governments (including that of Massachusetts, where we are headquartered) and the federal government have enacted legislation aimed at increasing transparency of our interactions with healthcare providers. As a result, we are required by law to disclose payments and other transfers for value to healthcare providers licensed by certain states and, starting with payments or other transfers of value made on or after August 1, 2013, to all U.S. physicians and U.S. teaching hospitals at the federal level. Any failure to comply with these legal and regulatory requirements could impact our business. In addition, we have and may continue to devote substantial additional time and financial resources to further develop and implement enhanced structure, policies, systems and processes to comply with enhanced legal and regulatory requirements, which may also impact our business.

Further, Supreme Court case law has clarified that the FDA's authority over medical devices preempts certain state tort laws, but recently federal appeals courts have determined that some state tort law claims remain, and legislation has been introduced at the federal level to allow state intervention, all of which could lead to increased and inconsistent regulation at the state level.

Changes in tax laws, unfavorable resolution of tax contingencies, or exposure to additional income tax liabilities could have a material impact on our financial condition, results of operations and/or liquidity.

We are subject to income taxes as well as non-income based taxes, in both the U.S. and various foreign jurisdictions. We are subject to on-going tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision and have established contingency reserves for material, known tax exposures, including potential tax audit adjustments related to transfer pricing methodology disputes. We have received Notices of Deficiency from the IRS reflecting proposed audit adjustments for Guidant Corporation for its 2001 through 2006 tax years and Boston Scientific Corporation for its 2006 and 2007 tax years. We have filed, or will timely file, petitions with the U.S. Tax Court contesting the Notices of Deficiency for the tax years in challenge. There can be no assurance that we will accurately predict the outcomes of these disputes or other tax audits or that issues raised by tax authorities will be resolved at a financial cost that does not exceed our related reserves, and the actual outcomes of these audits could have a material impact on our results of operations or financial condition. Additionally, changes in tax laws or tax rulings could materially impact our effective tax rate. For example, new legislation imposes on medical device

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manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in January 2013. Proposals for fundamental U.S. corporate tax reform, if enacted, could have a significant adverse impact on our future results of operations.

We may not effectively be able to protect our intellectual property or other sensitive Company data, which could have a material adverse effect on our business, financial condition or results of operations.

The medical device market in which we primarily participate is largely technology driven. Physician customers, particularly in interventional cardiology, have historically moved quickly to new products and new technologies. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. However, intellectual property litigation is inherently complex and unpredictable and appellate courts can overturn lower court patent decisions. Furthermore, as our business increasingly relies on technology systems and infrastructure, our intellectual property, other proprietary technology and other sensitive Company data is potentially vulnerable to loss, damage or misappropriation.

Competing parties in our industry frequently file multiple suits to leverage patent portfolios across product lines, technologies and geographies and to balance risk and exposure between the parties. In some cases, several competitors are parties in the same proceeding, or in a series of related proceedings, or litigate multiple features of a single class of devices. These forces frequently drive settlement not only of individual cases, but also of a series of pending and potentially related and unrelated cases. In addition, although monetary and injunctive relief is typically sought, remedies and restitution are generally not determined until the conclusion of the trial court proceedings and can be modified on appeal. Accordingly, the outcomes of individual cases are difficult to time, predict or quantify and are often dependent upon the outcomes of other cases in other geographies.

Several third parties have asserted that our current and former product offerings infringe patents owned or licensed by them. We have similarly asserted that products sold by our competitors infringe patents owned or licensed by us. Adverse outcomes in one or more of the proceedings against us could limit our ability to sell certain products in certain jurisdictions, or reduce our operating margin on the sale of these products and could have a material adverse effect on our financial condition, results of operations or liquidity.

Patents and other proprietary rights are and will continue to be essential to our business, and our ability to compete effectively with other companies will be dependent upon the proprietary nature of our technologies. We rely upon trade secrets, know-how, continuing technological innovations, strategic alliances and licensing opportunities to develop, maintain and strengthen our competitive position. We pursue a policy of generally obtaining patent protection in both the U.S. and abroad for patentable subject matter in our proprietary devices and attempt to review third-party patents and patent applications to the extent publicly available in order to develop an effective patent strategy, avoid infringement of third-party patents, identify licensing opportunities and monitor the patent claims of others. We currently own numerous U.S. and foreign patents and have numerous patent applications pending. We also are party to various license agreements pursuant to which patent rights have been obtained or granted in consideration for cash, cross-licensing rights or royalty payments. No assurance can be made that any pending or future patent applications will result in the issuance of patents, that any current or future patents issued to, or licensed by, us will not be challenged or circumvented by our competitors, or that our patents will not be found invalid. In addition, we may have to take legal action in the future to protect our patents, trade secrets or know-how or to assert them against claimed infringement by others. Any legal action of that type could be costly and time consuming and no assurances can be made that any lawsuit will be successful. We are generally involved as both a plaintiff and a defendant in a number of patent infringement and other intellectual property-related actions. The invalidation of key patents or proprietary rights that we own, or an unsuccessful outcome in lawsuits to protect our intellectual property, could have a material adverse effect on our business, financial condition or results of operations.

In addition, the laws of certain countries in which we market, and plan on manufacturing in the near future, some of our products do not protect our intellectual property rights to the same extent as the laws of the United States. If we are unable to protect our intellectual property in these countries, it could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, our intellectual property, other proprietary technology and other sensitive Company data is potentially vulnerable to loss, damage or misappropriation from system malfunction, computer viruses, unauthorized access to our data or misappropriation or misuse thereof by those with permitted access, and other events. While we have invested to protect our intellectual property and other data, and continue to work diligently in this area, there can be no assurance that our precautionary measures will prevent breakdowns, breaches, cyber-attacks or other events. Such events could have a material adverse effect on our reputation, business, financial condition or results of operations.

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Pending and future intellectual property litigation could be costly and disruptive to us.

We operate in an industry that is susceptible to significant intellectual property litigation and, in recent years, it has been common for companies in the medical device field to aggressively challenge the patent rights of other companies in order to prevent the marketing of new devices. We are currently the subject of various patent litigation proceedings and other proceedings described in more detail under Item 3. Legal Proceedings and Note K- Commitments and Contingencies to our 2012 consolidated financial statements included in Item 8 of this Annual Report. Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. Adverse outcomes in one or more of these matters could have a material adverse effect on our ability to sell certain products and on our operating margins, financial condition, results of operation or liquidity. Pending or future patent litigation may result in significant royalty or other payments or injunctions that can prevent the sale of products and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, we may be required to obtain a license on terms which may not be favorable to us, if at all. If we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected.

Pending and future product liability claims and other litigation, including private securities litigation, shareholder derivative suits and contract litigation, may adversely affect our business, reputation and ability to attract and retain customers.

The design, manufacture and marketing of medical devices of the types that we produce entail an inherent risk of product liability claims. Many of the medical devices that we manufacture and sell are designed to be implanted in the human body for long periods of time or indefinitely. A number of factors could result in an unsafe condition or injury to, or death of, a patient with respect to these or other products that we manufacture or sell, including physician technique and experience in performing the surgical procedure, component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information. These factors could result in product liability claims, a recall of one or more of our products or a safety alert relating to one or more of our products.

Product liability claims may be brought by individuals or by groups seeking to represent a class. We are currently the subject of product liability litigation proceedings and other proceedings described in more detail under Item 3. Legal Proceedings and Note K- Commitments and Contingencies to our 2012 consolidated financial statements included in Item 8 of this Annual Report. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, including not only actual damages, but also punitive damages. The magnitude of the potential losses relating to these lawsuits may remain unknown for substantial periods of time. In addition, the cost to defend against any future litigation may be significant. Further, we maintain an insurance policy providing limited coverage against securities claims, and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims and adverse decisions. Product liability claims, securities and commercial litigation and other litigation in the future, regardless of the outcome, could have a material adverse effect on our financial condition, results of operations or liquidity.

Any failure to meet regulatory quality standards applicable to our manufacturing and quality processes could have an adverse effect on our business, financial condition and results of operations.

As a medical device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with its Quality System Regulation requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the Federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA which may result in observations on Form 483, and in some cases warning letters, that require corrective action. In the European Community, we are required to maintain certain International Standards Organization

(ISO) certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. If we, or our manufacturers, fail to adhere to quality system regulations or ISO requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

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Interruption of our manufacturing operations could adversely affect our results of operations and financial condition.
Our products are designed and manufactured in technology centers around the world, either by us or third parties. In most cases, the manufacturing of our products is concentrated in one or a few locations. Factors such as a failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to one or more of our facilities could adversely affect our ability to manufacture our products. In the event of an interruption in manufacturing, we may be unable to quickly move to alternate means of producing affected products or to meet customer demand. In some instances, for example, if the interruption is a result of a failure to follow regulatory protocols and procedures, we may experience delays in resuming production of affected products due primarily to needs for regulatory approvals. As a result, we may experience loss of market share, which we may be unable to recapture, and harm to our reputation, which could adversely affect our results of operations and financial condition.
We rely on external manufacturers to supply us with certain materials, components and products. Any disruption in our sources of supply or the price of inventory supplied to us could adversely impact our production efforts and could materially adversely affect our business, financial condition or results of operations.
We purchase many of the materials and components used in manufacturing our products, some of which are custom made from third-party vendors. Certain supplies are purchased from single-sources due to quality considerations, expertise, costs or constraints resulting from regulatory requirements. In the event of a disruption in supply, we may not be able to establish additional or replacement suppliers for certain components, materials or products in a timely manner largely due to the complex nature of our and many of our suppliers' manufacturing processes. In addition, our products require sterilization prior to sale and we rely on a mix of internal resources and third-party vendors to perform this service. Production issues, including capacity constraint; the inability to sterilize our products; quality issues affecting us or our suppliers; an inability to develop and validate alternative sources if required; or a significant increase in the price of materials or components could adversely affect our results of operations and financial condition.
Our share price will fluctuate, and accordingly, the value of an investment in our common stock may also fluctuate.
Stock markets in general, and our common stock in particular, have experienced significant price and volume volatility over recent years. The market price and trading volume of our common stock may continue to be subject to significant fluctuations due not only to general stock market conditions, but also to variability in the prevailing sentiment regarding our operations or business prospects, as well as, among other things, changing investment priorities of our shareholders.

If we are unable to attract, retain and focus key personnel, it could have an adverse effect on our business, financial condition and results from operations.

We constantly monitor the dynamics of the economy, the healthcare industry and the markets in which we compete; and we continue to assess opportunities to improve operational effectiveness and better align expenses with revenues, while preserving our ability to make needed investments, research and development projects, capital and our people that we believe are essential to our long-term success. In our industry, there is substantial competition for key personnel in the regions in which we operate and we may face increased competition for such employees, particularly in emerging markets as the trend toward globalization continues. If we are unable to attract key personnel in a timely manner, including key sales and other personnel who have critical industry experience and relationships in the regions in which we operate, including in emerging markets such as Brazil, Russia, India and China, it may have an adverse effect on our business and our ability to drive growth, including through execution of our strategic initiatives. Furthermore, some of the key personnel for whom we compete have post-employment arrangements with their current or former employer that may impact our ability to hire them or expose us and them to claims. In addition, if we are unable to retain and focus our existing key personnel it may have an adverse effect on our business, financial condition and results from operations. Moreover, we recently completed changes in our senior management structure, which may lead to inefficiencies and have an adverse effect on our business and results of operations.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Our world headquarters are located in Natick, Massachusetts, with additional support provided from regional headquarters located in Singapore and Paris, France. On November 8, 2012 we announced that we are consolidating our Natick, Massachusetts headquarters into our Marlborough, Massachusetts location, where we expect to establish a new global headquarters campus. As of December 31, 2012, our principal manufacturing and technology centers were located in Minnesota, California, and Indiana within the U.S; as well as internationally in Ireland, Costa Rica and Puerto Rico. Our products are distributed worldwide from customer fulfillment centers in Massachusetts, The Netherlands and Japan. As of December 31, 2012, we maintained 12 major manufacturing facilities, including six in the U.S., three in Ireland, two in Costa Rica, and one in Puerto Rico, as well as various distribution and technology centers around the world. Many of these facilities produce and manufacture products for more than one of our divisions and include research facilities. The following is a summary of our facilities as of December 31, 2012 (in approximate square feet):

	Owned	Leased	Total
U.S.	4,739,000	1,329,000	6,068,000
International	1,512,000	1,227,000	2,739,000
	6,251,000	2,556,000	8,807,000

We regularly evaluate the condition and capacity of our facilities to ensure they are suitable for the development, manufacturing, and marketing of our products, and provide adequate capacity for current and expected future needs.

