BOSTON SCIENTIFIC CORP
Form 10-K
February 17, 2011

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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, 2010

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)

(508) 650-8000

(Registrant s telephone number)

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 $8.6 billion based on the closing price of the registrant s common stock on June 30, 2010, 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, 2011 was 1,523,368,979.

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 2011 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 improve the quality of patient care and the productivity of healthcare delivery through the development and advocacy of less-invasive medical devices and procedures. This is accomplished through the continuing refinement of existing products and procedures and the investigation and development of new technologies that are least- or less-invasive, reducing risk, trauma, procedure time and the need for aftercare; cost- and comparatively-effective and, where possible, reduce or eliminate refractory drug use. When used in this report, the terms we, us, our and the Company mean Boston Scientific Corporation and 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 and alliances designed to improve our ability to take advantage of growth opportunities in the medical device industry. On April 21, 2006, we consummated our acquisition of Guidant Corporation. With this acquisition, we became a major provider in the worldwide cardiac rhythm management (CRM) market, enhancing our overall competitive position and long-term growth potential and further diversifying our product portfolio. This acquisition has established us as one of the world s largest cardiovascular device companies and a global leader in microelectronic therapies. This and other 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, and better absorb the pressures of, the current healthcare environment of cost containment, managed care, large buying groups, government contracting and hospital consolidation and will generally assist us in navigating through the complexities of the global healthcare market, including healthcare reform.

Business Strategy

Our strategy is to lead global markets for less-invasive medical devices by developing and marketing innovative products, services and therapies that address unmet patient needs, provide superior clinical outcomes and demonstrate proven economic value. We intend to do so by building and buying products we understand, through sales forces we already have. The following are the five elements of our strategic plan:

Prepare our People

We believe that our success will be driven by strong leadership, robust communication and the high caliber of our employees. We have strengthened our focus on talent assessment and leadership development, and are committed to developing our people and providing them with opportunities to contribute to the Company s growth and success. Recently, we redefined the specific leadership criteria necessary for our people to allow us to win in our global marketplace. As a demonstration of our commitment to the preparation of our people, we have also developed a Leadership Academy, a set of integrated training and enrichment programs designed to support our goal of developing a culture of leadership at all levels within the organization.

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Optimize the Company

We plan to adapt our existing business model to allow us to operate in a more efficient manner and allow for enhanced execution, while providing better value to hospitals, better solutions to physicians and better outcomes to patients. In 2010, we began implementing several restructuring initiatives designed to strengthen and position us for long-term success, including the integration of our Cardiovascular and CRM groups into one stronger and more competitive organization that we believe will improve our ability to deliver innovative products and technologies, leading clinical science and exceptional service; as well as the restructuring of certain other businesses and corporate functions. We are centralizing corporate research and development to refocus and strengthen our innovation efforts, and are organizing our clinical organization to take full advantage of the global resources available to conduct more cost-effective clinical studies, accelerate the time to bring new products to market, and gain access to worldwide technological developments that we can implement across our product lines. In addition, we will look to transform the way we conduct research and development, leverage low-cost geographies, and scrutinize our cost structure, which we expect will generate significant savings over the next three years.

Win Global Market Share

Through our global presence, we seek to increase net sales and market share, and leverage our relationships with leading physicians and their clinical research programs. We plan to re-align our International regions to be more effective in executing our business strategy and renew our focus on selling in order to maximize our opportunities in countries whose economies and healthcare sectors are growing rapidly. We expect to invest $30 million to $40 million by the end of 2011 to introduce new products and strengthen our sales organization in emerging markets such as Brazil, China and India.

Expand our Sales and Marketing Focus

We are expanding our focus on sales, using new analytics, best practices and technologies to improve our sales methods and tools. We are also increasing our global sales focus through targeted sales force expansions and through delivering new global best practice capabilities in crucial areas such as training, management, forecasting and planning, and reaching the economic customer on a global basis. We offer products in numerous product categories, which are used by physicians throughout the world in a broad range of diagnostic and therapeutic procedures. The breadth and diversity of our product lines permit medical specialists and purchasing organizations to satisfy many of their less-invasive medical device requirements from a single source. In addition, we endeavor to expand our footprint in the hospital beyond our current product offerings to provide us greater strategic mass.

Realign our Business Portfolio

We are directing our research and development and business development efforts to products with higher returns and increasing our discipline and metrics to improve returns on our investments. We are realigning our business portfolio through strategic acquisitions and select divestitures in order to reduce risk, optimize operational leverage and accelerate profitable, sustainable revenue growth, while preserving our ability to meet the needs of physicians and their patients. We expect to continue to invest in our core franchises, and also investigate opportunities to further expand our presence in, and diversify into, priority growth areas including atrial fibrillation, autonomic modulation therapy, coronary artery disease, deep-brain stimulation, diabetes/obesity, endoluminal surgery, endoscopic pulmonary intervention, hypertension, peripheral vascular disease, structural heart disease, sudden cardiac arrest, and women s health. We have recently announced several acquisitions targeting many of the above conditions and disease states, and, in January 2011, closed the sale of our

Neurovascular business to Stryker Corporation. The sale of our Neurovascular business provides us with increased flexibility to fund acquisitions and repay debt.

We believe that the execution of this strategy will drive innovation, accelerate profitable revenue growth and increase shareholder value.

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Products

During 2010, our products were offered for sale by seven dedicated business groups CRM; Cardiovascular, including our Interventional Cardiology and Peripheral Interventions businesses; Electrophysiology; Endoscopy; Urology/Women s Health; Neuromodulation; and Neurovascular. In 2010, we began the restructuring of our organization, which we believe will allow us to operate in a more effective and efficient manner, and includes the integration of our CRM and Cardiovascular groups into a newly formed Cardiology, Rhythm and Vascular group, which includes an Endovascular unit encompassing Peripheral Interventions, Imaging and Electrophysiology.

During 2010, we derived 28 percent of our net sales from our CRM business, 42 percent from our Cardiovascular group, two percent from our Electrophysiology business, 14 percent from our Endoscopy business, six percent from our Urology/Women s Health business, four percent from our Neuromodulation business, and four percent from our Neurovascular business. The following section describes certain of our product offerings:

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 implantable cardiac resynchronization therapy defibrillator (CRT-D) systems used to treat heart failure; and

- 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. In 2010, we launched several new CRM products, including an upgrade to our LATITUDE® system, providing enhanced functionality, as well as our new 4-SITE lead delivery system. We have experienced continued success with our next-generation COGNIS® CRT-D and TELIGEN® ICD systems, as well as our ALTRUA® family of pacemaker systems and, in 2011 and 2012, we will continue to execute on our product pipeline with the expected launch of our next-generation INGENIO pacemaker system, and our next-generation line of defibrillators, INCEPTA , ENERGEN and PUNCTUA . This product line includes new features designed to improve functionality, diagnostic capability and ease of use.

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. Our VeriFLEX (Liberté®) bare-metal coronary stent system is designed to enhance deliverability and conformability, particularly in challenging lesions. We have further enhanced the outcomes associated with the use of coronary stents, particularly the processes that lead to restenosis[1], through dedicated internal and external product development, strategic alliances and scientific research of drug-eluting stent systems. 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 are the industry leader for

[1] The growth of neointimal tissue within an artery after angioplasty and stenting.

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widest range of coronary stent sizes. In 2010, we launched our third-generation TAXUS® Element paclitaxel-eluting stent system in our Europe/Middle East/Africa (EMEA) region and certain Inter-Continental countries, and continue to sell our second-generation TAXUS® Liberté® paclitaxel-eluting stent system in the U.S. and Japan. We also market the PROMUS® everolimus-eluting stent system, currently supplied to us in the U.S. and Japan by Abbott Laboratories, as well as our next-generation internally-developed and manufactured everolimus-eluting stent system, the PROMUS® Element stent system, currently marketed in our EMEA region and certain Inter-Continental countries. We expect to launch our PROMUS® Element stent system in the U.S. and Japan in mid-2012, and our TAXUS® Element stent system in the U.S. (to be commercialized as ION) mid-2011 and Japan in late 2011 or early 2012.

Coronary Revascularization

We market a broad line of products used to treat patients with atherosclerosis. Atherosclerosis, a principal cause of coronary artery obstructive disease, 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). In 2010, we launched our Apex pre-dilatation balloon catheter with platinum marker bands for improved radiopacity, our NC Quantum Apex post-dilatation balloon catheter, developed specifically to address physicians needs in optimizing coronary stent deployment, which has been received very positively in the market, as well as our Kinetix family of guidewires. We continue to hold a strong leadership position in the PTCA balloon catheter market with an estimated 56 percent share of the U.S. market, and 38 percent worldwide.

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.

Structural Heart Therapy

In January 2011, as part of our priority growth initiatives, we completed the acquisition of Sadra Medical, Inc. Sadra is developing a fully repositionable and retrievable device for percutaneous aortic valve replacement (PAVR) to treat patients with severe aortic stenosis and recently completed a series of European feasibility studies for its Lotus Valve System, which 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. PAVR is one of the fastest growing medical device markets.

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 generators, intracardiac ultrasound and steerable ablation catheters, and diagnostic catheters. Our leading products include the Blazer line of ablation catheters, including our next-generation Blazer Prime ablation catheter, designed to deliver enhanced performance, responsiveness and durability, and the Chilli II® cooled ablation catheter. In January 2011, as part of our priority growth initiatives, we announced the signing of a definitive merger agreement under which we will acquire Atritech, Inc., subject to customary closing conditions. Atritech has 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, 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.

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Peripheral Interventions

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 and peripheral vascular stenting. Our peripheral product offerings include stents, balloon catheters, sheaths, wires and vena cava filters, and we hold the number one position in the worldwide Peripheral Interventions market. We market the PolarCath peripheral dilatation system used in CryoPlasty® Therapy, an innovative approach to the treatment of peripheral artery disease in the lower extremities. In 2010, we successfully launched several of our market-leading products internationally, including the launch in Japan of our Carotid WALLSTENT® Monorail® Endoprosthesis for the treatment of patients with carotid artery disease who are at high risk for surgery.

We also sell products designed to treat patients with non-vascular disease (disease which 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. In 2010, our Express LD Stent System received U.S. Food and Drug Administration (FDA) approval for an iliac indication, and we continued to market our Express® SD Renal Monorail® premounted stent system for use as an adjunct therapy to percutaneous transluminal renal angioplasty in certain lesions of the renal arteries; as well as our Sterling® Monorail® and Over-the-Wire balloon dilatation catheter for use in the renal and lower extremity arteries, and our extensive line of Interventional Oncology product solutions.

Embolic Protection

Our FilterWire EZ Embolic Protection System is a low profile filter designed to capture embolic material that may become dislodged during a procedure, which could otherwise travel into the microvasculature where it could cause a heart attack or stroke. It is commercially available in the U.S., our EMEA region and certain Inter-Continental countries for multiple indications, including the treatment of disease in peripheral, coronary and carotid vessels. It is also available in the U.S. for the treatment of saphenous vein grafts and carotid artery stenting procedures.

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 and, in 2010, expanded our offering of this product to include a wider variety of sizes. 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. In 2010, we continued commercialization of our WallFlex® family of stents, in particular, the WallFlex® Biliary line and WallFlex® Esophageal line; and our Resolution® Clip Device, used to treat gastrointestinal bleeding. Our Resolution® Clip is the only currently-marketed mechanical clip designed to open and close, up to five times, before deployment to help enable a physician to see the effects of the clip before committing to deployment.