ITEM 3. LEGAL PROCEEDINGS

See Note K – Commitments and Contingencies to our 2012 consolidated financial statements included in Item 8 of this Annual Report and incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is traded on the New York Stock Exchange (NYSE) under the symbol "BSX." The following table provides the market range for the closing price of our common stock for each of the last eight quarters based on reported sales prices on the NYSE.

2012	High	Low
First Quarter	$6.36	$5.30
Second Quarter	6.31	5.51
Third Quarter	5.82	4.97
Fourth Quarter	5.82	5.07
2011		
First Quarter	$7.78	$6.85
Second Quarter	7.79	6.57
Third Quarter	7.28	5.62
Fourth Quarter	5.90	5.09

Holders

The closing price of our common stock on February 15, 2013 was $7.54. As of February 15, 2013, there were 14,707 holders of record of our common stock.

Dividends

We did not pay a cash dividend in 2012 or 2011. We currently do not intend to pay dividends, and intend to retain all of our earnings to invest in the continued growth of our business and return value to shareholders by buying back shares of our common stock pursuant to our share repurchase authorizations. We may consider declaring and paying a dividend in the future; however, there can be no assurance that we will do so.

Securities Authorized for Issuance under Equity Compensation Plans

Please see Item 12 "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" under Part III of this Annual Report for information on where to find information required by Item 201(d) of Regulation S-K.

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Purchases of Equity Securities by the Issuer and Affiliated Purchases

During 2012, we used $600 million of cash generated from operations to repurchase approximately 105 million shares of our common stock pursuant to our share repurchase authorizations and in 2011 we used $492 million of cash generated from operations to repurchase approximately 82 million shares of our common stock pursuant to our share repurchase authorizations discussed in Note L - Stockholders' Equity to our 2012 consolidated financial statements contained in Item 8 of this Annual Report.

The following table provides information with respect to purchases by Boston Scientific Corporation of equity securities that are registered by us pursuant to Section 12 of the Securities Exchange Act of 1934 during the fourth quarter of 2012:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs *	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs *
10/01/12 - 10/31/12	—	$—	—	
11/01/12 - 11/30/12	17,937,915	$5.55	17,937,915	
12/01/12 - 12/31/12	—	$—	—	
Total	17,937,915	$5.55	17,937,915	$119,551,196

* On July 28, 2011, we announced that our Board of Directors had approved a program authorizing the repurchase of up to $1.0 billion of our common stock and re-approved approximately 37 million shares remaining under our previous share repurchase program. The approximate aggregate dollar value of the remaining shares that may yet be purchased under the plans and programs in the table above, was calculated using a stock price of $5.73 for the approximately 21 million shares authorized under our previous share repurchase program, which was the closing stock price of our common stock on December 31, 2012, as reported on the New York Stock Exchange. As of December 31, 2012, we had no remaining authorization available under our 2011 share repurchase program.

On January 25, 2013, our Board of Directors approved a new program authorizing the repurchase up to $1.0 billion of our common stock.

Sale of Unregistered Securities

During the three years ended December 31, 2012, fewer than 20 employees purchased approximately 3,150 shares of our common stock. The issuance of such shares was pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended (Securities Act), pursuant to Section 4(2) of the Securities Act.

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Stock Performance Graph

The graph below compares the five-year total return to stockholders on our common stock with the return of the Standard & Poor's (S&P) 500 Stock Index and the S&P Health Care Equipment Index. The graph assumes $100 was invested in our common stock and in each of the named indices on December 31, 2007, and that all dividends were reinvested.

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ITEM 6. SELECTED FINANCIAL DATA

FIVE-YEAR SELECTED FINANCIAL DATA

(in millions, except per share data)

Operating Data

Year Ended December 31,	2012	2011	2010	2009	2008
Net sales	$7,249	$7,622	$7,806	$8,188	$8,050
Gross profit	4,900	4,963	5,207	5,612	5,581
Total operating expenses	8,768	4,059	5,863	6,506	7,086
Operating income (loss)	(3,868)	904	(656)	(894)	(1,505)
Income (loss) before income taxes	(4,107)	642	(1,063)	(1,308)	(2,031)
Net income (loss)	(4,068)	441	(1,065)	(1,025)	(2,036)
Net income (loss) per common share:					
Basic	$(2.89)	$0.29	$(0.70)	$(0.68)	$(1.36)
Assuming dilution	$(2.89)	$0.29	$(0.70)	$(0.68)	$(1.36)

Balance Sheet Data

As of December 31,	2012	2011	2010	2009	2008
Cash, cash equivalents and marketable securities	$207	$267	$213	$864	$1,641
Working capital (1)	1,250	1,298	1,006	1,577	2,219
Total assets	17,154	21,290	22,128	25,177	27,139
Borrowings (long-term and short-term)	4,256	4,261	5,438	5,918	6,745
Stockholders' equity	6,870	11,353	11,296	12,301	13,174
Book value per common share	$5.07	$7.84	$7.43	$8.14	$8.77

(1) In 2010, we reclassified certain assets to the 'assets held for sale' caption in our consolidated balance sheets. These assets are labeled as 'current' in our 2010 consolidated balance sheet to give effect to the short term nature of those assets that were divested in the first quarter of 2011 in connection with the sale of our Neurovascular business and other assets that were expected to be sold in 2011. We reclassified 2009 balances for comparative purposes in the working capital metric above. We have not restated working capital for these items in years prior to 2009.

See also Note C - Divestitures and Assets Held for Sale to our 2012 consolidated financial statements included in Item 8 of this Annual Report.

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the consolidated financial statements and accompanying notes included in Item 8 of this Annual Report.

Executive Summary

Financial Highlights and Trends

In 2012, we generated net sales of $7.249 billion, as compared to $7.622 billion in 2011, a decrease of $373 million, or five percent. Our net sales were unfavorably impacted by $123 million from foreign currency fluctuations in 2012 as compared to 2011 and sales related to our divested Neurovascular business declined $19 million in 2012. Refer to Note C - Divestitures and Assets Held for Sale included in Item 8 of this Annual Report for additional information on the Neurovascular divestiture. Excluding the impact of foreign currency and sales from divested businesses, our net sales decreased $232 million, or three percent, as compared to the prior year. This decrease was due primarily to constant currency declines in net sales from our Interventional Cardiology business of $266 million and Cardiac Rhythm Management (CRM) business of $145 million. These decreases were partially offset by constant currency increases in net sales from our Endoscopy business of $84 million, from our Peripheral Interventions business of $56 million, and net sales from our Neuromodulation business of $32 million, as compared to the same period in the prior year.[1] Refer to the Business and Market Overview section for further discussion of our sales results.

Our reported net loss in 2012 was $4.068 billion, or $2.89 per share. Our reported results for 2012 included goodwill and intangible asset impairment charges; acquisition- and divestiture-related net credits, restructuring- and litigation-related charges; discrete tax items and amortization expense (after-tax) of $5.001 billion, or $3.55 per share. Excluding these items, net income for 2012 was $933 million, or $0.66 per share[1].

Our reported net income in 2011 was $441 million, or $0.29 per share. Our reported results for 2011 included goodwill and intangible asset impairment charges; acquisition-, divestiture-, restructuring- and litigation-related charges and credits; discrete tax items; and amortization expense (after-tax) of $577 million, or $0.38 per share. Excluding these items, net income for 2011 was $1.018 billion, or $0.67 per share[1]. The following is a reconciliation of our results of operations prepared in accordance with U.S. GAAP to those adjusted results considered by management. Refer to Results of Operations for a discussion of each reconciling item:

	Year Ended December 31, 2012			
in millions, except per share data	Pre-Tax	Tax Impact	After-Tax	Impact per share
GAAP results	$(4,107)	$39	$(4,068)	$(2.89)
Non-GAAP adjustments:				
Goodwill and other intangible asset impairment charges	4,492	(46)	4,446	3.15
Acquisition- and divestiture-related net credits	(50)	14	(36)	(0.02)
Restructuring-related charges	160	(38)	122	0.09
Litigation-related charges	192	(74)	118	0.08
Discrete tax items		2	2	—
Amortization expense	395	(46)	349	0.25
Adjusted results	$1,082	$(149)	$933	$0.66

[1] Sales growth rates that exclude the impact of changes in foreign currency exchange rates and net income and net income per share excluding certain items required by GAAP are not prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP). Refer to Additional Information in this Item 7 for a discussion of management's use of these non-GAAP financial measures.

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	Year Ended December 31, 2011			
in millions, except per share data	Pre-Tax	Tax Impact	After-Tax	Impact per share
GAAP results	$642	$(201)	$441	$0.29
Non-GAAP adjustments:				
Goodwill and other intangible asset impairment charges	718	(5)	713	0.47
Acquisition- and divestiture-related net credits	(798)	229	(569)	(0.37)
Restructuring-related charges	129	(39)	90	0.06
Litigation-related charges	48	(18)	30	0.02
Discrete tax items		(27)	(27)	(0.02)
Amortization expense	421	(81)	340	0.22
Adjusted results	$1,160	$(142)	$1,018	$0.67

[1] Sales growth rates that exclude the impact of changes in foreign currency exchange rates and net income and net income per share excluding certain items required by GAAP are not prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP). Refer to Additional Information in this Item 7 for a discussion of management’s use of these non-GAAP financial measures.

Cash generated by operating activities was $1.260 billion in 2012, as compared to $1.008 billion in 2011. Our operating cash flows in 2011 included approximately $300 million of one-time litigation-related payments. Our cash generated from operations continues to be a significant source of funds for investing in our growth and returning value to shareholders by buying back shares of our common stock, pursuant to our share repurchase authorizations discussed in Note L - Stockholders' Equity to our 2012 consolidated financial statements contained in Item 8 of this Annual Report. During 2012, we used approximately $600 million of cash generated from operations to repurchase approximately 105 million shares of our common stock, as compared to 2011 in which approximately $492 million of cash generated from operations was used to repurchase approximately 82 million shares of our common stock. As of December 31, 2012, we had total debt of $4.256 billion, cash and cash equivalents of $207 million and working capital of $1.250 billion. In February 2012, Moody's Investors Service upgraded our corporate credit rating to Baa3, an investment-grade rating, with a stable outlook. We now hold investment-grade ratings with all three major credit-rating agencies. We believe our investment grade credit profile reflects the size and diversity of our product portfolio, our leading share position in several of our served markets, our strong cash flow, our solid financial fundamentals and our financial strategy.

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Business and Market Overview

Endoscopy

Our Endoscopy division develops and manufactures devices to treat a variety of medical conditions including diseases of the digestive and pulmonary systems. Our worldwide net sales of these products were $1.252 billion in 2012, as compared to $1.187 billion in the 2011, an increase of $65 million, or five percent. U.S. net sales of our Endoscopy products were $605 million in 2012, as compared to $562 million in the prior year. Our international net sales were $647 million in 2012, as compared to $625 million in 2011, and included a $19 million negative impact from changes in foreign currency exchange rates. Excluding the impact of changes in foreign currency exchange rates, our worldwide Endoscopy net sales increased $84 million, or seven percent, in 2012, as compared to 2011. This performance was primarily the result of growth across several of our key product franchises, including our biopsy business; our biliary device franchise driven by continued growth in our Expect™ Endoscopic Ultrasound Aspiration Needle; our metal stent franchise driven by our industry-leading WallFlex® product family, which now includes our WallFlex® Biliary Transhepatic stent system for treatment of biliary strictures, launched in the first quarter of 2012; and our hemostasis franchise on the continued adoption and utilization of our Resolution Clip for gastrointestinal bleeding.

In October 2010, we completed our acquisition of Asthmatx, Inc. Through Asthmatx, we design, manufacture and market a less-invasive, catheter-based bronchial thermoplasty procedure for the treatment of severe persistent asthma. The Alair® Bronchial Thermoplasty System, developed by Asthmatx, has both Conformite Europeenne (CE) Mark and U.S. Food and Drug Administration (FDA) approval and is the first device-based asthma treatment approved by the FDA. In the third quarter of 2012, the American Medical Association (AMA) Current Procedural Terminology (CPT) editorial panel assigned category I CPT codes specifically for bronchial thermoplasty beginning January 1, 2013. The Category I CPT procedure codes are recognized by all public and private health insurance payers in the United States, which will allow physicians and hospitals to seek reimbursement for bronchial thermoplasty procedures. We believe these codes will provide greater access to treatment for patients with poorly controlled severe asthma, help facilitate claims processing and help private payers' approve coverage for this form of treatment. We continue to focus on driving commercialization and increased awareness of the Alair® System. We expect this technology to strengthen our existing offering of pulmonary devices and contribute to future sales growth and diversification of the Endoscopy business. During 2012, we saw growth in our Alair® System product line with worldwide net sales of $11 million in 2012 as compared to approximately $4 million in 2011.

Peripheral Interventions (PI)

Our PI product offerings include stents, balloon catheters, wires, peripheral embolization devices and other devices used to diagnose and treat peripheral vascular disease. Our worldwide net sales of these products were $774 million in 2012, as compared to $731 million in 2011, an increase of $43 million, or six percent. Our U.S. net sales of these products were $340 million in 2012, as compared to $310 million in 2011. Our international net sales were $434 million in 2012, as compared to $421 million in 2011, and included a $13 million negative impact from changes in foreign currency exchange rates. Excluding the impact of changes in foreign currency exchange rates, our worldwide PI net sales increased $56 million, or eight percent, in 2012 as compared to 2011. The year-over-year increase in worldwide PI net sales was primarily driven by growth in our core PI franchise as the result of new product launches in stents, balloons and chronic total occlusions (CTO) devices, which we expect to continue to drive our future growth. We also recently announced the acquisition of Vessix Vascular, Inc., a developer of catheter-based renal denervation systems for the treatment of uncontrolled hypertension. Through the acquisition of Vessix we added a second generation, highly differentiated technology to our hypertension strategy, and we believe this technology will accelerate our entry into the hypertension market. We expect to launch this technology commercially in Europe and certain other international markets in 2013. We believe that offering these devices will enhance our position in assisting physicians in addressing the challenges of treating complex peripheral lesions.

Neuromodulation

Our Neuromodulation business offers the Precision® Spinal Cord Stimulation (SCS) system, used for the management of chronic pain. Our worldwide net sales of Neuromodulation products were $367 million in 2012, as

compared to $336 million in 2011, an increase of $31 million, or nine percent. Our U.S. net sales of Neuromodulation products were $342 million in 2012, as compared to $317 million in the prior year, and our international net sales of these products were $25 million in 2012 and $19 million in 2011. Excluding the negative impact of changes in foreign currency exchange rates of $1 million, our Neuromodulation worldwide net sales in 2012 grew nine percent as compared to the prior year. The increase was primarily driven by U.S. net sales as a result of strong sales of our Infinion™ 16 Percutaneous Lead, which received FDA approval in the fourth quarter of 2011, and continued focus on commercial execution. During the third quarter of 2012, we received CE Mark approval for use of our Vercise™ Deep Brain Stimulation (DBS) System for the treatment of Parkinson's disease in Europe and we expect to begin our U.S. pivotal study for the treatment of Parkinson's disease in 2013. We believe we have an exciting opportunity in DBS with our ability to customize

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the field designed to precisely stimulate the target without extraneous stimulation of adjacent areas that may cause unwanted side effects.

In addition, during the fourth quarter of 2012 we received CE Mark approval for the Precision Spectra™ Spinal Cord Stimulator (SCS) System. The Precision Spectra System is the world's first and only SCS system with 32 contacts and 32 dedicated power sources and is designed to provide improved pain relief to a wide range of patients who suffer from chronic pain.

Urology/Women’s Health

Our Urology/Women’s Health division develops and manufactures devices to treat various urological and gynecological disorders. Our worldwide net sales of these products were $500 million in 2012, as compared to $498 million in 2011, an increase of approximately $2 million, or less than one percent. Our U.S. net sales were $355 million in 2012, as compared to $362 million in 2011. Our international net sales were $145 million in 2012, as compared to $136 million for the prior year, and included a $3 million negative impact from changes in foreign currency exchange rates. Excluding the impact of changes in foreign currency exchange rates, our worldwide Urology/Women's Health net sales increased $5 million, or one percent, in 2012, as compared to 2011.

Our Urology business grew approximately five percent on strong sales execution and continued commercial expansion. However, our Women's Health business declined 11 percent primarily due to continued pressures on elective procedures and lower sales levels following the FDA release of a Public Health Notice update in July 2011 regarding complications related to the use of urogynecologic surgical mesh for pelvic organ prolapse.

Despite the recent performance of the Urology/Women's Health division, due primarily to the market contraction as a result of the 2011 FDA release of a Public Health Notice update, we believe that our Urology/Women's Health business has the opportunity for growth as a result of our pipeline of upcoming product launches and our plans to continue expanding the global footprint of this business.

Electrophysiology

Our Electrophysiology business develops less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart. Our leading products include the Blazer™ line of ablation catheters, designed to deliver enhanced performance, responsiveness and durability. Our Blazer™ line includes our next generation Blazer™ Prime ablation catheter, and our Blazer™ Open-Irrigated Catheter, launched in select European countries. Worldwide net sales of our Electrophysiology products were $147 million in 2012 and 2011. Our U.S. net sales of these products were $108 million in 2012, as compared to $107 million in 2011. Our international net sales of these products were $39 million in 2012 and $40 million in 2011 and included a negative impact from changes in foreign currency exchange rates of $2 million. Excluding the impact of changes in foreign currency exchange rates, our worldwide Electrophysiology net sales, increased $2 million, or one percent, in 2012, as compared to 2011.

Additionally, on October 9, 2012, we acquired Rhythmia Medical, Inc., a developer of next-generation mapping and navigation solutions for use in cardiac catheter ablations and other electrophysiology procedures, including atrial fibrillation and atrial flutter. We believe that this acquisition, as well as our other expected product launches, will help to position us to competitively participate in the fast-growing Electrophysiology market. In January 2013, the first patient was enrolled in the ZERO AF clinical trial to evaluate the safety and effectiveness of the Blazer® Open-Irrigated Temperature Ablation Catheter in patients with symptomatic, drug refractory paroxysmal atrial fibrillation. The results of the ZERO AF trial are expected to be used to support a FDA regulatory submission for a paroxysmal atrial fibrillation indication. The Blazer Open-Irrigated Catheter is our first entry into the open-irrigated catheter segment and is approved for use in CE Mark countries and Canada. The Blazer Open-Irrigated Catheter offers the Total Tip Cooling™ design, engineered to consistently cool the entire tip of the electrode during radiofrequency energy delivery to treat many heart rhythm disorders including paroxysmal atrial fibrillation.

Cardiac Rhythm Management

Our CRM division develops, manufactures and markets a variety of implantable devices including implantable cardioverter defibrillator (ICD) systems and pacemaker systems that monitor the heart and deliver electricity to treat cardiac abnormalities. Worldwide net sales of our CRM products of $1.908 billion represented approximately 26 percent of our consolidated net sales for 2012. Our worldwide CRM net sales decreased $179 million, or nine percent, in 2012, as compared to the prior year. Our U.S. CRM net sales decreased $114 million, or nine percent, in

2012 as compared to 2011. Our international CRM net sales decreased $65 million, or seven percent, in 2012, as compared to 2011, and included a $34 million negative impact from changes in foreign currency exchange rates. Excluding the impact of changes in foreign currency exchange rates our 2012 worldwide CRM net sales decreased $145 million, or seven percent, as compared to 2011.

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The following are the components of our worldwide CRM net sales:

(in millions)	Year Ended December 31, 2012			Year Ended December 31, 2011		
	U.S.	International	Total	U.S.	International	Total
ICD systems	$858	$521	$1,379	$949	$569	$1,518
Pacemaker systems	256	273	529	279	290	569
CRM products	$1,114	$794	$1,908	$1,228	$859	$2,087

The reduction in our CRM net sales during 2012 as compared to 2011, is primarily due to the impact of average selling price pressures driven by governmental, competitive and other pricing pressures, and lower procedural volumes as a result of continued contraction in the U.S. ICD market due to a variety of factors, including physician reaction to study results published by the Journal of the American Medical Association in prior years regarding evidence-based guidelines for ICD implants, U.S. Department of Justice (DOJ) investigations into hospitals' ICD implant practices and the expansion of Medicare recovery audits, as well as on-going physician alignment to hospitals. In addition, our sales levels related to replacement procedures were lower than the prior year due to historical product recalls and subsequent reductions in our denovo (first time) ICD implants following these recalls. However, we believe that our U.S. denovo ICD share increased throughout 2012 as a result of our INCEPTA™ and ENERGEN™ line of defibrillators launched in the fourth quarter of 2011, and our highly-reliable RELIANCE lead platform.

In the first half of 2012, we launched our INGENIO™ family of pacemaker systems in the U.S. and EMEA, and in July 2012, we received CE Mark approval for use of our INGENIO™ and ADVANTIO™ pacemakers in patients in need of a magnetic resonance imaging (MRI) scan, which we believe represents a significant advancement to our family of pacemaker devices. In the second quarter of 2012, we received FDA approval for our INVIVE™ cardiac resynchronization therapy pacemakers (CRT-Ps). During the second quarter of 2012, we completed the acquisition of Cameron Health, Inc. (Cameron). Cameron developed the world's first and only commercially available subcutaneous implantable cardioverter defibrillator - the S-ICD® System, which we believe is a differentiated technology that will provide us the opportunity to both increase our market share in the existing ICD market and expand that market over time. The S-ICD® system has received CE Mark approval and is available in EMEA. In September 2012 we received FDA approval for the S-ICD® system and commenced a limited commercial launch in the United States. We believe these recent product developments will help to better position us within the CRM market.

Net sales from our CRM products represent a significant source of our overall net sales. Therefore, increases or decreases in our CRM net sales could have a significant impact on our results of our consolidated operations. Variables that may impact the size of the CRM market and/or our share of that market include, but are not limited to:

- the on-going impact of physician alignment to hospitals, government investigations and audits of hospitals, and other market and economic conditions on the overall number of procedures performed and average selling prices;
- our ability to retain and attract key members of our CRM sales force and other key CRM personnel;
- the ability of CRM manufacturers to maintain the trust and confidence of the implanting physician community, the referring physician community and prospective patients in CRM technologies;
- future product field actions or new physician advisories issued by us or our competitors;
- our ability to timely and successfully acquire or develop and launch new or next-generation competitive products and technologies worldwide, in line with our commercialization strategies, including the S-ICD® system;
- new product launches by our competitors;
- variations in clinical results, reliability or product performance of our and our competitors' products; and
- delayed or limited regulatory approvals and unfavorable reimbursement policies.

During the third quarter of 2012, we recorded a goodwill impairment charge, primarily driven by the reduction in the estimated size of the U.S. CRM market and related adjustments to our business, and other competitive factors, which led to lower projected U.S. CRM results compared to prior forecasts. Additionally, during the second quarter of 2012, we recorded a goodwill impairment charge related to our EMEA business. The EMEA goodwill impairment charge was primarily driven by our revised projections for revenue growth in EMEA which were slightly lower than our previous estimates; which was primarily due to macro-economic factors and our performance in the European market.

Refer to Results of Operations for further details.

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Interventional Cardiology (Coronary Stent Systems)

We offer innovative products in the coronary stent market to treat coronary artery disease. We market our internally-developed and self-manufactured PROMUS® Element™ everolimus-eluting stent platform in all major markets worldwide, as well as our TAXUS® paclitaxel-eluting stent line, including our third-generation TAXUS® Element™ stent system. Beginning in the first quarter of 2013, we also received CE Mark approval and launched our next-generation Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System in Europe and other select geographies. We are the only company in the industry to offer a two-drug platform strategy with our paclitaxel-eluting and everolimus-eluting stent system offerings, and we offer a broad range of stent sizes. During the fourth quarter of 2012, we received CE Mark approval for the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System featuring an ultra-thin abluminal (outer) bioabsorbable polymer coating. The SYNERGY Stent is unique in that its proprietary polymer and everolimus drug coating dissipate by three months. This innovation has the potential to improve post-implant vessel healing and will eliminate long-term polymer exposure, a possible cause of late adverse events. During the fourth quarter of 2012 we also enrolled the first patient in the EVOLVE II clinical trial, which is designed to further assess the safety and effectiveness of the SYNERGY Stent System and support U.S. FDA and Japanese regulatory approvals for this technology.