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

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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 addition, as part of our priority growth initiatives, in October 2010, we completed our acquisition of Asthmatx, Inc. Asthmatx designs, manufactures and markets 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 CE Mark and FDA approval and is the first device-based asthma treatment approved by the FDA.

Urology/Women s Health

Our Urology/Women s Health division develops and manufactures devices to treat various urological and gynecological disorders. We sell a variety of products designed to treat patients with urinary stone disease, stress urinary incontinence, pelvic organ prolapse and excessive uterine bleeding. We offer a full line of stone management products, including ureteral stents, wires, lithotripsy devices, stone retrieval devices, sheaths, balloons and catheters.

We continue to expand our focus on Women s Health. 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 recently launched 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.

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. The Precision System utilizes a rechargeable battery and features a programming system. In 2010, we received FDA approval and launched two lead splitters, as well as the Linear 3-4 and Linear 3-6 Percutaneous Leads for use with our SCS systems, offering a broader range of lead configurations and 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. We believe that we continue to have a technology advantage over 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, and are involved in various studies designed to evaluate the use of spinal cord stimulation in the treatment of additional sources of pain. As a demonstration of our commitment to strengthening clinical evidence with spinal cord stimulation, we have initiated a trial to assess the therapeutic effectiveness and cost-effectiveness of spinal cord stimulation compared to reoperation in patients with failed back surgery syndrome. We believe that this trial could result in consideration of spinal cord stimulation much earlier in the continuum of care. In addition, in late 2010 we initiated a European clinical trial for the treatment of Parkinson s disease using our Vercise deep-brain stimulation system, and, 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 advances the field of deep-brain stimulation.

Neurovascular

In January 2011, we closed the sale of our Neurovascular business to Stryker Corporation. This business markets a broad line of coated and uncoated detachable coils, micro-delivery stents, micro-guidewires, micro-catheters, guiding catheters and embolics to neuro-interventional radiologists and neurosurgeons to treat diseases of the neurovascular system. In 2010, we marketed the GDC® Coils (Guglielmi Detachable Coil) and Matrix® systems to treat brain aneurysms and, in late 2010, we received FDA approval for the next-generation family of detachable coils, which includes an enhanced delivery system designed to reduce coil detachment times, and began a phased

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launch of the product. We also offered the NeuroForm® stent system, and launched the Neuroform EZ stent system, a fourth-generation intracranial aneurysm stent system designed for use in conjunction with endovascular coiling to treat wide-necked aneurysm, and the Wingspan® Stent System with Gateway® PTA Balloon Catheter, each under a Humanitarian Device Exemption approval granted by the FDA. The Wingspan Stent System is designed to treat atherosclerotic lesions or accumulated plaque in brain arteries. Designed for the brain s fragile vessels, the Wingspan Stent System is a self-expanding, nitinol stent sheathed in a delivery system that enables it to reach and open narrowed arteries in the brain. The Wingspan Stent System is currently the only device available in the U.S. for the treatment of intracranial atherosclerotic disease (ICAD) and is indicated for improving cerebral artery lumen diameter in patients with ICAD who are unresponsive to medical therapy.

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. Since 1995, we have undertaken strategic acquisitions to assemble the lines of business necessary to achieve the critical mass that allows 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, priority growth areas including atrial fibrillation, autonomic modulation therapy, coronary artery disease, deep-brain stimulation, diabetes/obesity, endoluminal surgery, endoscopic pulmonary intervention, hypertension, peripheral vascular disease, structural heart disease, sudden cardiac arrest, and women s health. We have recently announced several acquisitions targeting many of the above conditions and disease states. In 2010, we completed the acquisition of Asthmatx, Inc., and in January 2011, we completed the acquisitions of Sadra Medical, Inc. and Intelect Medical, Inc., and announced the signing of a definitive merger agreement to acquire Atritech, Inc., each 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 future growth.

Research and Development

Our investment in research and development is critical to driving our future growth. We expended $939 million on research and development in 2010, $1.035 billion in 2009 and $1.006 billion in 2008, representing approximately 12 to 13 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 others obtained through our strategic acquisitions and alliances; and
- sustaining 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 new markets. We are looking to transform the way we conduct research and development, leverage low-cost geographies, and scrutinize our cost structure, which we expect will generate significant savings over the next three years. 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 2010, we marketed our products to over 10,000 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. A network of distributors and dealers who offer our products worldwide accounts for our remaining sales. We will 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 2010 or 2009; 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 business groups 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 44 percent of our net sales in 2010. Net sales and operating income attributable to our 2010 geographic regions are presented in *Note P Segment Reporting* to our 2010 consolidated financial statements included in Item 8 of this Annual Report. 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 plan to invest $30 million to $40 million through the end of 2011 to introduce new products and strengthen our sales capabilities in emerging markets such as Brazil, China and India. A discussion of the risks associated with our international operations is included in Item 1A of this Annual Report.

As of December 31, 2010, we had six international manufacturing facilities, including three in Ireland, two in Costa Rica and one in Puerto Rico. Approximately 55 percent of our products sold worldwide during 2010 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 new product development, including the enhancement of existing products, and their commercial launch. We are implementing 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 continue to focus on examining our operations and general business activities to identify cost-improvement opportunities in order to enhance our operational effectiveness, including our Plant Network Optimization program and our recently completed 2007 Restructuring plan, discussed in Item 7 of this Annual Report.

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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, any significant interruption in our ability to manufacture these products over an extended duration may result in delays in our ability to resume production of affected products, due to needs for regulatory approvals. As a result, we may suffer 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.

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. 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. However, 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 redundant capabilities that are 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.

Certain products are manufactured for us by third parties. We are currently reliant on Abbott Laboratories for our supply of everolimus-eluting stent systems in the U.S. and Japan. Our supply agreement with Abbott for everolimus-eluting stent systems in these regions extends through the end of the second quarter of 2012. At present, we believe that our supply of everolimus-eluting stent systems from Abbott, coupled with our current launch plans for our next-generation internally-developed and manufactured everolimus-eluting stent system in these regions, is sufficient to meet customer demand. However, any production or capacity issues that affect Abbott s manufacturing capabilities or our process for forecasting, ordering and receiving shipments may impact the ability to increase or decrease our level of supply in a timely manner; therefore, our supply of everolimus-eluting stent systems supplied to us by Abbott may not align with customer demand, which could have an adverse effect on our operating results. Further, a delay in the launch of our internally-developed and manufactured next-generation PROMUS® Element everolimus-eluting stent system in the U.S. and Japan, currently expected in mid-2012, could result in an inability to meet customer demand for everolimus-eluting stent systems. We launched our PROMUS® Element stent system in our EMEA region and certain Inter-Continental countries in the fourth quarter of 2009, quickly gaining market share, exiting 2010 with approximately one quarter share of the drug-eluting stent market in EMEA.

Quality Assurance

In January 2006, we received a corporate warning letter from the FDA notifying us of serious regulatory problems at three of our facilities and advising us that our corporate-wide corrective action plan relating to three site-specific warning letters issued to us in 2005 was inadequate. We identified solutions to the quality system issues cited by the FDA and implemented those solutions throughout our organization. During 2008, the FDA reinspected a number of our facilities and, in October 2008, informed us that our quality system was in substantial compliance with its Quality System Regulations. In November 2009 and January 2010, the FDA reinspected two of our sites to follow up on observations from the 2008 FDA inspections. Both of these FDA inspections confirmed that all issues at the sites have been resolved and all restrictions related to the corporate warning letter were removed. On August 11, 2010, we were notified by the FDA that the corporate warning letter had been lifted.

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

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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 ISO13485:2003 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, ten of our 14 manufacturing and distribution facilities have attained ISO14001 certification. We are committed to achieving ISO14001 certification at all of our 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 Johnson & Johnson (including its subsidiary, Cordis Corporation); Medtronic, Inc.; Abbott Laboratories; 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, including 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.

Regulatory Environment

The medical devices that we manufacture and market are subject to regulation by numerous 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, the most comprehensive of which requires that a clinical evaluation be conducted before a device receives approval for commercial distribution.

In the U.S., approval to distribute a new device generally can be met in one of three ways. The first process requires that a pre-market notification (510(k) Submission) be made to the FDA to demonstrate that the device is as safe and effective as, or substantially equivalent to, a legally marketed device that is not subject to pre-market approval (PMA), i.e., the predicate device. An appropriate predicate device for a pre-market notification is one that (i) was legally marketed prior to May 28, 1976, (ii) was approved under a PMA but then subsequently reclassified from Class III to Class II or I, or (iii) has been found to be substantially equivalent and cleared for

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commercial distribution under a 510(k) Submission. Applicants must submit descriptive data and, when necessary, performance data to establish that the device is substantially equivalent to a predicate device. In some instances, data from human clinical trials must also be submitted in support of a 510(k) Submission. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption (IDE) regulations. The FDA must issue an order finding substantial equivalence before commercial distribution can occur. Changes to existing devices covered by a 510(k) Submission that are not significant can generally be made without additional 510(k) Submissions. Changes that could significantly affect the safety or effectiveness of the device, such as significant changes in designs or materials, may require a new 510(k) with data to support that the modified device remains substantially equivalent. In August 2010, the FDA released numerous draft proposals on the 510(k) process aimed at increasing transparency and streamlining the process, while adding more scientific rigor to the review process. In January 2011, the FDA released the implementation plan for changes to the 510(k) Submission program, which includes additional training of FDA staff, the creation of various guidance documents intended to provide greater clarity to certain processes, as well as various internal changes to the FDA s procedures. We have a portfolio of products that includes numerous Class II medical devices. Several of the FDA s proposals could increase the regulatory burden on our industry, including those that could increase the cost, complexity and time to market for certain high-risk Class II medical devices.

The second process requires the submission of an application for PMA to the FDA to demonstrate that the device is safe and effective for its intended use as manufactured. This approval process applies to certain Class III devices. In this case, two steps of FDA approval are generally required before marketing in the U.S. can begin. First, we must comply with the applicable IDE regulations in connection with any human clinical investigation of the device in the U.S. Second, the FDA must review our PMA application, which contains, among other things, clinical information acquired under the IDE. 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.

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). A 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. This approval process demonstrates that there is no comparable device available to treat or diagnose the condition, the device will not expose patients to unreasonable or significant risk, and the benefits to health from use outweigh the risks. 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.

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 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. to take advantage of differing regulatory requirements. 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.

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 certification, granted following approval from an independent notified body, is an international symbol of adherence to quality assurance standards and

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compliance with applicable European Medical Devices Directives. We are also required to comply with other foreign regulations 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 time required to obtain these foreign approvals to market our products may vary from U.S. approvals, and requirements for these approvals may differ from those required by the FDA.

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 influence a myriad of legislative and administrative policies impacting us, both on a domestic and an international front. The Government Affairs office works closely with members of Congress, key Congressional committee staff and White House and Administration staff, which facilitates our active engagement 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 and Current Economic Climate

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 managed-care arrangements, 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 comparative effectiveness may be significant. In addition, uncertainty remains regarding proposed significant reforms to the U.S. healthcare system.

Further, certain state governments have recently enacted, and the federal government has proposed, legislation aimed at increasing transparency in relationships between industry and healthcare professionals (HCPs). As a result, we are required by law to report many types of direct and indirect payments and other transfers of value to HCPs licensed by certain states and expect that we will have to make similar reports at the federal level in the near future. 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 legal and regulatory

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requirements. These systems are designed to provide enhanced visibility and consistency across our businesses with respect to our interactions with healthcare professionals. Implementation of these policies, systems and processes, or failure to comply with these policies could have a negative impact on our results of operations.