Worldwide net sales of our coronary stent systems, with the inclusion of bare-metal stent systems, was $1.363 billion or approximately 19 percent of our consolidated net sales in 2012. Our worldwide net sales of these products decreased $257 million, or 16 percent, in 2012, as compared to 2011. Excluding the impact of changes in foreign currency exchange rates, which had a $33 million negative impact on our coronary stent system net sales in 2012, as compared to the prior year, net sales of these products decreased $224 million, or 14 percent. Our U.S. net sales of drug-eluting stent systems decreased $193 million, or 26 percent, in 2012, as compared to 2011. This decrease was primarily related to lower market share due to competitive launches in 2012, continued average selling price declines in the U.S. drug-eluting stent (DES) market as a result of continued competitive pressures and declines in procedural volumes. Our international drug-eluting stent system net sales decreased $39 million, or five percent, in 2012, as compared to the previous year. Excluding the impact of changes in foreign currency exchange rates, our international drug-eluting stent system net sales decreased $11 million, or two percent due to continued lower market share related to competitive launches. During 2012, we substantially completed the conversion of our U.S. and international drug-eluting stent system sales to our self-manufactured PROMUS® Element™ and TAXUS® stent systems, which has positively impacted our gross profit margins.

The following are the components of our worldwide coronary stent system sales:

	Year Ended			Year Ended		
(in millions)	December 31, 2012			December 31, 2011		
	U.S.	International	Total	U.S.	International	Total
Drug-eluting	$557	$720	$1,277	$750	$759	$1,509
Bare-metal	24	62	86	32	79	111
	$581	$782	$1,363	$782	$838	$1,620

Historically, the worldwide coronary stent market has been dynamic and highly competitive with significant market share volatility. In addition, in the ordinary course of our business, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial end points. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, our competitors or third parties, or the market's perception of these clinical data, may adversely impact our position in, and share of, the drug-eluting stent market and may contribute to increased volatility in the market.

We believe that we will continue to maintain a strong position within the worldwide drug-eluting stent market for a variety of reasons, including:

- the performance benefits of our current and future technology;
- the strength of our pipeline of drug-eluting stent products, which has shown favorable results in clinical trials to date;
- the broad and consistent long-term results of our TAXUS® clinical trials, and the favorable results of PROMUS® Element™ and TAXUS® Element™ (ION™) stent system clinical trials to date;
-

our overall position in the interventional medical device market and our experienced interventional cardiology sales force;

- the strength of our clinical, selling, marketing and manufacturing capabilities; and
- our increased presence and investment in rapidly growing emerging markets, including Brazil, Russia, India and China.

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However, a decline in net sales from our drug-eluting stent systems could have a significant adverse impact on our operating results. Significant variables that may impact the size of the drug-eluting stent market and our position within this market include, but are not limited to:

- the impact of competitive pricing pressure on average selling prices of drug-eluting stent systems available in the market;
- the impact and outcomes of on-going and future clinical results involving our or our competitors' products, including those trials sponsored by our competitors, or perceived product performance of our or our competitors' products;
- new product launches by our competitors;
- our ability to timely and successfully launch new or next-generation products and technologies, in line with our commercialization strategies;
- physician and patient confidence in our current and next-generation technology;
- changes in the overall number of percutaneous coronary intervention procedures performed, drug-eluting stent penetration rates and the average number of stents used per procedure;
- delayed or limited regulatory approvals and unfavorable reimbursement policies; and
- the outcome of intellectual property litigation.

Interventional Cardiology (Excluding Coronary Stent Systems)

In addition to coronary stent systems, our Interventional Cardiology business markets balloon catheters, rotational atherectomy systems, guide wires, guide catheters, embolic protection devices, and diagnostic catheters used in percutaneous transluminal coronary angioplasty (PTCA) procedures, as well as intravascular ultrasound (IVUS) imaging systems. Our worldwide net sales of these products were $816 million in 2012, as compared to $875 million in 2011, a decrease of $59 million, or seven percent. Our U.S. net sales were $311 million in 2012, as compared to $342 million in 2011. Our international net sales of these products were $505 million in 2012, as compared to $533 million in 2011, and included a $17 million unfavorable impact from changes in foreign currency exchange rates for 2012, as compared to the prior year. Excluding the impact of changes in foreign currency exchange rates, Interventional Cardiology (excluding coronary stent systems) worldwide net sales decreased $42 million, or five percent, as compared to the prior year primarily due to competitive launches and pricing pressures. In April 2012, we received CE Mark approval for and launched our Emerge™ PTCA Dilatation Catheter in our EMEA region and we received FDA clearance for this product in September 2012. The Emerge™ Catheter is a next-generation pre-dilatation balloon catheter designed specifically to offer exceptional deliverability for physicians to address challenging lesions in coronary arteries. In addition, in October 2012, we completed the acquisition of BridgePoint Medical, Inc., a developer of proprietary, catheter-based systems to treat coronary chronic total occlusions (CTOs). Through this acquisition we expect to augment our current portfolio of Interventional Cardiology products, which we believe will enable us to be a single-source supplier for complex percutaneous coronary intervention (PCI) procedures.

In January 2011, we completed the acquisition of Sadra Medical, Inc. Through our acquisition of Sadra, we are developing a fully repositionable and retrievable device for transcatheter aortic valve replacement (TAVR) to treat patients with severe aortic stenosis. The Lotus™ Valve System consists of a stent-mounted tissue valve prosthesis and catheter delivery system for guidance and placement of the valve. The low-profile delivery system and introducer sheath are designed to enable accurate positioning, repositioning and retrieval at any time prior to release of the aortic valve implant. We believe TAVR is one of the fastest growing medical device markets.

In April 2012, we completed enrollment in the REPRISE I clinical trial, designed to evaluate the acute safety of the Lotus™ Valve System. In October 2012, we enrolled the first patients in the REPRISE II clinical trial to evaluate the safety and performance of the Lotus™ Valve System. The results of the REPRISE II trial are expected to be used to support CE Mark and other international regulatory approvals, which we anticipate receiving in the second half of 2013.

Due to revised expectations of the required effort, time and cost involved in completing Sadra's in-process research and development projects and bringing the related products to market, we recorded an intangible asset impairment charge in the second quarter of 2012. Refer to Results of Operations for further details. We continue to believe that the technology associated with the Sadra acquisition represents a significant future opportunity for us in the structural

heart market.

In March 2011, we completed the acquisition of Atritech, Inc. Atritech developed a novel device designed to close the left atrial appendage in patients with atrial fibrillation who are at risk for ischemic stroke. The WATCHMAN® Left Atrial Appendage Closure Technology is the first device proven in a randomized clinical trial to offer an alternative to anticoagulant drugs, and is approved for use in CE Mark countries. In August 2012, European regulators approved an expanded indication for the WATCHMAN®

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Left Atrial Appendage Closure Device. The new indication offers patients with atrial fibrillation (AF), and a contraindication to warfarin and the newer oral anticoagulants, a new treatment option for stroke reduction. We are integrating the operations of the Atritech business and are leveraging expertise from both our Electrophysiology and Interventional Cardiology divisions in the commercialization of the WATCHMAN® device.

Emerging Markets

As part of our strategic imperatives to drive global expansion, described in Item 1 of this Annual Report, we are seeking to grow net sales and market share by expanding our global presence. In particular, we are focusing our efforts and increasing our investment in certain countries whose economies and healthcare sectors are growing rapidly, in order to maximize opportunities in those countries. We significantly increased sales in Brazil, Russia, India and China and continued investments in infrastructure in those countries, as well as others, in 2011 and throughout 2012. As a result of these efforts, during 2012, we experienced double-digit sales growth in these markets, as compared to 2011. We recently created a new Asia-Pacific regional organization under new leadership to further increase our capabilities and strengthen our position in this fast growing region.

Restructuring Initiatives

On an on-going basis, we monitor the dynamics of the economy, the healthcare industry, and the markets in which we compete; and we continue to assess opportunities for improved operational effectiveness and efficiency, and better alignment of expenses with revenues, while preserving our ability to make the investments in research and development projects, capital and our people that are essential to our long-term success. As a result of these assessments, we have undertaken various restructuring initiatives in order to enhance our growth potential and position us for long-term success. These initiatives are described below, and additional information can be found in Results of Operations and Note H – Restructuring-related Activities to our 2012 consolidated financial statements included in Item 8 of this Annual Report.

2011 Restructuring Plan

On July 26, 2011, our Board of Directors approved, and we committed to, a restructuring initiative (the 2011 Restructuring plan) designed to strengthen operational effectiveness and efficiencies, increase competitiveness and support new investments, thereby increasing shareholder value. The original estimate of the plan was a reduction of annual pre-tax operating expenses by approximately $225 million to $275 million exiting 2013, a substantial portion of which is expected to be reinvested in targeted areas necessary for future growth, including strategic growth initiatives and emerging markets. Key activities under the plan include standardizing and automating certain processes and activities; relocating select administrative and functional activities; rationalizing organizational reporting structures; leveraging preferred vendors; and other efforts to eliminate inefficiency. Among these efforts, we are expanding our ability to deliver best-in-class global shared services for certain functions and divisions at several locations in emerging markets. This action is intended to enable us to grow our global commercial presence in key geographies and take advantage of many cost-reducing and productivity-enhancing opportunities. In addition, we are undertaking efforts to streamline various corporate functions, eliminate bureaucracy, increase productivity and better align corporate resources to our key business strategies.

On January 25, 2013, our Board of Directors approved, and we committed to, an expansion of our 2011 restructuring program (the Expansion). The Expansion is intended to further strengthen our operational effectiveness and efficiencies and support new investments, which we expect to increase shareholder value. We estimate that the Expansion will reduce gross annual pre-tax operating expenses by approximately $100 million to $115 million exiting 2013; and that the total 2011 restructuring program, including the Expansion (the Total Program), will reduce gross annual pre-tax operating expenses by approximately $340 million to $375 million exiting 2013. We expect a substantial portion of the Total Program savings to be reinvested in targeted areas for future growth, including strategic growth initiatives and emerging markets. Key activities under the Expansion include further initiatives to: standardize and automate certain processes and activities; relocate select administrative and functional activities; rationalize organizational reporting structures; expand shared services; and align expenses to revenues within certain divisions and geographic regions. In addition, they include further efforts to streamline various corporate functions,

eliminate bureaucracy, increase productivity and better align corporate resources to our key business strategies. Key activities under the Total Program are expected to be substantially completed by the end of 2013.

2010 Restructuring Plan

On February 6, 2010, our Board of Directors approved, and we committed to, a series of management changes and restructuring initiatives (the 2010 Restructuring plan) designed to focus our business, drive innovation, accelerate profitable revenue growth and increase both accountability and shareholder value. Key activities under the plan included the restructuring of certain of our businesses and corporate functions; the re-alignment of our international structure to reduce our administrative costs and invest in expansion opportunities including significant investments in emerging markets; and the reprioritization and diversification of

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our product portfolio. Activities under the 2010 Restructuring plan were initiated in the first quarter of 2010 and were completed by the end of 2012, and resulted in gross reductions in pre-tax operating expenses of approximately $250 million. A portion of these savings were reinvested into customer-facing positions and other commercial resources and infrastructure.

Plant Network Optimization

In January 2009, our Board of Directors approved, and we committed to, a Plant Network Optimization program, intended to simplify our manufacturing plant structure by transferring certain production lines among facilities and by closing certain other facilities. The program was a complement to our 2007 restructuring plan, and was intended to improve overall gross profit margins. The program has resulted in annualized run-rate reductions of manufacturing costs of approximately $65 million exiting 2012. These savings are in addition to the $35 million of annual reductions of manufacturing costs from activities under our 2007 restructuring plan. Activities under the Plant Network Optimization program were initiated in the first quarter of 2009 and were substantially completed during 2012.