Additionally, 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 and 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.

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), private insurance plans and managed care programs, for the healthcare services provided to their patients. Third-party payors may provide or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Reimbursement by third-party 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 covered automatically 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.

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 international 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.

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, 2010, we held more than 15,000 patents, and had approximately 9,000 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.

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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.

See Item 3 and *Note L Commitments and Contingencies* to our 2010 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 L,* which, individually or in the aggregate, could have a material effect on our financial condition, results of operations or liquidity.

Risk Management

The testing, marketing and sale of human healthcare products entails an inherent risk of product liability claims. In the normal course of business, product liability and securities claims are asserted against us. Product liability and securities claims may be asserted against us in the future related to events unknown at the present time. We are substantially self-insured with respect to product liability and intellectual property infringement claims. We maintain insurance policies providing limited coverage against securities claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims or adverse decisions. Product liability claims, securities and commercial litigation and other litigation in the future, regardless of outcome, could have a material adverse effect on our business. We believe that our risk management practices, including limited insurance coverage, are reasonably adequate to protect against anticipated product liability and securities litigation losses. However, unanticipated catastrophic losses could have a material adverse impact on our financial position, results of operations and liquidity.

Employees

As of December 31, 2010, we had approximately 25,000 employees, including approximately 13,000 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 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

In line with our corporate mission to improve the quality of patient care and the productivity of healthcare delivery, 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 addresses disparities in cardiovascular care for the underserved patient populations of women, black Americans, and Latino Americans. Close the Gap increases awareness of 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.

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Through the Boston Scientific Foundation, we fund non-profit organizations in our local communities and medical education fellowships at institutions throughout the U.S. Our community grants support programs aimed at improving the lives of those with unmet needs by engaging in partnerships that promote long-term, systemic change. The Foundation is committed to funding organizations focused on increasing access to quality healthcare and improving educational opportunities, particularly with regards to science, technology, engineering and math. We have committed to contributing $15 million to our Close the Gap program and Science, Technology, Engineering and Math (STEM) education over the next three years.

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, 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 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 connected 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 report and information incorporated by reference into this report, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like anticipate, expect, project, believe, plan, may, estimate, intend and simila 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 growth strategy; our intentions and expectations regarding our business strategy; the completion of planned acquisitions, divestitures and strategic investments, as well as integration of acquired businesses; our ability to successfully separate our Neurovascular business; the timing and impact of our restructuring initiatives, expected costs and cost savings; our intention not to pay dividends and to instead use our cash flow to repay debt and invest in our business; changes in the market and our market share; product development and iterations; timing of regulatory approvals; our regulatory and quality compliance; expected research and development efforts and the reallocation of research and development expenditures; new and existing product launches, including their timing in new geographies and their impact on our market share and financial position; our sales and marketing strategy and our investments in our sales organization; reimbursement practices; our market position in the marketplace for our products; our initiatives regarding plant certifications and reductions; the ability of our suppliers and sterilizers to meet our requirements; our ability to meet customer demand for our products; the effect of new accounting pronouncements on our financial results; competitive pressures; the impact of new or recently enacted excise taxes; the effect of proposed tax laws; the outcome of matters before taxing authorities; our tax position; intellectual property, governmental proceedings and litigation matters; anticipated expenses and capital expenditures and our ability to finance them; and our ability to meet the financial covenants required by our term loan and revolving credit facility, 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.

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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. We have identified these forward-looking statements, which are based on certain risks and uncertainties, including the risk factors described in Item 1A of this Annual Report. Factors that could cause actual results to differ materially from those expressed in forward-looking statements are contained below and described further in Item 1A.

CRM Business

Our ability to minimize loss of and recapture market share following the ship hold and product removal of our ICD and CRT-D systems in the U.S.;

Our ability to retain and attract key members of our CRM sales force and other key CRM personnel, particularly following the ship hold and product removal of our ICD and CRT-D systems in the U.S.;

Our estimates for the U.S. and worldwide CRM markets, as well as our ability to increase CRM net sales and recapture market share;

The overall performance of, and referring physician, implanting physician and patient confidence in, our and our competitors CRM products and technologies, including our COGNIS® CRT-D and TELIGEN® ICD systems and our LATITUDE® Patient Management System;

The results of CRM clinical trials and market studies undertaken by us, our competitors or other third parties;

Our ability to successfully launch next-generation products and technology features worldwide, including our INGENIO pacemaker system and our next-generation INCEPTA , ENERGEN and PUNCTUA defibrillators in additional geographies;

Our ability to grow sales of both new and replacement implant units;

Competitive offerings in the CRM market and related declines in average selling prices, as well as the timing of receipt of regulatory approvals to market existing and anticipated CRM products and technologies; and

Our ability to avoid disruption in the supply of certain components, materials or products; or to quickly secure additional or replacement components, materials or products on a timely basis.

Coronary Stent Business

Volatility in the coronary stent market, our estimates for the worldwide coronary stent market, our ability to increase coronary stent system net sales, competitive offerings and the timing of receipt of regulatory approvals, both in the U.S. and internationally, to market existing and anticipated drug-eluting stent technology and other stent platforms;

Our ability to successfully launch next-generation products and technology features, including our PROMUS® Element and TAXUS® Element stent systems in additional geographies;

The results of coronary stent clinical trials undertaken by us, our competitors or other third parties;

Our ability to maintain or expand our worldwide market positions through reinvestment in our two drug-eluting stent programs;

Our ability to manage the mix of net sales of everolimus-eluting stent systems supplied to us by Abbott relative to our total drug-eluting stent system net sales and to launch on-schedule in the U.S. and Japan our PROMUS® Element next-generation internally-developed and manufactured everolimus-eluting stent system with gross

profit margins more comparable to our TAXUS® stent systems;

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Our share of the U.S. and worldwide drug-eluting stent markets, the average number of stents used per procedure, average selling prices, and the penetration rate of drug-eluting stent technology in the U.S. and international markets;

The overall performance of, and continued physician confidence in, our and other drug-eluting stent systems;

Our reliance on Abbott s manufacturing capabilities and supply chain in the U.S. and Japan, and our ability to align our everolimus-eluting stent system supply from Abbott with customer demand in these regions;

Enhanced requirements to obtain regulatory approval in the U.S. and around the world and the associated impact on new product launch schedules and the cost of product approval and compliance; and

Our ability to retain and attract key members of our cardiology sales force and other key personnel.

Other Businesses

The overall performance of, and continued physician confidence in, our products and technologies;

Our ability to successfully launch next-generation products and technology features in a timely manner;

The results of clinical trials undertaken by us, our competitors or other third parties; and

Our ability to maintain or expand our worldwide market positions through investments in next-generation technologies.

Litigation and Regulatory Compliance

Risks generally associated with our regulatory compliance and quality systems in the U.S. and around the world;

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

Heightened global regulatory enforcement 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, and costs to resolve, our stockholder derivative and class action, patent, product liability, contract and other litigation, governmental investigations and legal proceedings;

Costs associated with our on-going compliance and quality activities and sustaining organizations;

The impact of increased pressure on the availability and rate of third-party reimbursement for our products and procedures worldwide; and

Legislative or regulatory efforts to modify the product approval or reimbursement process, including a trend toward demonstrating clinical outcomes, comparative effectiveness and cost efficiency.

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Innovation

Our ability to complete planned clinical trials successfully, to obtain regulatory approvals and to develop and launch products on a timely basis within cost estimates, including the successful completion of in-process projects from purchased research and development;

Our ability to manage research and development and other operating expenses consistent with our expected net sales growth;

Our ability to develop and launch next-generation products and technologies successfully across all of our businesses;

Our ability to fund with cash or common stock any acquisitions or alliances, or to fund contingent payments associated with these acquisitions or alliances;

Our ability to achieve benefits from our focus on internal research and development and external alliances and acquisitions as well as our ability to capitalize on opportunities across our businesses;

Our failure to succeed at, or our decision to discontinue, any of our growth initiatives, as well as competitive interest in the same or similar technologies;

Our ability to integrate the strategic acquisitions we have consummated or may consummate in the future;

Our ability to prioritize our internal research and development project portfolio and our external investment portfolio to identify profitable revenue growth opportunities and keep expenses in line with expected revenue levels, or our decision to sell, discontinue, write down or reduce the funding of any of these projects;

The timing, size and nature of strategic initiatives, market opportunities and research and development platforms available to us and the ultimate cost and success of these initiatives; and

Our ability to successfully identify, develop and market new products or the ability of others to develop products or technologies that render our products or technologies noncompetitive or obsolete.

International Markets

Our dependency on international net sales to achieve growth;

Changes in our international structure and leadership;

Risks associated with international operations, including compliance with local legal and regulatory requirements as well as changes in reimbursement practices and policies;

Our ability to maintain or expand our worldwide market positions through investments in emerging markets;

The potential effect of foreign currency fluctuations and interest rate fluctuations on our net sales, expenses and resulting margins; and

Uncertainties related to economic conditions.

Liquidity

Our ability to generate sufficient cash flow to fund operations, capital expenditures, litigation settlements

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and strategic investments and acquisitions, as well as to effectively manage 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;

Our ability to resolve open tax matters favorably and realize substantially all of our deferred tax assets and the impact of changes in tax laws; and

The impact of examinations and assessments by domestic and international taxing authorities on our tax provision, financial condition or results of operations.

Strategic Initiatives

Our ability to implement, fund, and achieve timely and sustainable cost improvement measures consistent with our expectations, including our 2010 Restructuring plan and Plant Network Optimization program;

Our ability to maintain or expand our worldwide market positions in the various markets in which we compete or seek to compete, as we diversify our product portfolio and focus on emerging markets;

Risks associated with significant changes made or to be made to our organizational structure pursuant to our 2010 Restructuring plan and Plant Network Optimization program, or to the membership and responsibilities of our executive committee or Board of Directors;

Our ability to direct our research and development efforts to conduct more cost-effective clinical studies, accelerate the time to bring new products to market, and develop products with higher returns;

The successful separation of divested businesses, including the performance of related transition services;

Our ability to retain and attract key employees and avoid business disruption and employee distraction as we execute our global compliance program, restructuring plans and divestitures of assets or businesses; and

Our ability to maintain management focus on core business activities while also concentrating on implementing strategic and restructuring initiatives.

Several important factors, in addition to the specific risk factors discussed in connection with forward-looking statements individually and the risk factors described in Item 1A under the heading Risk Factors, could affect our future results and growth rates and could cause those results and rates to differ materially from those expressed in the forward-looking statements and the risk factors contained in this report. These additional factors include, among other things, future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property, litigation and government 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. Therefore, we wish to caution each reader of this report to consider carefully these factors as well as the specific factors discussed with each forward-looking statement and risk factor in this report and as disclosed in our filings with the SEC. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this Annual Report.

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

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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.

We face various risks and uncertainties as a result of the ship hold and removal of field inventory of all implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) systems offered by our Cardiac Rhythm Management (CRM) business in the U.S., which we announced on March 15, 2010. Those risks and uncertainties include harm to our business, reputation, financial condition and results of operations.

On March 15, 2010, we announced the ship hold and removal of field inventory of all ICD systems and CRT-D systems offered by our CRM division in the U.S., after determining that certain instances of changes in the manufacturing process related to these products were not submitted for approval to the U.S. Food and Drug Administration (FDA). We have since submitted the required documentation and, on April 15, 2010, we resumed U.S. distribution of our COGNIS® CRT-D systems and TELIGEN® ICD systems, and, on May 21, 2010, we resumed U.S. distribution of all of our remaining CRT-D and ICD devices, in each case following required FDA clearance. As a result of these actions, we have suffered and may continue to suffer loss of market share for these products in the U.S. While we continue to work on recapturing lost market share, our on-going net sales and results of operations will likely continue to be negatively impacted. We may be unable to minimize this impact, or to offset with the release of future products, and we may suffer on-going harm to our reputation, among other risks and uncertainties, each of which may have an adverse impact on our business, financial condition and 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, including aggressive pricing offered by market entrants, 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 nine percent in 2010 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; interruption in supply of everolimus-eluting stent systems in the U.S. and Japan; changes in our sales personnel; 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 20 percent of our consolidated net sales during 2010. In 2010, lower average selling prices driven by competitive and other pricing pressures 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. Recent competitive launches and clinical trial enrollment limiting our access to certain drug-eluting stent system customers negatively impacted our share of the worldwide drug-eluting stent 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 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, we expect to launch our internally-developed and manufactured next-generation everolimus-eluting stent system, the PROMUS® Element platinum chromium coronary stent system, in the U.S. and Japan in mid-2012, and we expect to launch our next-generation TAXUS® Element stent system in the U.S. in mid-2011 and Japan in late 2011 or early 2012. A delay in the timing of the launch of next-generation products may result in a further decline in our market share and have an adverse impact on our results of operations.

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We share, with Abbott Laboratories, rights to everolimus-eluting stent technology, and are reliant on Abbott for our supply of PROMUS® everolimus-eluting stent systems in the U.S. and Japan. Any production or capacity issues that affect Abbott s manufacturing capabilities or our process for forecasting, ordering and receiving shipments may impact our ability to increase or decrease the level of supply to us in a timely manner; therefore, our supply of everolimus-eluting stent systems supplied to us by Abbott may not align with customer demand. Our supply agreement for the PROMUS® stent system from Abbott extends through the end of the second quarter of 2012 in the U.S. and Japan. Our inability to obtain regulatory approval and timely launch our PROMUS® Element stent system in these regions could result in an inability to meet customer demand for everolimus-eluting stent systems and may materially adversely affect our results of operations or financial condition.

Net sales from our CRM group represented approximately 28 percent of our consolidated net sales in 2010. Worldwide CRM market growth rates, including the U.S. ICD market, remain low. Further, physician reaction to study results published by the *Journal of the American Medical Association* regarding evidence-based guidelines for ICD implants and the U.S. Department of Justice investigation into ICD implants may have a negative impact on the size of the CRM market. Our U.S. ICD sales represented approximately 48 percent of our worldwide CRM net sales in 2010, and any changes in this market could have a material adverse effect on our financial condition or results of operations. We have suffered, and may continue to suffer, loss of net sales and market share in the U.S. due to the ship hold and removal of field inventory of all of our ICDs and CRT-Ds offered in the U.S., which we announced on March 15, 2010. 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. We expect to launch our next-generation wireless pacemaker in our Europe/Middle East/Africa (EMEA) region and certain Inter-Continental countries during the second half of 2011, and in the U.S. in late 2011 or early 2012. Variability in the timing of the launch of next-generation products may result in excess or expired inventory positions and future inventory charges, which may result in a loss of market share and adversely impact our results of operations.

The profit margin of everolimus-eluting stent systems supplied to us by Abbott Laboratories, including any improvements or iterations approved for sale during the term of the applicable supply arrangements and of the type that could be approved by a supplement to an approved FDA pre-market approval, is significantly lower than that of our TAXUS® stent systems, TAXUS® Element stent systems and PROMUS® Element stent systems, and an increase in sales of everolimus-eluting stent systems supplied to us by Abbott relative to TAXUS® stent system, TAXUS® Element stent system and PROMUS® Element stent system net sales may continue to adversely impact our gross profit and operating profit margins. The price we pay Abbott for our supply of everolimus-eluting stent systems supplied to us by Abbott is further impacted by our arrangements with Abbott and is subject to retroactive adjustment, which may also negatively impact our profit margins.

As a result of the terms of our supply arrangement with Abbott, the gross profit and operating profit margin of everolimus-eluting stent systems supplied to us by Abbott, including any improvements or iterations approved for sale during the term of the applicable supply arrangements and of the type that could be approved by a supplement to an approved FDA pre-market approval, are significantly lower than that of our TAXUS® stent system, TAXUS® Element stent system and PROMUS® Element stent system. Therefore, if sales of everolimus-eluting stent systems supplied to us by Abbott continue to increase in relation to our total drug-eluting stent system sales, our profit margins will continue to decrease. Further, the price we pay for our supply of everolimus-eluting stent systems supplied to us by Abbott is determined by our contracts with Abbott. Our cost is based, in part, on previously fixed estimates of Abbott s manufacturing costs for everolimus-eluting stent systems and third-party reports of our average selling price of these stent systems. Amounts paid pursuant to this pricing arrangement are subject to a retroactive adjustment approximately every two years based on their actual costs to manufacture these stent systems for us and our average selling price of everolimus-eluting stent systems supplied to us by Abbott. Pursuant to these adjustments, we may make a payment to Abbott based on the differences between their actual manufacturing costs and the contractually stipulated manufacturing costs and differences between our actual average selling price and third-party reports of our

average selling price, in each

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case, with respect to our purchases of everolimus-eluting stent systems from Abbott. As a result, our profit margins in the years in which we record payments related to purchases of everolimus-eluting stent systems from Abbott may decrease.

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. 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. While our strategic initiatives include measures to address these trends, there can be no assurance that these measures 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 reduce competition and 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 Johnson & Johnson (including its subsidiary, Cordis Corporation); Medtronic, Inc.; Abbott Laboratories; and St. Jude Medical, Inc.; as well as a wide range of companies that sell a single or a 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 market is 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, attract and retain skilled development personnel, 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, 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 44 percent of our net sales in 2010. Additionally, a significant percentage of our future growth is expected to come from international operations, including from investments in emerging markets such as Brazil, China and India. As a result, our sales growth and operating profits from our international operations may be limited by risks and uncertainties related to economic conditions in these regions, foreign currency fluctuations, interest rate fluctuations, regulatory and reimbursement approvals, competitive offerings, infrastructure development, rights to intellectual property and our ability to implement our overall business strategy. Further, international markets are also being affected by economic pressure to contain

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reimbursement levels and healthcare costs; and 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. Certain foreign governments may allow favorable reimbursements for locally-manufactured products, which may put us at a competitive disadvantage and negatively affect our market share. The trend in countries around the world, including Japan, toward more stringent regulatory requirements for product clearance, changing reimbursement models and more rigorous inspection and enforcement activities has generally caused or may cause medical device manufacturers to experience more uncertainty, delay, risk and expense. In addition, most international jurisdictions have adopted regulatory approval and periodic renewal requirements for medical devices, and we must comply with these requirements in order to market our products in these jurisdictions. 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. We have recently realigned our international structure and are devoting resources to focus on increasing net sales in emerging markets. Sales practices in certain international markets may be inconsistent with our desired business practices and U.S. legal requirements, which may impact our ability to expand as planned.

We incurred substantial indebtedness in connection with our acquisition of Guidant and if we are unable to manage our debt levels, it could have an adverse effect on our financial condition or results of operations.

We had total debt of $5.438 billion as of December 31, 2010, attributable in large part to our 2006 acquisition of Guidant Corporation. During 2010, we completed the refinancing of the majority of our 2011 debt maturities, establishing a $1.0 billion term loan and syndicating a new $2.0 billion revolving credit facility, and prepaid in full our $900 million loan from Abbott Laboratories and all $600 million of our senior notes due in June 2011. Additionally, in January 2011, we prepaid $250 million of our senior notes due in January 2011 and borrowed $250 million under our credit and security facility secured by our U.S. trade receivables, using the proceeds to pre-pay all $100 million of our 2011 term loan maturities and $150 million of our 2012 term loan maturities. As part of our strategy to increase operational leverage and continue to strengthen our financial flexibility, we are continuing to assess opportunities for improved operational effectiveness and efficiency, closed the sale of our Neurovascular business and implemented other strategic initiatives to generate proceeds that would be available for debt repayment. There can be no assurance that we will be able to repay our indebtedness. Further, certain of our current credit ratings are below investment grade and our inability to regain investment grade credit ratings could increase our cost of borrowing funds in the future. Any disruption in our cash flow or our ability to effectively manage our debt levels could have an adverse effect on our financial condition or results of operations. In addition, our term loan and revolving credit facility agreement contains 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 under this facility on demand.

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

We test our April 1 goodwill balances for impairment during the second quarter of each year, 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. In 2010, we recorded a goodwill impairment charge of $1.817 billion associated with our U.S. CRM reporting unit. In addition, as a result of signing of a definitive agreement to sell our Neurovascular business, we performed an interim impairment test on our international reporting units, excluding the assets of that business, and determined that the remaining goodwill balances were not impaired. However, we have identified four reporting units with a material amount of goodwill that are at higher risk of potential failure of the first step of the impairment test in future reporting periods. These reporting units include our U.S. CRM unit, our U.S. Cardiovascular unit, our U.S. Neuromodulation unit, and our EMEA region, which together hold approximately $9 billion of allocated goodwill. Although we use consistent methodologies in developing the assumptions and estimates underlying the fair value calculations used in our

impairment tests, these estimates are uncertain by nature and

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can vary from actual results. For each of these reporting units, relatively small declines in the future performance and cash flows of the reporting unit or small changes in other key assumptions may result future goodwill impairment charges, which could materially adversely impact our results of operations.

Failure to integrate acquired businesses into our operations successfully could adversely affect our business.

As part of our strategy to realign our business portfolio, we have recently completed or announced several acquisitions 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. Factors that will affect the success of our acquisitions include 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. 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.

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 establish an acquisition, investment or alliance on terms that are satisfactory to us, if at all; and
- intellectual property and litigation related to these technologies.

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

We may not realize the expected benefits from our restructuring and Plant Network 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 February 2010, we announced our 2010 Restructuring plan designed to strengthen and position us for long-term success. Key activities under the plan include the integration of our Cardiovascular and CRM businesses, as well as the restructuring of certain other businesses and corporate functions; the centralization of our research and development organization; the realignment of our international structure; and the reprioritization and diversification of our product portfolio. In connection with this plan and our strategy to reduce risk, increase operational leverage, realign our business portfolio and accelerate profitable revenue growth, we recently closed the sale of our Neurovascular business and may explore opportunities to divest additional select businesses or assets in the future. However, our ability to complete further divestitures may be limited by the inability to locate a buyer or to agree to terms that are favorable to us. Additionally, in January 2009, we announced our Plant Network

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Optimization program, aimed at simplifying our plant network, reducing our manufacturing costs and improving gross margins. Cost reduction initiatives under both plans include cost improvement measures, including resource reallocations, head count reductions, the sale of certain non-strategic assets and 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, head count 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.

The divestiture of our Neurovascular business could pose significant risks and may materially adversely affect our business, financial condition and operating results.

As part of our strategy to realign our business portfolio, in January 2011, we closed the sale of our Neurovascular business to Stryker Corporation. The divestiture of this business may involve a number of risks, including the diversion of management and employee attention and significant costs and expenses, particularly unexpected costs and delays occurring during the period of separation. In addition, we will provide post-closing services through a transition services agreement, and will also supply products to Stryker. These transition services and supply agreements are expected to be effective for a period of approximately 24 months following the closing of the transaction, subject to extension, and could involve the expenditure of significant employee resources, among other resources, and under which we will be reliant on third parties for the provision of services. Our inability to effectively manage the post-separation activities and events could adversely affect our business, financial condition and results of operations.