Neurovascular Divestiture

In January 2011, we closed the sale of our Neurovascular business to Stryker Corporation for a purchase price of $1.5 billion in cash. We received $1.450 billion during 2011, $10 million during 2012, and will receive an additional $40 million contingent upon the transfer or separation of certain manufacturing facilities, which we expect will occur during 2013. We are providing transitional services through a transition services agreement, and are also manufacturing and supplying products to Stryker through a supply agreement. These transition services and supply arrangements are expected to end in 2013. We recorded revenue of $122 million during 2012 related to this divested business as compared to $141 million during 2011 and $344 million of sales of Neurovascular and other divested product lines in 2010. Our sales related to divested businesses will continue to decline as the various transition services and supply agreements terminate in 2013. See Results of Operations and Note C - Divestitures and Assets Held for Sale for additional information.

Healthcare Reform

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act were enacted into law in the U.S. in 2010. Certain provisions of the law have yet to be implemented and there are many programs and requirements for which the details have not yet been fully established or consequences not yet fully understood; therefore, it is unclear what the full impact will be from the law. The legislation imposes on medical device manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in January 2013. We intend to record this tax within our selling, general and administrative expenses and expect that our excise tax liability for 2013 will be up to $80 million. Other provisions of this law, including Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, could meaningfully change the way healthcare is developed and delivered, and will place a significant emphasis on clinical and economic data to demonstrate efficacy and justify the economic benefits of technology purchases. Any changes that lower reimbursement for our products or reduce medical procedure volumes could adversely affect our business and results of operations. Further, we cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation in the U.S. or internationally.

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Results of Operations

Net Sales

As of December 31, 2012, we had four reportable segments based on geographic regions: the United States; EMEA, consisting of Europe, the Middle East and Africa; Japan; and Inter-Continental, consisting of our Asia Pacific and the Americas operating segments, which include the emerging markets of Brazil, China and India. The reportable segments represent an aggregate of all operating divisions within each segment. We manage our international operating segments on a constant currency basis, and we manage market risk from currency exchange rate changes at the corporate level. Management excludes the impact of changes in foreign currency exchange rates for purposes of reviewing regional and divisional revenue growth rates to facilitate an evaluation of current operating performance and comparison to past operating performance. To calculate revenue growth rates that exclude the impact of changes in foreign currency exchange rates, we convert current period and prior period net sales from local currency to U.S. dollars using standard currency exchange rates. The regional constant currency growth rates in the tables below can be recalculated from our net sales by reportable segment as presented in Note O – Segment Reporting to our 2012 consolidated financial statements contained in Item 8 of this Annual Report.

The following tables provide our worldwide net sales by region and the relative change on an as reported and constant currency basis. We have restated regional net sales for 2011 and 2010 to exclude sales from our former Neurovascular business, which we sold to Stryker Corporation in January 2011, and present net sales from this business within divested businesses in the tables below. Net sales that exclude the impact of changes in foreign currency exchange rates and net sales from divested businesses are not financial measures prepared in accordance with U.S. GAAP and should not be considered in isolation from, or as a replacement for, the most directly comparable GAAP financial measure. Refer to Additional Information of this Item 7 for a further discussion of management's use of this non-GAAP financial measure.

				2012 versus 2011		2011 versus 2010	
	Year Ended December 31,			As Reported Currency Basis	Constant Currency Basis	As Reported Currency Basis	Constant Currency Basis
(in millions)	2012	2011 (restated)*	2010 (restated)*				
United States	$3,756	$4,010	$4,215	(6)%	(6)%	(5)%	(5)%
EMEA	1,568	1,721	1,662	(9)%	(3)%	4%	(1)%
Japan	931	951	886	(2)%	(2)%	7%	(2)%
Inter-Continental	872	799	699	9%	11%	14%	9%
International	3,371	3,471	3,247	(3)%	1%	7%	1%
Subtotal Core Businesses	7,127	7,481	7,462	(5)%	(3)%	0%	(2)%
Divested Businesses	122	141	344	N/A	N/A	N/A	N/A
Worldwide	$7,249	$7,622	$7,806	(5)%	(3)%	(2)%	(5)%

* We have restated prior year regional detail to conform to current year presentation.

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The following tables provide our worldwide net sales by division and the relative change on an as reported and constant currency basis.

	Year Ended December 31,			2012 versus 2011		2011 versus 2010	
				As Reported Currency	Constant Currency	As Reported Currency	Constant Currency
(in millions)	2012	2011	2010	Basis	Basis	Basis	Basis
Interventional Cardiology	$2,179	$2,495	$2,602	(13)%	(11)%	(4)%	(7)%
Cardiac Rhythm Management	1,908	2,087	2,180	(9)%	(7)%	(4)%	(7)%
Endoscopy	1,252	1,187	1,079	5 %	7 %	10 %	6 %
Peripheral Interventions	774	731	669	6 %	8 %	9 %	5 %
Urology/Women's Health	500	498	481	— %	1 %	4 %	2 %
Neuromodulation	367	336	304	9 %	9 %	11 %	10 %
Electrophysiology	147	147	147	— %	1 %	— %	(2)%
Subtotal Core Businesses	7,127	7,481	7,462	(5)%	(3)%	— %	(2)%
Divested Businesses	122	141	344	N/A	N/A	N/A	N/A
Worldwide	$7,249	$7,622	$7,806	(5)%	(3)%	(2)%	(5)%

The divisional constant currency growth rates in the tables above can be recalculated from the reconciliations provided below. Growth rates are based on actual, non-rounded amounts and may not recalculate precisely.

	2012 Net Sales as compared to 2011 Change			2011 Net Sales as compared to 2010 Change		
(in millions)	As Reported Currency Basis	Constant Currency Basis	Estimated Impact of Foreign Currency	As Reported Currency Basis	Constant Currency Basis	Estimated Impact of Foreign Currency
Interventional Cardiology	$(316)	$(266)	$(50)	$(107)	$(180)	$73
Cardiac Rhythm Management	(179)	(145)	(34)	(93)	(144)	51
Endoscopy	65	84	(19)	108	69	39
Peripheral Interventions	43	56	(13)	62	36	26
Urology/Women's Health	2	5	(3)	17	9	8
Neuromodulation	31	32	(1)	32	31	1
Electrophysiology	—	2	(2)	—	(3)	3
Subtotal Core Businesses	(354)	(232)	(122)	19	(182)	201
Divested Businesses	(19)	(18)	(1)	(203)	(206)	3
Worldwide	$(373)	$(250)	$(123)	$(184)	$(388)	$204

U.S. Net Sales

During 2012, our U.S. net sales decreased $254 million, or six percent, as compared to 2011. The decrease was driven primarily by lower U.S. Interventional Cardiology net sales of $232 million primarily as a result of lower market share due to competitive launches in 2012, continued average selling price declines in the U.S. DES market as a result of continued competitive pressures and declines in procedural volumes. In addition our U.S. CRM sales declined $114 million due to lower procedural volumes as a result of a contraction in the U.S. ICD market, lower average selling prices, and lower replacement volumes. Partially offsetting these decreases were our Endoscopy business that increased U.S. net sales $43 million, as compared to 2011, due to growth across several of its key product franchises; our Neuromodulation division which increased U.S. net sales $25 million, as compared to 2011, due to market share increases from strong commercial execution and continued market expansion; and our Peripheral Interventions business which increased U.S. net sales of $30 million, as compared to 2011, on the strength of several new product launches. Refer to Business and Market Overview for further discussion of our net sales.

During 2011, our U.S. net sales decreased $205 million, or five percent, as compared to 2010. The decrease was driven primarily by lower U.S. CRM net sales of $129 million resulting from the contraction in the U.S. ICD market in 2011, as well as lower U.S. Interventional Cardiology net sales of $119 million driven by competitive and other pricing pressures and reductions in procedural volumes across our key markets. Partially offsetting these decreases, our Endoscopy business increased U.S. net sales $21 million,

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as compared to 2010, due primarily to continued commercialization and adoption of products within our stent franchise, and our Neuromodulation division increased U.S. net sales $29 million, as compared to 2010, due primarily to higher procedural volumes and positive momentum from new product launches.

International Net Sales

During 2012, our international net sales decreased $100 million, or three percent, as compared to 2011. Changes in foreign currency exchange rates negatively impacted our international net sales by $122 million in 2012 as compared to 2011. Excluding the negative impact of changes in foreign currency exchange rates of $122 million, international net sales grew $22 million or one percent as compared to 2011. Excluding the negative impact of changes in foreign currency exchange of $13 million, sales in our Inter-Continental region increased $86 million, or 11 percent, in 2012, as compared to 2011. The increase in our Inter-Continental sales was due to growth across several of our businesses and continued growth in Brazil, India and China. Excluding the negative impact of changes in foreign currency exchange of $105 million, net sales in our EMEA region decreased $48 million, or three percent, in 2012, as compared to 2011; driven primarily by a decline in CRM and Interventional Cardiology net sales of $33 million and $37 million, respectively, partially offset by growth in all other businesses. Excluding the impact of changes in foreign currency exchange of $4 million, our net sales in Japan decreased $16 million, or two percent, in 2012, as compared to 2011, due primarily to a decline in Interventional Cardiology net sales. Refer to Business and Market Overview for further discussion of our net sales.

During 2011, our international net sales increased $224 million, or seven percent, as compared to 2010. Changes in foreign currency exchange rates contributed $201 million to our international net sales in 2011 as compared to 2010. Excluding the impact of changes in foreign currency exchange rates, net sales in our Inter-Continental region increased $64 million, or nine percent, in 2011, as compared to 2010, primarily as a result of strong growth in Brazil, India and China as we began to see a return on our commercial investment in these areas. Net sales in our EMEA region decreased $20 million, or one percent, in 2011, as compared to 2010, excluding the impact of changes in foreign currency exchange rates, driven primarily by a decline in CRM net sales. Our net sales in Japan decreased $21 million, or two percent, in 2011, as compared to 2010, excluding the impact of changes in foreign currency exchange rates, due primarily to a decline in Interventional Cardiology net sales.

Gross Profit

Our gross profit was $4.900 billion in 2012, $4.963 billion in 2011, and $5.207 billion in 2010. As a percentage of net sales, our gross profit increased to 67.6 percent in 2012, as compared to 65.1 percent in 2011 and 66.7 percent in 2010. The following is a reconciliation of our gross profit margins and a description of the drivers of the change from period to period:

	Year Ended December 31,	
	2012	2011
Gross profit - prior year	65.1 %	66.7 %
PROMUS® supply true-up	(0.6)%	0.6 %
Neurovascular divestiture	— %	(1.4)%
Manufacturing cost reductions	1.4 %	— %
Transition-related inventory charges (credits)	0.7 %	(0.7)%
All other, including other inventory charges, other period expense and net impact of foreign currency	1.3 %	(0.3)%
Sales mix and pricing	(0.3)%	0.2 %
Gross profit - current year	67.6 %	65.1 %

The increase in our gross profit margin for 2012, as compared to 2011, is primarily the result of cost reductions from our restructuring and other process improvement programs. Our gross margin was negatively impacted by declines in average selling prices related primarily to sales of our drug-eluting stent and CRM products; however, these declines were largely offset by the full conversion to our internally-developed and self-manufactured next-generation PROMUS® Element™ stent system during 2012. Our PROMUS® Element™ stent system has significantly higher gross

margins than the prior generation PROMUS® stent system, which was supplied to us by Abbott Laboratories. Additionally, affecting our year over year comparison of year to date gross margin was the impact of a one-time $50 million credit to cost of products sold, related to a two-year retroactive pricing adjustment pursuant to our PROMUS® supply arrangement with Abbott and product transition-related inventory charges of $54 million recorded in 2011, discussed further below.