Current economic conditions could adversely affect our results of operations.

The recent global financial crisis caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. There can be no assurance that there will not be further deterioration in the global economy. 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. Further, we have experienced significant delays in the collectability of receivables in certain international countries and there can be no assurance that these payments will ultimately be collected. 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. The strength and timing of any economic recovery remains uncertain, and we cannot predict to what extent the global economic slowdown 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.

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 managed-care arrangements, 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.

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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 legislation will materially impact us. Certain provisions of the legislation will not be effective for a number of years, there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impact of the legislation will be. 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 2013. U.S. net sales represented 56 percent of our worldwide net sales in 2010 and, therefore, this tax burden may have a material, negative impact on our results of operations and our cash flows. Other provisions of this legislation, 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 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 or reduce medical procedure volumes 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. After 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 lead 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. In connection with Guidant s product recalls, certain third-party payors have sought, and others may seek, recourse against us for amounts previously reimbursed.

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.

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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. The FDA has recently been reviewing its clearance process in an effort to make it more rigorous, and there have been a number of recommendations made by various task forces and working groups to change the 510(k) Submission program. Some of these proposals, if enacted, could increase the level and complexity of premarket data requirements for certain higher-risk Class II products. Others could increase the cost of maintaining the legal status of Class II devices entered into the market via 510(k) Submissions. We have a portfolio of products that includes numerous Class II medical devices. If implemented as currently proposed, the changes to the 510(k) Submission program could substantially increase the cost, complexity and time to market for certain higher-risk Class II medical devices. In addition, most major markets for medical devices outside the U.S. require clearance, approval or compliance with certain standards before a product can be commercially marketed. The process of obtaining marketing approval or clearance from the FDA 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.

Countries around the world have adopted more stringent regulatory requirements than in the past and that have added or are expected to add to the delays and uncertainties associated with new product releases, as well as the clinical and regulatory costs of supporting those releases. Even after products have received marketing approval or clearance, product approvals and clearances by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. There can be no assurance that we will receive the required clearances for new products 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.

In addition, regulations regarding the development, manufacture and sale of medical devices are 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 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

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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. We expect to launch our internally-manufactured next-generation everolimus-eluting stent system, the PROMUS® Element platinum chromium coronary stent, in the U.S. and Japan in mid-2012, subject to regulatory approval. In addition, we expect to continue to invest in our CRM technologies, including our LATITUDE® Patient Management System and our next-generation products and technologies. If we are unable to develop and launch these and other products as anticipated, our ability to maintain or expand our market position in the drug-eluting stent and CRM markets 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, areas including, but not limited to, atrial fibrillation, underserved defibrillator populations, coronary artery disease, peripheral vascular disease, structural heart disease, hypertension, women s health, endoluminal surgery, diabetes/obesity, endoscopic pulmonary intervention and deep-brain stimulation. 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 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. These investigations relate primarily to financial arrangements with healthcare providers, regulatory compliance and product promotional practices. We are cooperating with these investigations and are responding to these requests. We cannot predict when the investigations will be resolved, the outcome of these investigations or their impact on us. 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 will involve employee resources costs and diversion of employee focus. Cooperation typically also involves document production costs. We may incur greater 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.

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In addition, certain state governments (including that of Massachusetts, where we are headquartered) have enacted, and the federal government has proposed, legislation aimed at increasing transparency of our interactions with healthcare professionals (HCPs). As a result, we are required by law to disclose payments and other transfers for value to HCPs licensed by certain states and expect similar requirements at the federal level in the future. Any failure to comply with the enhanced legal and regulatory requirements could impact our business. In addition, we devoted 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, recent Supreme Court case law has clarified that the FDA s authority over medical devices preempts state tort laws, but legislation has been introduced at the Federal level to allow state intervention, which could lead to increased and inconsistent regulation at the state level. We anticipate that the government will continue to scrutinize our industry closely and that we will be subject to more rigorous regulation by governmental authorities in the future.

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 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 ongoing 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 in connection with the technology license agreements between domestic and foreign subsidiaries of Guidant Corporation, in relation to which we recently received Notices of Deficiency from the Internal Revenue Service for the 2001-2003 tax years. However, there can be no assurance that we will accurately predict the outcomes of these audits or 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, proposals for fundamental U.S. corporate tax reform, if enacted, could have a significant adverse impact on our future results of operations. In addition, the recently enacted Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 impose on medical device manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in 2013. U.S. net sales represented 56 percent of our worldwide net sales in 2010 and, therefore, this tax burden may have a material, negative impact on our results of operations and our cash flows.

We may not effectively be able to protect our intellectual property rights, 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. Furthermore, appellate courts can overturn lower court patent decisions.

In addition, competing parties 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.

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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.

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 L- Commitments and Contingencies* to our 2010 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 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

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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.

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 are substantially self-insured with respect to product liability and intellectual property infringement claims. We maintain insurance policies providing limited coverage against securities 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.

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 suffer 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

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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.

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 Tokyo, Japan and Paris, France. As of December 31, 2010, our principal manufacturing and technology centers were located in Minnesota, California, Florida, Indiana, and Utah 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, 2010, we maintained 14 manufacturing facilities, including eight 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, 2010 (in approximate square feet):

	Owned	Leased	Total
U.S.	5,386,000	1,141,000	6,527,000
International	1,513,000	960,000	2,473,000
	6,899,000	**2,101,000**	**9,000,000**

In connection with our Plant Network Optimization program, described in Items 1 and 8 of this Annual Report, we intend to close one of our manufacturing plants in the U.S. by the end of 2012, representing a total of approximately 350,000 owned square feet. In addition, as part of the January 2011 sale of our Neurovascular business to Stryker Corporation, we intend to transfer portions of certain owned and leased facilities to Stryker. 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 L Commitments and Contingencies* to our 2010 consolidated financial statements included in Item 8 of this Annual Report.

ITEM 4. [REMOVED AND RESERVED]

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PART II

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

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.

	High	Low
2010		
First Quarter	$ 9.62	$6.80
Second Quarter	7.35	5.44
Third Quarter	6.59	5.13
Fourth Quarter	7.85	5.97
2009		
First Quarter	$ 9.41	$6.14
Second Quarter	10.42	8.05
Third Quarter	11.75	9.63
Fourth Quarter	10.29	7.99

The closing price of our common stock on February 10, 2011 was $6.91.

We did not pay a cash dividend in 2010 or 2009. We currently do not intend to pay dividends, and intend to retain all of our earnings to repay indebtedness and invest in the continued growth of our business. We may consider declaring and paying a dividend in the future; however, there can be no assurance that we will do so.

We did not repurchase any of our common stock in 2010 or 2009. There are approximately 37 million remaining under previous share repurchase authorizations, which do not expire.

As of February 10, 2011, there were 17,524 holders of record of our common stock.

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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 in each of the named indices on December 31, 2005, 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,	2010	2009	2008	2007	2006
Net sales	$ 7,806	$ 8,188	$ 8,050	$ 8,357	$ 7,821
Gross profit	5,207	5,612	5,581	6,015	5,614
Total operating expenses	5,863	6,506	7,086	6,029	8,563
Operating loss	(656)	(894)	(1,505)	(14)	(2,949)
Loss before income taxes	(1,063)	(1,308)	(2,031)	(569)	(3,535)
Net loss	(1,065)	(1,025)	(2,036)	(495)	(3,577)
Net loss per common share:					
Basic	$ (0.70)	$ (0.68)	$ (1.36)	$ (0.33)	$ (2.81)
Assuming dilution	$ (0.70)	$ (0.68)	$ (1.36)	$ (0.33)	$ (2.81)

Balance Sheet Data

As of December 31,	2010	2009	2008	2007	2006
Cash, cash equivalents and marketable securities	$ 213	$ 864	$ 1,641	$ 1,452	$ 1,668
Working capital*	1,006	1,577	2,219	2,691	3,399
Total assets	22,128	25,177	27,139	31,197	30,882
Borrowings (long-term and short-term)	5,438	5,918	6,745	8,189	8,902
Stockholders equity	11,296	12,301	13,174	15,097	15,298
Book value per common share	$ 7.43	$ 8.14	$ 8.77	$ 10.12	$ 10.37

* In 2010, we reclassified certain assets to the assets held for sale caption in our consolidated balance sheets. These assets are labeled as current 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, or assets that are expected to be sold in 2011. We have reclassified 2009 balances for comparative purposes on the face of the consolidated balance sheets, as well as in the working capital metric above. We have not restated working capital for these items in years prior to 2009 above.

See also the notes to our 2010 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 2010, we generated net sales of $7.806 billion, as compared to $8.188 billion in 2009, a decrease of $382 million, or five percent. Foreign currency fluctuations contributed $62 million to our net sales in 2010, as compared to 2009. Excluding the impact of foreign currency, our net sales decreased $444 million, or five percent, as compared to the prior year. This decrease was attributable in part to the ship hold and removal of field inventory of all implantable cardioverter defibrillator (ICD) systems and cardiac resynchronization therapy defibrillator (CRT-D) systems offered by our Cardiac Rhythm Management (CRM) division in the U.S., which we announced on March 15, 2010, after determining that certain instances of changes in the manufacturing process related to these products were not submitted for approval to the U.S. Food and Drug Administration (FDA). We have since submitted the required documentation and, on April 15, 2010, we received clearance from the FDA for certain of the manufacturing changes and immediately resumed distribution of our COGNIS® CRT-D systems and TELIGEN® ICD systems, which represent virtually all of our defibrillator implant volume in the U.S. We returned earlier generations of these products to the U.S. market on May 21, 2010, following required FDA clearance. We are working with our physician and patient customers to recapture market share lost as a result of the ship hold and have experienced better-than-expected recovery to date. However, our U.S. CRM net sales decreased $237 million in 2010, as compared to our market share exiting 2009, and we estimate that our U.S. defibrillator market share decreased approximately 300 basis points exiting 2010, as compared to the prior year, due primarily to these product actions.

In addition, throughout 2010 we continued to experience competitive and other pricing pressures across our businesses and, particularly, on our drug-eluting coronary stent system offerings. Net sales of our drug-eluting coronary stent systems decreased $171 million in 2010, as compared to 2009, and we estimate that the average selling price of our drug-eluting stent systems in the U.S. decreased nine percent in 2010, as compared to the prior year. Further, our net sales have been adversely impacted by reductions in procedural volumes, due to unemployment levels and other economic factors.

During 2010, net sales from our Endoscopy, Urology/Women s Health, and Neuromodulation businesses increased $117 million, or eight percent, as compared to 2009, on the strength of new product introductions, increased sales investments and further expansion into international markets. Refer to the *Business and Market Overview* and *Results of Operations* sections for more discussion of our net sales by division and region.

Our reported net loss in 2010 was $1.065 billion, or $0.70 per share, and was driven primarily by a goodwill impairment charge related to our U.S. CRM reporting unit following the ship hold and product removal actions described above. Our reported results for 2010 included goodwill and intangible asset impairment charges; acquisition-, divestiture-, litigation- and restructuring-related net charges; discrete tax items and amortization expense (after-tax) of $2.116 billion, or $1.39 per share. Excluding these items, net income for 2010 was $1.051 billion, or $0.69 per share. Our reported net loss in 2009 was $1.025 billion, or $0.68 per share. Our reported results for 2009 included intangible asset impairment charges; acquisition-, divestiture-, litigation- and restructuring-related net charges; discrete tax items and amortization expense of $2.207 billion (after-tax), or $1.46 per share. Excluding these items, net income for 2009 was $1.182 billion, or $0.78 per share.