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The primary factor contributing to the decrease in our gross profit margin during 2011, as compared to 2010, was the negative impact of lower sales of Neurovascular products and at significantly lower gross profit margins as result of the divestiture of our Neurovascular business. In addition, we recognized transition-related inventory charges of $54 million in 2011, primarily related to PROMUS® excess inventory and purchase commitments as a result of our fourth quarter 2011 launch of our internally-developed and self-manufactured next-generation PROMUS® Element™ stent system in the U.S. The decreases in 2011 were partially offset by the positive impact of a $50 million credit to cost of products sold recognized in the first quarter of 2011, related to a two-year retroactive pricing adjustment pursuant to our PROMUS® supply arrangement with Abbott for historical purchases of PROMUS® stent systems. Declines in average selling prices of our products, particularly our drug-eluting stent systems, were offset by the positive impact of product mix related to sales of our drug-eluting stent systems, as we began shifting sales to our internally-developed and manufactured stent systems with more favorable gross profit margins during 2011. In addition, our gross profit margin in 2010 was negatively impacted by the ship hold and product removal actions associated with our U.S. CRM business.

We are subject to a final retroactive pricing adjustment pursuant to our PROMUS® supply arrangement with Abbott for historical purchases of PROMUS® stent systems. We may record a one-time benefit or charge to our gross profit in the future as a result of this adjustment process.

Operating Expenses

The following table provides a summary of certain of our operating expenses:

	Year Ended December 31,					
	2012		2011		2010	
(in millions)	$	% of Net Sales	$	% of Net Sales	$	% of Net Sales
Selling, general and administrative expenses	2,535	35.0	2,487	32.6	2,580	33.1
Research and development expenses	886	12.2	895	11.7	939	12.0
Royalty expense	153	2.1	172	2.3	185	2.4

Selling, General and Administrative (SG&A) Expenses

In 2012, our SG&A expenses increased $48 million, or two percent, as compared to 2011, and were 240 basis points higher as a percentage of net sales. This increase was driven primarily by continued investments in acquisitions and in commercial resources and infrastructure for global expansion, particularly in emerging markets, and a non-recurring asset impairment charge as a result of a program termination. Also contributing to the year-over-year increase was a benefit recorded in 2011 as a result of a reversal of previously established allowances for doubtful accounts against long-outstanding receivables in Greece. These increases in SG&A were partially offset by declines in spending as a result of our restructuring and other cost reduction initiatives and the impact of changes in foreign currency exchange rates. Beginning in January 2013, as a result of new legislation, all medical device manufacturers will be subject to a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices. We intend to record this tax within our selling, general and administrative expenses and expect that our excise tax liability for 2013 will be up to $80 million.

In 2011, our SG&A expenses decreased $93 million, or four percent, as compared to 2010, and were 50 basis points lower as a percentage of net sales. Our SG&A expenses were lower in 2011, as compared to 2010, as a result of the sale of our Neurovascular business to Stryker in January 2011 and lower expenses due to our restructuring initiatives and cost containment discipline. In addition, our SG&A expenses for 2011 benefited from the reversal of $20 million of previously established allowances for doubtful accounts against long-outstanding receivables in Greece in 2011. These receivables had previously been fully reserved as we had determined that they had a high risk of being uncollectible due to the economic situation in Greece. During the first quarter of 2011, the Greek government converted these receivables into bonds, which we were able to monetize, reducing our allowance for doubtful accounts as a credit to SG&A expense. These decreases were partially offset by the unfavorable impact of changes in foreign currency exchange rates, as well as additional SG&A expenses related to acquisitions and global expansion initiatives.

Research and Development (R&D) Expenses

In 2012, our R&D expenses decreased $9 million, or approximately one percent, as compared to 2011, and were 50 basis points higher as a percentage of net sales. The slight decrease in overall spending in 2012 was due to continued focus on cost reduction initiatives associated with our restructuring programs and the benefits from our strategy to transform our research and development efforts to be more effective and cost efficient, partially offset by increased R&D funding for our acquisitions. We remain committed

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to advancing medical technologies and investing in meaningful research and development projects across our businesses in order to maintain a healthy pipeline of new products that we believe will contribute to profitable sales growth.

In 2011, our R&D expenses decreased $44 million, or approximately five percent, as compared to 2010, and were 30 basis points lower as a percentage of net sales. The decrease in 2011 was due to the elimination of spending related to our Neurovascular business and cost reductions associated with our restructuring programs.

Royalty Expense

In 2012, our royalty expense decreased $19 million, or 11 percent, as compared to 2011, and was 20 basis points lower as a percentage of net sales. The decrease relates primarily to lower sales of our royalty-bearing products within our Interventional Cardiology business.

In 2011, our royalty expense decreased $13 million, or seven percent, as compared to 2010, and was slightly lower as a percentage of net sales. The decrease relates primarily to royalty expense attributable to Neurovascular products which was eliminated with the sale of our Neurovascular business in January 2011. These royalties represented $12 million of expense in 2010.

Amortization Expense

Our amortization expense was $395 million in 2012, as compared to $421 million in 2011, a decrease of $26 million or six percent. This decrease was due primarily to certain intangible assets associated with our acquisition of Guidant Corporation in 2006 reaching the end of their useful lives during the second quarter of 2011. This non-cash charge is excluded by management for purposes of evaluating operating performance and assessing liquidity.

Amortization expense was $421 million in 2011, as compared to $513 million in 2010, a decrease of $92 million, or 18 percent. This decrease was due primarily to certain intangible assets associated with our acquisition of Guidant Corporation in 2006 reaching the end of their useful lives during the second quarter of 2011.

Goodwill Impairment Charges

2012 Charges

We test our goodwill balances during the second quarter of each year for impairment, or more frequently if indicators are present or changes in circumstances suggest that impairment may exist. In the second quarter of 2012, we performed our annual goodwill impairment test for all of our reporting units and concluded that the goodwill within our EMEA reporting unit was impaired and recorded a $3.602 billion ($3.579 billion after-tax) charge in the second quarter of 2012. We finalized the second step of the EMEA goodwill impairment test during the third quarter of 2012, in accordance with ASC Topic 350, Intangibles -Goodwill and Other, and there were no adjustments to the charge upon finalization.

In the third quarter of 2012, we performed an interim goodwill impairment test and recorded a non-cash $748 million (pre- and after-tax) charge associated with our U.S. CRM reporting unit, primarily driven by the reduction in the estimated size of the U.S. CRM market, related adjustments to our business and other competitive factors, which led to lower projected U.S. CRM results compared to prior forecasts. We finalized the second step of the U.S. CRM goodwill impairment test during the fourth quarter of 2012, in accordance with ASC Topic 350, Intangibles -Goodwill and Other, and there were no adjustments to the charge upon finalization.

In our goodwill impairment tests we used the income approach, specifically the discounted cash flow (DCF) method, to derive the fair value of our EMEA and U.S. CRM reporting units, as described in our accounting policies. We updated all aspects of the DCF models associated with the EMEA and U.S. CRM businesses, including the amount and timing of future expected cash flows, terminal value growth rates and the appropriate market-participant risk-adjusted weighted average costs of capital (WACC) to apply.

EMEA

As a result of revised estimates developed during our annual strategic planning process and analysis performed in conjunction with our annual goodwill impairment test in the second quarter, we concluded that the revenue growth rates projected for the EMEA reporting unit would be slightly lower than our previous estimates primarily driven by macro-economic factors and our performance in the European market. We updated short-term operating projections based on our most recent strategic plan for EMEA prepared by management. We reduced the EMEA long-term growth rates and terminal value growth rate projections and increased the discount rate within our 15-year DCF model

for EMEA by approximately 100 basis points due to increased risk associated with our projections in this market primarily as a result of the economic uncertainty in Europe. While we continue to

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project revenue growth in our EMEA business, our expectations for future growth and profitability were lower than our previous estimates and reflected declines in average selling prices and volume pressures due to austerity measures. The declines expected in the EMEA market did not impact our assumptions related to other reporting units.

The aggregate amount of goodwill that remains associated with our EMEA reporting unit is $556 million as of December 31, 2012. In addition, the remaining book value of our other EMEA intangible assets allocated to our EMEA reporting unit is approximately $1.563 billion as of December 31, 2012. In accordance with ASC Topic 350, we tested our EMEA amortizable intangible assets as of April 1, 2012 for impairment on an undiscounted cash flow basis, and determined that these assets were not impaired. We also tested our indefinite-lived intangible assets associated with EMEA as of April 1, 2012 and recorded an impairment charge related to the in-process research and development associated with our acquisition of Sadra Medical, Inc. See Intangible Asset Impairment Charges below for a further discussion of this impairment.

U.S. CRM

The U.S. CRM market is dynamic, highly competitive and difficult to forecast; in the third quarter of 2012, we lowered our projections for the U.S. CRM market size and our future revenue levels within this market, primarily to reflect recent changes in expectations of average selling prices and unit growth, adjustments to our business and other competitive factors. This reduction warranted an interim goodwill impairment test for our U.S. CRM reporting unit. The declines expected in the U.S. CRM market did not impact our assumptions related to other reporting units. The increased pricing pressure and lower unit volumes are primarily due to physician alignment with hospitals, efforts to reduce health care costs, focus on appropriate device usage, replacement volumes and competition, and have been more impactful to the U.S. CRM business than previously estimated. In addition, we recently aligned certain elements of our business and shifted investments to focus on areas expected to provide the highest future growth and financial return. As a result of these factors, we reduced the compound annual revenue growth rate of our 15 year DCF model for the U.S. CRM reporting unit by approximately 250 basis points. We continue to analyze business trends using all available information and our U.S. CRM goodwill remains sensitive to changes in expectations of future growth of this market and our performance.

Based on the remaining book value of our U.S. CRM reporting unit following the goodwill impairment charge recorded during the third quarter of 2012, the carrying value of our U.S. CRM reporting unit continues to exceed its fair value, due primarily to the value of amortizable intangible assets allocated to this reporting unit. The remaining book value of the amortizable intangible assets allocated to the U.S. CRM reporting unit was approximately $3.303 billion as of December 31, 2012. In accordance with ASC Topic 350, we tested the amortizable intangible assets as of September 30, 2012, in conjunction with the interim goodwill impairment test of our U.S. CRM reporting unit. We performed the impairment analysis of the amortizable intangible assets on an undiscounted cash flow basis, and concluded that these assets were not impaired. However, following the recent declines in our CRM projections, the recoverability of our CRM-related amortizable intangibles ($4.636 billion globally) are sensitive to changes in future cash flow assumptions and our CRM business performance. The $4.636 billion of CRM-related amortizable intangibles are at higher risk of potential failure of the first step of the amortizable intangible recoverability test in future reporting periods. An impairment of a material portion of our CRM-related amortizable intangibles carrying value would occur if the second step of the amortizable intangible test is required in a future reporting period.

We continue to identify three reporting units with goodwill that is at higher risk of potential failure of the first step of the goodwill impairment test in future reporting periods. These reporting units include our U.S. CRM reporting unit, which holds $216 million of remaining allocated goodwill; our U.S. Cardiovascular reporting unit, which holds $2.380 billion of allocated goodwill; and our U.S. Neuromodulation reporting unit, which holds $1.266 billion of allocated goodwill, each as of December 31, 2012. As of December 31, 2012, the level of excess fair value over carrying value for these reporting units identified as being at higher risk (with the exception of the U.S. CRM reporting unit, whose carrying value continues to exceed its fair value) was approximately seven to 11 percent. During the fourth quarter of 2012, the level of excess fair value over carrying value of our U.S. Cardiovascular reporting unit declined as a result of our performance, declines in our market share due to competitive launches, and continued average selling price declines in the U.S. drug-eluting stent (DES) market as a result of continued competitive pressures and declines in procedural volumes.

On a quarterly basis, we monitor the key drivers of fair value for these reporting units to detect events or other changes that would warrant an interim impairment test of our goodwill and intangible assets. The key variables that drive the cash flows of our reporting units and amortizable intangibles are estimated revenue growth rates and levels of profitability. Terminal value growth rate assumptions, as well as the WACC rate applied are additional key variables for reporting unit cash flows. These assumptions are subject to uncertainty, including our ability to grow revenue and improve profitability levels. Relatively small declines in the future performance and cash flows of a reporting unit or asset group or small changes in other key assumptions may result in the recognition of significant asset impairment charges. For example, keeping all other variables constant, a 80 basis point decrease in the long term revenue and terminal growth rates would require that we perform the second step of the goodwill impairment test for the U.S. Neuromodulation reporting unit. A 90 basis point decrease in the long term revenue and terminal growth rates would

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require that we perform the second step of the goodwill impairment test for the U.S. Cardiovascular reporting unit. An increase in the WACC applied of 70 basis points would require that we perform the second step of the goodwill impairment test for the U.S. Neuromodulation and U.S. Cardiovascular reporting units. Given that the carrying value of the U.S. CRM reporting unit continues to exceed its fair value, any negative changes in the key variables or values associated with this reporting unit would likely require that we perform the second step of the goodwill impairment test in a future reporting period. The estimates used for our future cash flows and discount rates represent management's best estimates, which we believe to be reasonable, but future declines in business performance may impair the recoverability of our goodwill and intangible asset balances.