Net income and net income per share that exclude certain items are not measures prepared in accordance with generally accepted accounting principles in the United States (U.S. GAAP). See *Additional Information* for an explanation of management s use of these non-GAAP measures. 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:

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in millions, except per share data	Year Ended December 31, 2010 Pre-Tax	Tax Impact	After-Tax	Impact per share	
GAAP results	**$ (1,063)**	**$ (2)**	**$ (1,065)**	**$ (0.70)**	
Non-GAAP adjustments:					
Goodwill impairment charge	1,817		1,817	1.20	*
Intangible asset impairment charges	65	(10)	55	0.03	*
Acquisition-related credits	(245)	34	(211)	(0.13)	*
Divestiture-related charges	2		2	0.00	*
Restructuring-related charges	169	(48)	121	0.08	*
Litigation-related net credits	(104)	27	(77)	(0.05)	*
Discrete tax items		(11)	(11)	(0.01)	*
Amortization expense	513	(93)	420	0.27	*
Adjusted results	**$ 1,154**	**$ (103)**	**$ 1,051**	**$ 0.69**	

* Assumes dilution of 10.0 million shares for the year ended December 31, 2010 for all or a portion of these non-GAAP adjustments.

in millions, except per share data	Year Ended December 31, 2009 Pre-Tax	Tax Impact	After-Tax	Impact per share	
GAAP results	**$ (1,308)**	**$ 283**	**$ (1,025)**	**$ (0.68)**	
Non-GAAP adjustments:					
Intangible asset impairment charges	12	(2)	10	0.01	
Acquisition-related charges	21	(1)	20	0.01	
Divestiture-related credits	(8)	1	(7)	0.00	
Restructuring-related charges	130	(33)	97	0.06	
Litigation-related net charges	2,022	(251)	1,771	1.17	*
Discrete tax items		(106)	(106)	(0.07)	*
Amortization expense	511	(89)	422	0.28	*
Adjusted results	**$ 1,380**	**$ (198)**	**$ 1,182**	**$ 0.78**	

* Assumes dilution of 8.0 million shares for the year ended December 31, 2009 for all or a portion of these non-GAAP adjustments.

Cash generated by operating activities was $325 million in 2010 and $835 million in 2009, and included approximately $1.6 billion of litigation-related net payments in 2010, as compared to approximately $800 million in 2009, as well as the receipt of an acquisition-related milestone payment of $250 million. Our cash generated by operations continues to be a significant source of funds for servicing our outstanding debt obligations and investing in our growth. As of December 31, 2010, we had total debt of $5.438 billion, cash and cash equivalents of $213 million and working capital of $1.006 billion. During 2010, we completed the refinancing of the majority of our 2011 debt maturities, establishing a $1.0 billion term loan and syndicating a new $2.0 billion revolving credit facility, and prepaid in full our $900 million loan from Abbott and all $600 million of our senior notes due in June 2011. Further,

in January 2011, we paid at maturity $250 million of our senior notes. In 2009, Standard & Poor s upgraded our credit rating to investment grade with a stable outlook. In 2010, Fitch Ratings upgraded our outlook to positive from stable, and Moody s raised our liquidity rating to its highest level. We believe these rating improvements reflect the strength of our product portfolio, our commitment to debt reduction, our improving financial fundamentals, and the progress we are making towards driving profitable sales growth.

Recent Events

As part of our strategy, we are realigning our business portfolio through select divestitures and targeted acquisitions in order to reduce risk, optimize operational leverage and accelerate profitable, sustainable revenue growth, while preserving our ability to meet the needs of physicians and their patients. We have recently announced several acquisitions targeting many of our priority growth areas, and, in January 2011, closed the sale of our Neurovascular business to Stryker Corporation.

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Acquisitions

We expect to continue to invest in our core franchises, and are also investigating opportunities to further expand our presence in, and diversify into, priority growth areas including atrial fibrillation, autonomic modulation therapy, coronary artery disease, deep-brain stimulation, diabetes/obesity, endoluminal surgery, endoscopic pulmonary intervention, hypertension, peripheral vascular disease, structural heart disease, sudden cardiac arrest, and women s health. In late 2010 and early 2011, we announced the acquisitions of Asthmatx, Inc.; Sadra Medical, Inc.; Atritech, Inc.; and Intelect Medical, Inc., targeting many of the above conditions and disease states. Each of these acquisitions is discussed in the *Business and Market Overview* section below.

Business 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 at closing, including an upfront payment of $1.426 billion, and $24 million which was placed into escrow to be released upon the completion of local closings in certain foreign jurisdictions, and will receive an additional $50 million contingent upon the transfer or separation of certain manufacturing facilities, which we expect will be completed over a period of approximately 24 months. We will provide transitional services through a transition services agreement, and will also supply products to Stryker. These transition services and supply agreements are expected to be effective for a period of up to 24 months following the closing of the transaction, subject to extension. 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. Refer to *Note C Divestitures and Assets Held for Sale* to our 2010 consolidated financial statements included in Item 8 of this Annual Report for more information.

Business and Market Overview

Cardiac Rhythm Management (CRM)

Our CRM division develops, manufactures and markets a variety of implantable devices that monitor the heart and deliver electricity to treat cardiac abnormalities. Worldwide net sales of these products of $2.180 billion represented approximately 28 percent of our consolidated net sales in 2010. Our worldwide CRM net sales decreased $233 million, or ten percent, in 2010, as compared to 2009. Foreign currency fluctuations did not materially impact our CRM net sales in 2010, as compared to the prior year. This decrease was driven primarily by the negative impact of the ship hold and product removal actions associated with our ICD and CRT-D systems earlier in the year. We experienced market share loss in the U.S. as a result of these actions; however, we believe that our products, including our COGNIS® CRT-D and TELIGEN® ICD systems, among the world s smallest and thinnest high-energy devices, will continue to be successful in the global market.

While we have recaptured a portion of our lost market share, the extent and timing of our recovery is difficult to predict. We estimate that our U.S. defibrillator market share exiting 2010 decreased approximately 300 basis points, as compared to our market share exiting 2009, due primarily to these product actions. Further, overall expectations of future CRM market growth have declined, driven primarily by competitive and other pricing pressures, as well as fewer launches of market-expanding technologies than previously anticipated. We estimate that the worldwide CRM market approximated $11.4 billion in 2010, representing a slight increase over the 2009 market size of $11.1 billion. In addition, physician reaction to study results published by the *Journal of the American Medical Association* regarding evidence-based guidelines for ICD implants and the U.S. Department of Justice investigation into ICD implants may have a negative impact on the CRM market. However, in September 2010, we received FDA approval for an exclusive expanded indication for use of our CRT-D systems with certain patients in earlier stages of heart failure. We believe this indication could potentially create an opportunity to expand the worldwide CRM market by approximately $250 million to $350 million over the next few years, and further enhance our position within that market.

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

(in millions)	Year Ended December 31, 2010			Year Ended December 31, 2009		
	U.S.	International	Total	U.S.	International	Total
Defibrillator systems	$ 1,037	$ 562	$ 1,599	$ 1,248	$ 544	$ 1,792
Pacemaker systems	320	261	581	346	275	621
CRM products	**$ 1,357**	**$ 823**	**$ 2,180**	**$ 1,594**	**$ 819**	**$ 2,413**

Our U.S. CRM net sales decreased $237 million, or 15 percent, in 2010 as compared to 2009, driven primarily by the ship hold and product removal actions involving our ICD and CRT-D systems, discussed above. We are committed to advancing our technologies to strengthen our CRM business. In 2010, we continued to execute on our product pipeline and expect to launch our next-generation line of defibrillators in the U.S. in late 2011 or early 2012, which include new features designed to improve functionality, diagnostic capability and ease of use. Due in part to anticipated changes to current FDA regulatory requirements industry-wide, which would increase the number of patients and length of time needed for certain clinical studies, we now expect to launch our next-generation INGENIO pacemaker system, which leverages the strength of our high-voltage platform and will be compatible with our LATITUDE® Patient Management System, in the U.S. in late 2011 or early 2012, depending on final FDA requirements. Refer to *Regulatory Environment* included in Item 1 of this Annual Report for more information.

Our international CRM net sales increased $4 million, or less than one percent, in 2010, as compared to 2009. International net sales of our defibrillator systems increased $18 million, or three percent, in 2010, as compared to 2009, driven by strong market acceptance of our COGNIS® CRT-D and TELIGEN® ICD systems, and our recently-launched 4-SITE lead delivery system. In addition, in July 2009, we received CE Mark approval for our LATITUDE® Patient Management System and have since launched this technology in the majority of our European markets. The LATITUDE® technology, which is designed to enable physicians to monitor device performance remotely while patients are in their homes, is a key component of many of our CRM systems. In late 2010, we received CE Mark approval for our next-generation line of defibrillators, INCEPTA , ENERGEN and PUNCTUA , and plan to launch these products in our Europe/Middle East/Africa (EMEA) region and certain Inter-Continental countries in the first half of 2011. These products provide physicians and their patients with more options to customize therapy and enhance our market advantage in size, shape and longevity. We also plan to launch our next-generation INGENIO pacemaker system in these regions in the second half of 2011 and believe that these launches position us well within the worldwide 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 operations. The variables that may impact the size of the CRM market and/or our share of that market include, but are not limited to:

- our ability to retain and attract key members of our CRM sales force and other key CRM personnel;
- our ability to recapture lost market share following the ship hold and product removal of our ICD and CRT-D systems in the U.S.;
- the impact of market and economic conditions on average selling prices and the overall number of procedures performed;
- 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 by us or our competitors;

our ability to successfully develop and launch next-generation products and technology;

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clinical trials that may provide opportunities to expand indications for use, particularly in light of anticipated changes to current FDA regulatory requirements industry-wide;

variations in clinical results, reliability or product performance of our and our competitors products;

delayed or limited regulatory approvals and unfavorable reimbursement policies; and

new competitive launches.

Coronary Stent Systems

Our coronary stent system offerings include the VeriFLEX (Liberté®) bare-metal coronary stent system, designed to enhance deliverability and conformability, particularly in challenging lesions, as well as drug-eluting coronary stent systems. We are the only company in the industry to offer a two-drug platform strategy, which has enabled us to maintain our leadership position in the drug-eluting stent market. We currently market our TAXUS® paclitaxel-eluting stent line, including our third-generation TAXUS® Element stent system, launched in our EMEA region and certain Inter-Continental countries during the second quarter of 2010. The CE Mark approval for our TAXUS® Element stent system includes a specific indication for treatment in diabetic patients. We also offer our everolimus-eluting stent line, consisting of the PROMUS® stent system, currently supplied to us by Abbott Laboratories, and our next-generation internally-developed and manufactured everolimus-eluting stent system, the PROMUS® Element stent system, which we launched in our EMEA region and certain Inter-Continental countries in the fourth quarter of 2009. In September 2010, we received CE Mark approval for expanded indications for the use of our PROMUS® Element stent system in diabetic and heart attack patients. Our Element stent platform incorporates a unique platinum chromium alloy designed to offer greater radial strength and flexibility than older alloys, enhanced visibility and reduced recoil. The innovative stent design improves deliverability and allows for more consistent lesion coverage and drug distribution. These product offerings demonstrate our commitment to drug-eluting stent market leadership and continued innovation. We expect to launch our TAXUS® Element stent system in the U.S. (to be commercialized as ION) in mid-2011 and Japan in late 2011 or early 2012. We expect to launch our PROMUS® Element stent system in the U.S. and Japan in mid-2012.