Future events that could have a negative impact on the levels of excess fair value over carrying value of our reporting units and/or amortizable intangible assets include, but are not limited to:

- decreases in estimated market sizes or market growth rates due to greater-than-expected declines in procedural volumes, pricing pressures, product actions, and/or competitive technology developments;
- declines in our market share and penetration assumptions due to increased competition, an inability to develop or launch new and next-generation products and technology features in line with our commercialization strategies, and market and/or regulatory conditions that may cause significant launch delays or product recalls;
- decreases in our profitability due to an inability to successfully implement and achieve timely and sustainable cost improvement measures consistent with our expectations, increases in our market-participant tax rate, and/or changes in tax laws;
- negative developments in intellectual property litigation that may impact our ability to market certain products or increase our costs to sell certain products;
- the level of success of on-going and future research and development efforts, including those related to recent acquisitions, and increases in the research and development costs necessary to obtain regulatory approvals and launch new products;
- the level of success in managing the growth of acquired companies, achieving sustained profitability consistent with our expectations, establishing government and third-party payer reimbursement, and increases in the costs and time necessary to integrate acquired businesses into our operations successfully;
- changes in our reporting units or in the structure of our business as a result of future reorganizations or divestitures of assets or businesses;
- increases in our market-participant risk-adjusted WACC; and
- declines in revenue as a result of loss of key members of our sales force and other key personnel.

Negative changes in one or more of these factors, among others, could result in additional impairment charges.

2011 Charge

Based on market information that became available to us toward the end of the first quarter of 2011, we concluded that there was a reduction in the estimated size of the U.S. ICD market, which led to lower projected U.S. CRM results compared to prior forecasts and created an indication of potential impairment of the goodwill balance attributable to our U.S. CRM business unit. Therefore, we performed an interim impairment test in accordance with U.S. GAAP and our accounting policies and recorded a non-deductible goodwill impairment charge of $697 million, on both a pre-tax and after-tax basis, associated with this business unit during the first quarter of 2011.

2010 Charge

As a result of ship hold and product removal actions associated with our U.S. ICD and CRT-D products, which we announced on March 15, 2010, and the forecasted corresponding financial impact on our operations we concluded there was an indication of potential impairment of the goodwill balance attributable to our U.S. CRM reporting unit during the first quarter of 2010. Therefore, we performed an interim impairment test in accordance with U.S. GAAP and our accounting policies and recorded a non-deductible goodwill impairment charge of $1.817 billion, on both a pre-tax and after-tax basis, associated with our U.S. CRM reporting unit.

Goodwill impairment charges do not impact our debt covenants or our cash flows, and are excluded by management for purposes of evaluating operating performance and assessing liquidity.

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Intangible Asset Impairment Charges

On a quarterly basis, we monitor for events or other potential indicators of impairment that would warrant an interim impairment test of our intangible assets.

2012 Charges

During the third quarter of 2012, we performed our annual impairment test of all in-process research and development projects, and our indefinite lived core technology assets. Based on the results of our annual test, we recorded total impairment charges of $13 million to write-down the balances of certain in-process projects to their fair value. These charges were primarily due to increased expectations in the cost to bring an in-process project to market in a certain geographic region and lower future revenue expectations associated with an in-process project.

Following the recent declines in our CRM projections, the recoverability of our CRM-related amortizable intangibles ($4.636 billion globally) are sensitive to changes in future cash flow assumptions and our CRM business performance. The $4.636 billion of CRM-related amortizable intangibles are at higher risk of potential failure of the first step of the amortizable intangible recoverability test in future reporting periods. An impairment of a material portion of our CRM-related amortizable intangibles carrying value would occur if the second step of the amortizable intangible test is required in a future reporting period. See Goodwill Impairment Charges above for discussion of future events that could have a negative impact on the levels of excess fair value over carrying value of our reporting units and/or amortizable intangible assets.

During the second quarter of 2012, as a result of revised estimates developed in conjunction with our annual strategic planning process and annual goodwill impairment test, we performed an interim impairment test of our in-process research and development projects associated with our acquisition of Sadra Medical, Inc. Based on our impairment analysis, we revised our expectations of the required effort, time and cost involved in completing the in-process projects and bringing the related products to market. As a result of these changes, we recorded an impairment charge of $129 million to write-down the balance of these intangible assets to their fair value during the second quarter of 2012.

2011 Charges

During the third quarter of 2011, we recorded a $9 million intangible asset impairment charge attributable to lower projected cash flows associated with certain technologies. During the second quarter of 2011, we recorded a $12 million intangible asset impairment charge associated with changes in the timing and amount of the expected cash flows related to certain purchased research and development projects.

2010 Charges

During the first quarter of 2010, due to lower than anticipated net sales of one of our Peripheral Interventions technology offerings, as well as changes in our expectations of future market acceptance of this technology, we lowered our sales forecasts associated with a product. In addition, during the third quarter of 2010, as part of our initiatives to reprioritize and diversify our product portfolio, we discontinued one of our internal research and development programs to focus on those with a higher likelihood of success. As a result of these factors, we tested the related intangible assets for impairment and recorded a $60 million charge in the first quarter of 2010, and a $5 million charge in the third quarter of 2010 to write down the balance of these intangible assets to their fair value. Intangible asset impairment charges are non-cash charges that are excluded by management for purposes of evaluating operating performance and assessing liquidity.

Contingent Consideration Expense

Certain of our acquisitions involve contingent consideration arrangements. Payment of additional consideration is generally contingent on the acquired company reaching certain performance milestones, including attaining specified revenue levels, achieving product development targets or obtaining regulatory approvals. In accordance with U.S. GAAP, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We re-measure this liability each reporting period and record changes in the fair value through a separate line item within our consolidated statements of operations. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, as well as changes in the

timing and amount of revenue estimates or in the timing or likelihood of achieving regulatory, revenue or commercialization-based milestones.

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We recorded a net benefit related to the change in fair value of our contingent consideration liabilities of $6 million in 2012 and net expenses of $7 million in 2011 and $2 million in 2010. Contingent consideration expense is excluded by management for purposes of evaluating performance. See Note B – Acquisitions to our 2012 consolidated financial statements contained in Item 8 of this Annual Report for further discussion of our contingent consideration associated with our acquisitions.

Acquisition-related Milestone

In connection with Abbott Laboratories' 2006 acquisition of Guidant's vascular intervention and endovascular solutions businesses, Abbott agreed to pay us a milestone payment of $250 million upon receipt of an approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) to market the XIENCE V® stent system in Japan. The MHLW approved the XIENCE V® stent system in the first quarter of 2010 and we received the milestone payment from Abbott, which we recorded as a $250 million pre-tax gain. This non-recurring acquisition-related gain is excluded by management for purposes of evaluating operating performance.

Restructuring Charges and Restructuring-related Activities

2011 Restructuring Plan

On July 26, 2011, our Board of Directors approved, and we committed to, a restructuring initiative (the 2011 Restructuring plan) designed to strengthen operational effectiveness and efficiencies, increase competitiveness and support new investments, thereby increasing shareholder value. The original estimate of the plan was a reduction of annual pre-tax operating expenses by approximately $225 million to $275 million exiting 2013, a substantial portion of which is expected to be reinvested in targeted areas necessary for future growth, including strategic growth initiatives and emerging markets. Key activities under the plan include standardizing and automating certain processes and activities; relocating select administrative and functional activities; rationalizing organizational reporting structures; leveraging preferred vendors; and other efforts to eliminate inefficiency. Among these efforts, we are expanding our ability to deliver best-in-class global shared services for certain functions and divisions at several locations in emerging markets. This action is intended to enable us to grow our global commercial presence in key geographies and take advantage of many cost-reducing and productivity-enhancing opportunities. In addition, we are undertaking efforts to streamline various corporate functions, eliminate bureaucracy, increase productivity and better align corporate resources to our key business strategies.

On January 25, 2013, our Board of Directors approved, and we committed to, an expansion of the 2011 restructuring program (the Expansion). The Expansion is intended to further strengthen our operational effectiveness and efficiencies and support new investments, which we expect to increase stockholder value. We estimate that the Expansion will reduce gross annual pre-tax operating expenses by approximately $100 million to $115 million exiting 2013; and that the total 2011 Restructuring plan, including the Expansion (Total Program), will reduce gross annual pre-tax operating expenses by approximately $340 million to $375 million exiting 2013. We expect a substantial portion of the Total Program savings to be reinvested in targeted areas for future growth, including strategic growth initiatives and emerging markets. Key activities under the Expansion include further initiatives to: standardize and automate certain processes and activities; relocate select administrative and functional activities; rationalize organizational reporting structures; expand shared services; and align expenses to revenues within certain divisions and geographic regions. In addition, they include further efforts to streamline various corporate functions, eliminate bureaucracy, increase productivity and better align corporate resources to our key business strategies. Key activities under the Total Program are expected to be substantially completed by the end of 2013.

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We estimate that the implementation of the Expansion will result in pre-tax charges of approximately $140 million to $160 million, of which approximately $100 million to $120 million is expected to result in future cash outlays. We estimate that the implementation of the Total Program will result in total pre-tax charges of approximately $300 million to $355 million, and that approximately $270 million to $300 million of these charges will result in future cash outlays, of which we had made payments of $128 million as of December 31, 2012. The following table provides a summary of our estimates of costs associated with the Expansion and the Total Program by major type of cost:

Type of cost	Total estimated amount expected to be incurred	
	Expansion	Total Program
Restructuring charges:		
Termination benefits	$55 million to $65 million	$185 million to $210 million
Other (1)	$50 million to $55 million	$70 million to $90 million
Restructuring-related expenses:		
Other (2)	$35 million to $40 million	$45 million to $55 million
	$140 million to $160 million	$300 million to $355 million

(1) Includes primarily consulting fees, fixed asset write-offs and costs associated with contractual cancellations.

(2) Comprised of other costs directly related to the restructuring program, including program management, accelerated depreciation, retention and infrastructure-related costs.

As of December 31, 2012, we have recorded costs of $184 million since the inception of the 2011 Restructuring plan, and are recording a portion of these expenses as restructuring charges and the remaining portion through other lines within our consolidated statements of operations.

2010 Restructuring Plan

On February 6, 2010, our Board of Directors approved, and we committed to, a series of management changes and restructuring initiatives (the 2010 Restructuring plan) designed to focus our business, drive innovation, accelerate profitable revenue growth and increase both accountability and shareholder value. Key activities under the plan included the restructuring of certain of our businesses and corporate functions; the re-alignment of our international structure to reduce our administrative costs and invest in expansion opportunities including significant investments in emerging markets; and the re-prioritization and diversification of our product portfolio. Activities under the 2010 Restructuring plan were initiated in the first quarter of 2010 and were complete by the end of 2012, and resulted in gross reductions in pre-tax operating expenses of approximately $250 million. A portion of these savings were reinvested into customer-facing positions and other commercial resources and infrastructure.

The execution of the 2010 Restructuring plan resulted in total pre-tax charges of $160 million, and required cash outlays of $145 million, of which we had made payments of $144 million to date. We have recorded a portion of these expenses as restructuring charges and the remaining portion through other lines within our consolidated statements of operations.

Plant Network Optimization Program

In January 2009, our Board of Directors approved, and we committed to, a plant network optimization initiative (the Plant Network Optimization program), intended to simplify our manufacturing plant structure by transferring certain production lines among facilities and by closing certain other facilities. The program was a complement to the restructuring initiatives approved by our Board of Directors in 2007 (the 2007 Restructuring plan), and was intended to improve overall gross profit margins. The program has resulted in annualized run-rate reductions of manufacturing costs of approximately $65 million exiting 2012. These savings are in addition to the $35 million of annual reductions of manufacturing costs from activities under our 2007 Restructuring plan. Activities under the Plant Network Optimization program were initiated in the first quarter of 2009 and were substantially completed during 2012.