Net sales of our coronary stent systems, including bare-metal stent systems, of $1.670 billion represented approximately 21 percent of our consolidated net sales in 2010. Worldwide sales of these products decreased $209 million, or 11 percent, in 2010, as compared to the prior year. Excluding the impact of foreign currency fluctuations, which contributed $26 million to our coronary stent system net sales in 2010, as compared to 2009, net sales of these products decreased 12 percent, as compared to the prior year. Despite continued competition and pricing pressures resulting in a decline in sales of these products, we maintained our leadership position in 2010 with an estimated 36 percent share of the worldwide drug-eluting stent market, as compared to 41 percent in 2009. We estimate that the worldwide coronary stent market approximated $5.0 billion in 2010, consistent with the 2009 market size. The size of the coronary stent market is driven primarily by the number of percutaneous coronary intervention (PCI) procedures performed, as well as the percentage of those in which stents are implanted; the number of devices used per procedure; average selling prices; and the drug-eluting stent penetration rate[2].

[2] A measure of the mix between bare-metal and drug-eluting stents used across procedures.

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

(in millions)	Year Ended December 31, 2010			Year Ended December 31, 2009		
	U.S.	International	Total	U.S.	International	Total
TAXUS®	$ 277	$ 223	$ 500	$ 431	$ 596	$ 1,027
PROMUS®	528	282	810	480	201	681
PROMUS® Element		227	227			
Drug-eluting stent systems	805	732	1,537	911	797	1,708
Bare-metal stent systems	44	89	133	57	114	171
	$ 849	**$ 821**	**$ 1,670**	**$ 968**	**$ 911**	**$ 1,879**

Our U.S. net sales of drug-eluting stent systems decreased $106 million, or 12 percent, in 2010, as compared to 2009. This decrease resulted primarily from a decline in our share of the U.S. drug-eluting stent market, as well as an overall decrease in the size of this market, resulting principally from lower average selling prices driven by competitive and other pricing pressures. We estimate our share of the U.S. drug-eluting stent market approximated 46 percent for the last five quarters, as compared to an average of 49 percent during 2009, and estimate that the average selling price of drug-eluting stent systems in the U.S. decreased approximately nine percent in 2010, as compared to 2009. This decline was due primarily to lower sales of our TAXUS® drug-eluting stent systems, which we believe was due to customer perceptions of data from a single-center, non-double-blinded, underpowered study sponsored by one of our competitors. We believe that average drug-eluting stent penetration rates in the U.S. were 77 percent in 2010, as compared to an average of 75 percent during 2009, which partially offset the impact of lower average selling prices on the size of the U.S. drug-eluting stent market. We believe we have maintained our leadership position in this market due to the success of our two-drug platform strategy and the breadth of our product offerings, including the industry s widest range of coronary stent sizes.

Our international drug-eluting stent system net sales decreased $65 million, or eight percent, in 2010, as compared to 2009. Net sales of our drug-eluting stent systems in Japan decreased $49 million, or 19 percent, in 2010, as compared to the prior year and our estimated share of the drug-eluting stent market in Japan declined to an average of 39 percent in 2010 (exiting at 36 percent), as compared to an average of 49 percent in 2009 (exiting at 44 percent). We believe that aggressive pricing offered by market entrants and clinical trial enrollment limiting our access to certain customers contributed to the decline in our market share in Japan in 2010, as compared to the prior year. This decrease was partially offset by our first quarter 2010 launch of the PROMUS® stent system in Japan, enabling us to begin the execution of our two-drug platform strategy in this region. Our net sales of drug-eluting stent systems in our EMEA region decreased $26 million, or eight percent in 2010, as compared to 2009, due primarily to declines in average selling prices, partially offset by increased penetration rates. However, in the second quarter of 2010, we launched our third-generation TAXUS® Element stent system in our EMEA region and certain Inter-Continental countries. We believe that this launch, coupled with the November 2009 launch of our PROMUS® Element stent system, which has quickly gained market share, exiting 2010 with approximately one quarter share of the drug-eluting stent market in EMEA, position us well in this market going forward. Net sales of drug-eluting stent systems in our Inter-Continental region increased $10 million, or five percent, driven by an increase in penetration rates and procedural volume.

We market the PROMUS® everolimus-eluting coronary stent system, a private-labeled XIENCE V® stent system supplied to us by Abbott Laboratories. As of the closing of Abbott s 2006 acquisition of Guidant Corporation s vascular intervention and endovascular solutions businesses, we obtained a perpetual license to the intellectual property used in Guidant s drug-eluting stent system program purchased by Abbott. We believe that being the only company to offer

two distinct drug-eluting stent platforms provides us a considerable advantage in the drug-eluting stent market and has enabled us to sustain our worldwide leadership position. However, under the terms of our supply arrangement with Abbott, the gross profit and operating profit margin of everolimus-eluting stent systems supplied to us by Abbott, including any improvements or iterations approved for sale during the term of the applicable supply arrangements and of the type that could be approved by a supplement to an approved FDA pre-market approval, is significantly lower than that of our TAXUS® and PROMUS® Element stent systems. Specifically, the PROMUS® stent system has operating profit margins that approximate half of our TAXUS® stent system operating profit margin. Therefore, if sales of everolimus-eluting stent systems supplied to

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us by Abbott increase in relation to our total drug-eluting stent system sales, our profit margins will decrease. Refer to our *Gross Profit* discussion for more information on the impact this sales mix has had on our gross profit margins. Our internally-developed and manufactured PROMUS® Element everolimus-eluting stent system, launched in our EMEA region and certain Inter-Continental countries in the fourth quarter of 2009, generates gross profit margins more favorable than the PROMUS® stent system and we expect will positively affect our overall gross profit and operating profit margins in these regions as sales shift from PROMUS® to PROMUS® Element .

Further, the price we pay for our supply of everolimus-eluting stent systems from Abbott is determined by contracts with Abbott and is based, in part, on previously fixed estimates of Abbott s manufacturing costs for everolimus-eluting stent systems and third-party reports of our average selling price of these stent systems. Amounts paid pursuant to this pricing arrangement are subject to a retroactive adjustment approximately every two years based on Abbott s actual costs to manufacture these stent systems for us and our average selling price of everolimus-eluting stent systems supplied to us by Abbott. Our gross profit margin may be positively or negatively impacted in the future as a result of this adjustment process.

We are currently reliant on Abbott for our supply of everolimus-eluting stent systems in the U.S. and Japan. Our supply agreement with Abbott for everolimus-eluting stent systems in the U.S. and Japan extends through the end of the second quarter of 2012. At present, we believe that our supply of everolimus-eluting stent systems from Abbott, coupled with our current launch plans for our internally-developed and manufactured PROMUS® Element everolimus-eluting stent system, is sufficient to meet customer demand. However, any production or capacity issues that affect Abbott s manufacturing capabilities or our process for forecasting, ordering and receiving shipments may impact the ability to increase or decrease our level of supply in a timely manner; therefore, our supply of everolimus-eluting stent systems supplied to us by Abbott may not align with customer demand, which could have an adverse effect on our operating results. Further, a delay in the launch of our internally-developed and manufactured PROMUS® Element everolimus-eluting stent system in the U.S. and Japan, currently expected in mid-2012, could result in an inability to meet customer demand for everolimus-eluting stent systems.

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 can sustain our leadership position within the worldwide drug-eluting stent market in the foreseeable future for a variety of reasons, including:

- our two-drug platform strategy, including specialty stent sizes;
- the broad and consistent long-term results of our TAXUS® clinical trials, and the favorable results of the XIENCE V®/PROMUS® and PROMUS® Element stent system clinical trials to date;
- the performance benefits of our current and future technology;
- the strength of our pipeline of drug-eluting stent products, including our PROMUS® Element and TAXUS® Element stent systems, in additional geographies;
- our overall position in the worldwide interventional medicine market and our experienced interventional cardiology sales force; and
- the strength of our clinical, selling, marketing and manufacturing capabilities.

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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 and operating cash flows. The most 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;
- physician and patient confidence in our current and next-generation technology;
- our ability to successfully launch next-generation products and technology features, including the PROMUS® Element and TAXUS® Element stent systems in additional geographies;
- changes in drug-eluting stent penetration rates, the overall number of PCI procedures performed and the average number of stents used per procedure;
- delayed or limited regulatory approvals and unfavorable reimbursement policies;
- new competitive product launches; and
- the outcome of intellectual property litigation.

During 2009 and early 2010, we successfully negotiated closure of several long-standing legal matters, including multiple matters with Johnson & Johnson; all outstanding litigation between us and Medtronic, Inc. with respect to interventional cardiology and endovascular repair cases; and all outstanding litigation between us and Bruce Saffran, M.D., Ph.D. However, there continues to be significant intellectual property litigation particularly in the coronary stent market. In particular, although we have resolved multiple litigation matters with Johnson & Johnson, we continue to be involved in patent litigation with them, particularly relating to drug-eluting stent systems. 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 position, results of operations or liquidity.

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 ultrasound imaging systems. Our worldwide net sales of these products decreased to $932 million in 2010, as compared to $980 million in 2009, a decrease of $48 million, or five percent. Excluding the impact of foreign currency fluctuations which contributed $12 million to our Interventional Cardiology (excluding coronary stent systems) net sales in 2010, as compared to the prior year, net sales of these products decreased $60 million, or six percent. Our U.S. net sales of these products were $394 million in 2010, as compared to $409 million in 2009. Our international net sales of these products were $538 million in 2010, as compared to $571 million for the prior year. This decrease was the result of a delay in new product introductions, pricing pressures and competitive product launches. We continue to hold a strong leadership position in the PTCA balloon catheter market, maintaining an estimated 56 percent average share of the U.S. market and 38 percent worldwide in 2010. We have executed and are planning a number of additional new product launches during 2011, including the full launch of our Apex pre-dilatation balloon catheter with platinum marker bands for improved radiopacity, launched in limited markets during the second quarter of 2010. In June 2010, we launched the NC Quantum Apex post-dilatation balloon catheter, developed specifically to address physicians needs in optimizing coronary stent deployment, which has been received positively in the market. In addition, we began a phased launch of our Kinetix family of guidewires in the U.S., our EMEA region and certain Inter-Continental countries in April 2010.

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As part of our strategic plan, we are investigating opportunities to further expand our presence in, and diversify into, other areas and disease states, including structural heart. In January 2011, we completed the acquisition of Sadra Medical, Inc. Sadra is developing a repositionable and retrievable device for percutaneous aortic valve replacement (PAVR) to treat patients with severe aortic stenosis and recently completed a series of European feasibility studies for its Lotus Valve System, which 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. PAVR is one of the fastest growing medical device markets.

Peripheral Interventions

Our Peripheral Interventions business product offerings include stents, balloon catheters, sheaths, wires and vena cava filters, which are used to diagnose and treat peripheral vascular disease, and we continue to hold the number one position in the worldwide Peripheral Interventions market. Our worldwide net sales of these products increased to $669 million in 2010, as compared to $661 million in 2009, an increase of $8 million, or one percent. Excluding the impact of foreign currency fluctuations, which contributed $6 million to our Peripheral Interventions net sales in 2010, as compared the prior year, net sales of these products increased $2 million, or less than one percent, as compared to 2009. Our U.S. net sales of these products were $310 million in 2010, as compared to $320 million for the prior year. Our international net sales were $359 million in 2010, as compared to $341 million in 2009, driven by several international product launches, including the second quarter 2010 launch in Japan of our Carotid WALLSTENT® Monorail® Endoprosthesis. We look forward to new product launches, including our next-generation percutaneous transluminal angioplasty balloon, expected in the second half of 2011 and believe that these launches, coupled with the strength of our Express® SD Renal Monorail® premounted stent system; our Express LD Stent System, which received FDA approval in the first quarter of 2010 for an iliac indication; our Sterling® Monorail® and Over-the-Wire balloon dilatation catheter and our extensive line of Interventional Oncology product solutions, will continue to position us well in the growing Peripheral Interventions market.