We expect that the execution of the Plant Network Optimization program will result in total pre-tax charges of approximately $132 million to $135 million, and that approximately $105 million to $110 million of these charges will result in cash outlays, of which we had made payments of $102 million to date. We have recorded related costs of

$132 million since the inception of the plan, and recorded a portion of these expenses as restructuring charges and the remaining portion through cost of products sold within our consolidated statements of operations.

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In aggregate, we recorded restructuring charges pursuant to our restructuring plans of $136 million during 2012, $89 million during 2011, and $116 million during 2010. In addition, we recorded expenses within other lines of our accompanying consolidated statements of operations related to our restructuring initiatives of $24 million during 2012, $40 million during 2011, and $53 million during 2010. Restructuring and restructuring-related costs are excluded by management for purposes of evaluating operating performance.

We made cash payments of $149 million in 2012, $114 million in 2011 and $133 million in 2010 associated with our restructuring initiatives.

See Note H - Restructuring Related Activities to our 2012 consolidated financial statements included in Item 8 of this Annual Report for additional details related to our restructuring plans.

Litigation-related Charges and Credits

During 2012 and 2011, we recorded net litigation-related charges in the amount of $192 million and $48 million, respectively. In 2010, we recorded a litigation-related credit of $104 million associated with a settlement of a dispute we had with Medinol Ltd. These charges and credits are excluded by management for purposes of evaluating operating performance. We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants.

Gain on Divestiture

In January 2011, we closed the sale of our Neurovascular business to Stryker Corporation for a purchase price of $1.500 billion in cash. We received $1.450 billion during 2011, including an upfront payment of $1.426 billion, and $24 million which was placed into escrow and released throughout 2011 upon the completion of local closings in certain foreign jurisdictions. During 2012, we received an additional $10 million of consideration, which we recorded as a gain in our accompanying consolidated statements of operations. We will receive the remaining $40 million of consideration upon the transfer or separation of certain manufacturing facilities, which we expect will occur during 2013. Due to our continuing involvement in the operations of the Neurovascular business, the divestiture does not meet the criteria for presentation as a discontinued operation. We recorded a pre-tax gain of $778 million during 2011 associated with the transaction and a gain of $15 million during 2012. These divestiture-related gains are excluded by management for purposes of evaluating operating performance.

Interest Expense

Our interest expense decreased to $261 million in 2012, as compared to $281 million in 2011. The decrease in our interest expense was a result of lower average debt levels, due to repayment of $1.250 billion of debt during 2011, and the refinancing of our credit facility in April 2012 at lower average costs. Our average borrowing rate was 5.5 percent in 2012 and 5.4 percent in 2011. Our 2011 interest expense included $6 million associated with the write-off of debt issuance costs, and a $3 million benefit associated with interest rate derivative contracts terminated during 2011. Refer to Liquidity and Capital Resources and Note F – Borrowings and Credit Arrangements to our 2012 consolidated financial statements contained in Item 8 of this Annual Report for information regarding our debt obligations.

Our interest expense was $281 million in 2011, as compared to $393 million in 2010. The decrease in our interest expense was a result of lower average debt levels, due to repayment of $1.250 billion of debt during 2011, as well as lower average borrowing rates. Our average borrowing rate was 5.4 percent in 2011 and 6.0 percent in 2010. Our 2010 interest expense included $25 million of write-offs of debt issuance costs, discounts, and the impacts of the early termination of interest rate derivative contracts associated with loan prepayments.

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Other, net

Our other, net reflected income of $22 million in 2012, income of $19 million in 2011, and expense of $14 million in 2010. The following are the components of other, net:

	Year Ended December 31,		
(in millions)	2012	2011	2010
Interest income	$5	$7	$13
Foreign currency losses	(18)	(12)	(9)
Net gains (losses) on investments	37	27	(12)
Other expense, net	(2)	(3)	(6)
	$22	$19	$(14)

During 2012, we recognized gains of $39 million associated with 2012 acquisitions in which we held prior equity interests, which were partially offset by net losses of $2 million related to our investment portfolio. During 2011, we recognized gains of $38 million associated with 2011 acquisitions in which we held prior equity interests, which were partially offset by net losses of $11 million on our investment portfolio. During 2010, we recognized net losses of $12 million relating to the write-down of investments in our portfolio. The acquisition-related gains from previously held investments are excluded by management for purposes of evaluating operating performance.

Tax Rate

The following table provides a summary of our reported tax rate:

	Year Ended December 31,		
	2012	2011	2010
Reported tax rate	(1.0)%	31.3 %	0.2 %
Impact of certain receipts/charges*	12.7 %	(12.0)%	18.0 %
	11.7 %	19.3 %	18.2 %

*These receipts/charges are taxed at different rates than our effective tax rate.

The change in our reported tax rate for 2012, as compared to 2011 and 2010, relates primarily to the impact of certain receipts and charges that are taxed at different rates than our effective tax rate. In 2012, these receipts and charges include goodwill and intangible asset impairment charges, acquisition- and divestiture-related net credits, and litigation- and restructuring-related charges. Our reported tax rate was also affected by discrete tax items related primarily to the resolution of an uncertain tax position resulting from an unfavorable court ruling. In addition, the decrease in the tax rate excluding the impact of these receipts and charges in 2012 as compared to 2011 is primarily the result of shifts in the geographic mix of our business. In 2011, these receipts and charges included a gain on our divestiture of the Neurovascular business, a non-deductible goodwill impairment charge, other intangible asset impairment charges and restructuring-, litigation- and acquisition-related charges and credits. Our reported tax rate was also affected by discrete tax items, related primarily to a release of valuation allowances resulting from a change in our expected ability to realize certain deferred tax assets, changes in various state tax laws, the resolution of various uncertain tax positions resulting from closing agreements with the Internal Revenue Service (IRS), the resolution of various uncertain tax positions resulting from the expiration of the statute of limitations for assessing tax in certain jurisdictions, and the finalization of our 2010 U.S. Federal tax return. In 2010, these receipts and charges included goodwill and intangible asset impairment charges, a gain associated with the receipt of an acquisition-related milestone payment, and restructuring-related charges. In 2010, our reported tax rate was also affected by discrete tax items, related primarily to the re-measurement of an uncertain tax position resulting from a favorable court ruling issued in a similar third-party case and the resolution of an uncertain tax position resulting from a favorable taxpayer motion issued in a similar third-party case.

We have received Notices of Deficiency from the IRS reflecting proposed audit adjustments for Guidant Corporation for its 2001 through 2006 tax years and Boston Scientific Corporation for its 2006 and 2007 tax years. Subsequent to issuing these Notices, the IRS conceded a portion of its original assessment. The total incremental tax liability now

asserted by the IRS for the applicable periods is $1.162 billion plus interest. The primary issue in dispute for all years is the transfer pricing in connection with the technology license agreements between domestic and foreign subsidiaries of Guidant. In addition, the IRS has proposed adjustments in connection with the financial terms of our Transaction Agreement with Abbott Laboratories pertaining to the sale of Guidant's vascular intervention business to Abbott in April 2006. We do not agree with the transfer pricing methodologies applied by the

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IRS or its resulting assessment and we believe that the IRS has exceeded its authority by attempting to adjust the terms of our negotiated third-party agreement with Abbott. In addition, we believe that the IRS positions with regard to these matters are inconsistent with the applicable tax laws and the existing Treasury regulations.

We believe we have meritorious defenses for our tax filings and we have filed, or will timely file, petitions with the U.S. Tax Court contesting the Notices of Deficiency for the tax years in challenge. No payments on the net assessment would be required until the dispute is definitively resolved, which, based on experiences of other companies, could take several years. We believe that our income tax reserves associated with these matters are adequate and the final resolution will not have a material impact on our financial condition or results of operations. However, final resolution is uncertain and could have a material impact on our financial condition or results of operations.

In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012. Our current financial position and results of operations are not impacted by this Act. However, for 2013, our results of operations are expected to be favorably impacted as certain provisions, including the U.S. R&D tax credit, are retroactively reenacted for the year ending December 31, 2012. Refer to Note J - Income Taxes for our 2012 consolidated financial statements contained in Item 8 of this Annual Report for more information.

Liquidity and Capital Resources

As of December 31, 2012, we had $207 million of cash and cash equivalents on hand, comprised of $39 million invested in money market and government funds and $168 million in interest bearing and non-interest bearing bank accounts. We invest excess cash on hand in short-term financial instruments that earn market interest rates while mitigating principal risk through instrument and counterparty diversification as well as what we believe to be prudent instrument selection. We limit our direct exposure to securities in any one industry or issuer. We also have full access to our $2.000 billion revolving credit facility and $350 million of available borrowings under our credit and security facility secured by our U.S. trade receivables, both described below.

The following provides a summary and description of our net cash inflows (outflows) for the years ended December 31, 2012, 2011 and 2010:

	Year Ended December 31,		
(in millions)	2012	2011	2010
Cash provided by operating activities	$1,260	$1,008	$325
Cash provided by (used for) investing activities	(579)	776	(468)
Cash used for financing activities	(744)	(1,728)	(508)

Operating Activities

During 2012, we generated $1.260 billion from operating activities, as compared to $1.008 billion in 2011, an increase of $252 million. This increase was driven primarily by accounts receivable and inventory reductions, which generated approximately $103 million; the impact of litigation-related payments of approximately $300 million to the U.S. Department of Justice in 2011; and lower tax-related net cash outflows of approximately $40 million during 2012. Partially offsetting these items was the impact of lower operating profit in 2012 and a $35 million increase in restructuring-related payments as compared to 2011. Our cash provided by operating activities in 2011 also included proceeds of approximately $80 million related to the termination of our outstanding interest rate derivative contracts and the receipt of a $75 million manufacturing cost true-up payment from Abbott in accordance with our supply agreement.

During 2011 we generated $683 million more of operating cash flows than in 2010. This increase was driven primarily by lower litigation-related payments of approximately $1.3 billion. Our 2011 litigation-related payments primarily consisted of a payment of approximately $300 million to the U.S. Department of Justice in the first quarter of 2011; during 2010, we made payments of $1.725 billion to Johnson & Johnson related to a patent litigation settlement and received $104 million in connection with a litigation settlement with Medinol. Our cash provided by operating activities in 2011 also included proceeds of approximately $80 million related to the termination of our outstanding interest rate derivative contracts and the receipt of a $75 million manufacturing cost true-up payment from Abbott in accordance with our supply agreement. In 2011 we incurred net tax payments in the amount of $138 million

as compared to net tax related receipts of $286 million in 2010. In addition, our 2010 cash flows include the receipt of a $250 million milestone payment from Abbott.

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Investing Activities

During 2012, cash used for investing activities was $579 million. Our investing activities included capital expenditures of $226 million and payments for the acquisitions of Cameron Health Inc., Bridgepoint Medical Inc., Rhythmia Medical Inc., and Vessix Vascular Inc., totaling $366 million. We expect to incur total capital expenditures of approximately $300 million during 2013.

During 2011, cash provided by investing activities was comprised primarily of proceeds from the sale of our Neurovascular business to Stryker. We received $1.440 billion of net cash proceeds during 2011 related to the sale of this business. This cash inflow was partially offset by payments of $370 million for acquisitions consummated during 2011; and capital expenditures of $304 million.

During 2010, our investing activities were comprised primarily of capital expenditures of $272 million, as well as payments of approximately $200 million to acquire Asthmatx, Inc. and certain other strategic assets.

Financing Activities

Our cash flows from financing activities reflect issuances and repayments of debt, proceeds from stock issuances related to our equity incentive programs and repurchases of common stock pursuant to our authorized repurchase programs, discussed in Note L - Stockholders' Equity to our 2012 consolidated financial statements included in Item 8 of this Annual Report. Additionally, our financing activities included $146 million of contingent payments primarily associated with the achievement of receiving FDA approval of the S-ICD® system in September 2012.

Debt

We had total debt of $4.256 billion as of December 31, 2012 and $4.261 billion as of December 31, 2011. The debt maturity schedule for the significant components of our debt obligations as of December 31, 2012 is as follows:

(in millions)	2013	2014	2015	2016	2017	Thereafter	Total
Senior notes		$600					