Electrophysiology

We develop 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, including our next-generation Blazer Prime ablation catheter, designed to deliver enhanced performance, responsiveness and durability, which we launched in the U.S. in the fourth quarter of 2009. Worldwide net sales of our Electrophysiology products decreased to $147 million in 2010, as compared to $149 million in 2009, a decrease of $2 million, or two percent, due principally to product availability constraints with our Chilli II catheter line. Foreign currency fluctuations did not materially impact our Electrophysiology net sales in 2010, as compared to the prior year. Our U.S. net sales of these products were $112 million, as compared to $116 million for the prior year, and our international net sales were $35 million in 2010, as compared to $33 million in 2009. We have begun a limited launch of our Blazer Prime ablation catheter in the U.S., our EMEA region and certain Inter-Continental countries, and believe that with the increasing adoption of this technology and other upcoming product launches, we are well-positioned within the Electrophysiology market. As part of our strategic plan, we are investigating opportunities to further expand our presence in, and diversify into, other areas and disease states, including atrial fibrillation. In January 2011, we announced the signing of a definitive merger agreement under which we will acquire Atritech, Inc., subject to customary closing conditions. Atritech has 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, 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.

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 increased to $1.079 billion in 2010, as compared to $1.006 billion in 2009, an increase of $73 million, or seven percent.

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Excluding the impact of foreign currency fluctuations, which contributed $9 million to our Endoscopy net sales in 2010, as compared to the prior year, net sales of these products increased $64 million, or six percent, as compared to 2009. Our U.S. net sales of these products were $541 million in 2010, as compared to $517 million for the prior year, and our international net sales were $538 million in 2010, as compared to $489 million in 2009. These increases were due primarily to higher net sales within our stent franchise, driven by the continued commercialization and adoption of our WallFlex® family of stents, in particular, the WallFlex Biliary line and WallFlex Esophageal line. In addition, our hemostasis franchise net sales benefited from increased utilization of our Resolution® Clip Device, an endoscopic mechanical clip to treat gastrointestinal bleeding, and our biliary franchise drove solid growth on the strength of our rapid exchange biliary devices. During 2010, we introduced expanded sizes of our Radial® Jaw 4 biopsy forceps, and have launched a number of new products targeting the biliary interventional market. As part of our strategic plan, we are investigating opportunities to further expand our presence in, and diversify into, other areas and disease states, including endoscopic pulmonary intervention. On October 26, 2010, we completed our acquisition of Asthmatx, Inc. Asthmatx designs, manufactures and markets 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 CE Mark and FDA approval and is the first device-based asthma treatment approved by the FDA. We expect this technology to strengthen our existing offering of pulmonary devices and contribute to the mid- to long-term growth and diversification of the Endoscopy business.

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 increased to $481 million in 2010 from $456 million in 2009, an increase of $25 million, or five percent. Foreign currency fluctuations did not materially impact our Urology/Women s Health net sales in 2010, as compared to the prior year. Our U.S. net sales of these products were $365 million in 2010, as compared to $353 million in 2009, and our international net sales were $116 million in 2010, as compared to $103 million for the prior year. These increases were driven by new product introductions and increased sales investments. In 2011, we plan to expand the launch of our recently-approved 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. We believe this new product offering will enable us to increase our share of this market.

Neuromodulation

Within our Neuromodulation business, we market the Precision® Spinal Cord Stimulation (SCS) system, used for the management of chronic pain. Our worldwide net sales of Neuromodulation products increased to $304 million in 2010, as compared to $285 million in 2009, an increase of $19 million, or seven percent. Foreign currency fluctuations did not materially impact our Neuromodulation net sales in 2010, as compared to the prior year. Our U.S. net sales of these products were $288 million in 2010 as compared to $271 million for the prior year, and our international net sales of these products were $16 million in 2010, as compared to $14 million in 2009, driven by an increase in procedural volume and new product launches. In 2010, we received FDA approval and launched two lead splitters, as well as the Linear 3-4 and Linear 3-6 Percutaneous Leads for use with our SCS systems, offering a broader range of lead configurations and designed to provide physicians more treatment options for their chronic pain patients. These represent the broadest range of percutaneous lead configurations in the industry. We believe that we continue to have a technology advantage over 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, and are involved in various studies designed to evaluate the use of spinal cord stimulation in the treatment of additional sources of pain. As a demonstration of our commitment to strengthening clinical evidence with spinal cord stimulation, we have initiated a trial to assess the therapeutic effectiveness and cost-effectiveness of spinal cord stimulation compared to reoperation in patients with failed back surgery syndrome. We believe that this trial could result in consideration of spinal cord stimulation much earlier in the continuum of care. In addition, in late 2010 we initiated a European clinical trial for the treatment of Parkinson s disease using our Vercise deep-brain stimulation

system, and, in January 2011, we completed the

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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 advances the field of deep-brain stimulation.

Neurovascular

In January 2011, we closed the sale our Neurovascular business to Stryker Corporation. We will provide transitional services through a transition services agreement, and will also supply products to Stryker. These transition services and supply agreements are expected to be effective for a period of up to 24 months following the closing of the transaction, subject to extension, and we will recognize net sales on the sale of Neurovascular products in certain countries during this period. Our future sales of Neurovascular products to Stryker will be significantly lower than our 2010 Neurovascular net sales and will be at significantly reduced gross margins. The Neurovascular business markets a broad line of coated and uncoated detachable coils, micro-delivery stents, micro-guidewires, micro-catheters, guiding catheters and embolics to neuro-interventional radiologists and neurosurgeons to treat diseases of the neurovascular system. Our worldwide net sales of Neurovascular products decreased to $340 million in 2010, as compared to $348 million in 2009, a decrease of $8 million, or two percent. Excluding the impact of foreign currency fluctuations, which contributed $7 million to Neurovascular net sales in 2010, as compared to the prior year, net sales of these products decreased $15 million, or four percent, in 2010, as compared to 2009. Our U.S. net sales of these products were $120 million, as compared to $125 million for the prior year, and our international net sales were $220 million in 2010, as compared to $223 million in 2009. These decreases resulted primarily from new competitive launches and a delay in the launch of the next-generation family of detachable coils, as well the impact of a field action initiated during the third quarter with respect to selective lots of the Matrix® Detachable Coil. However, in October 2010, we received FDA approval for the next-generation family of detachable coils, which includes an enhanced delivery system designed to reduce coil detachment times and began a phased launch of the product in 2010. In 2010, we also launched the Neuroform EZ stent system, the fourth-generation intracranial aneurysm stent system designed for use in conjunction with endovascular coiling to treat wide-necked aneurysms, in the U.S. and our EMEA region.

FDA Matters

In January 2006, we received a corporate warning letter from the FDA notifying us of serious regulatory problems at three of our facilities and advising us that our corporate-wide corrective action plan relating to three site-specific warning letters issued to us in 2005 was inadequate. We identified solutions to the quality system issues cited by the FDA and implemented those solutions throughout our organization. During 2008, the FDA reinspected a number of our facilities and, in October 2008, informed us that our quality system was in substantial compliance with its Quality System Regulations. In November 2009 and January 2010, the FDA reinspected two of our sites to follow-up on observations from the 2008 FDA inspections. Both of these FDA inspections confirmed that all issues at the sites have been resolved and all restrictions related to the corporate warning letter were removed. On August 11, 2010, we were notified by the FDA that the corporate warning letter had been lifted.

In August 2010, the FDA released numerous draft proposals on the 510(k) process aimed at increasing transparency and streamlining the process, while adding more scientific rigor to the review process. In January 2011, the FDA released the implementation plan for changes to the 510(k) Submission program, which includes additional training of FDA staff, the creation of various guidance documents intended to provide greater clarity to certain processes, as well as various internal changes to the FDA s procedures. We have a portfolio of products that includes numerous Class II medical devices. Several of the FDA s proposals could increase the regulatory burden on our industry, including those that could increase the cost, complexity and time to market for certain high-risk Class II medical devices.

Restructuring Initiatives

We are a diversified worldwide medical device leader and hold number one or two positions in the majority of the markets in which we compete. Since our inception, we have generated significant revenue growth driven by product innovation, strategic acquisitions and robust investments in research and development. We generate

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strong cash flow, which has enabled us to reduce our debt obligations and further invest in our growth. 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 I Restructuring-related Activities* to our 2010 consolidated financial statements included in Item 8 of this Annual Report.

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 include the integration of our Cardiovascular and CRM businesses, as well as the restructuring of certain other businesses and corporate functions; the centralization of our research and development organization; 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 our product portfolio. We estimate that the execution of this plan will result in gross reductions in pre-tax operating expenses of approximately $200 million to $250 million, once completed in 2012. We expect to reinvest a portion of the savings into customer-facing and other activities to help drive future sales growth and support the business. Activities under the 2010 Restructuring plan were initiated in the first quarter of 2010 and are expected to be substantially complete by the end of 2012. We expect the execution of the 2010 Restructuring plan will result in the elimination of approximately 1,000 to 1,300 positions worldwide.

Plant Network Optimization

In January 2009, our Board of Directors approved, and we committed to, a Plant Network Optimization program, which is intended to simplify our manufacturing plant structure by transferring certain production lines among facilities and by closing certain other facilities. The program is a complement to our 2007 Restructuring plan, discussed below, and is intended to improve overall gross profit margins. We estimate that the program will result in annualized run-rate reductions of manufacturing costs of approximately $65 million exiting 2012. These savings are in addition to the estimated $35 million of annual reductions of manufacturing costs from activities under our 2007 Restructuring plan, discussed below. Activities under the Plant Network Optimization program were initiated in the first quarter of 2009 and are expected to be substantially complete by the end of 2012.

2007 Restructuring plan

In October 2007, our Board of Directors approved, and we committed to, an expense and head count reduction plan (the 2007 Restructuring plan). The plan was intended to bring expenses in line with revenues as part of our initiatives to enhance short- and long-term shareholder value. Key activities under the plan included the restructuring of several businesses, corporate functions and product franchises in order to better utilize resources, strengthen competitive positions, and create a more simplified and efficient business model; the elimination, suspension or reduction of spending on certain research and development projects; and the transfer of certain production lines among facilities. The execution of this plan enabled us to reduce research and development and selling, general and administrative expenses by an annualized run rate of approximately $500 million exiting 2008. We have partially reinvested our savings from these initiatives into targeted head count increases, primarily in customer-facing positions. In addition, we expect reductions of annualized run-rate manufacturing costs of approximately $35 million exiting 2010 as a result of transfers of certain production lines. Due to the longer term nature of these initiatives, we do not expect to achieve the full benefit of these reductions in manufacturing costs until 2012. We initiated activities under the plan in the fourth quarter of 2007. The transfer of certain production lines contemplated under the 2007 Restructuring plan was completed as of December 31, 2010; all other major

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activities under the plan, with the exception of final production line transfers, were completed as of December 31, 2009.

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 legislation will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impact will be from the legislation. 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 2013. U.S. net sales represented 56 percent of our worldwide net sales in 2010 and, therefore, this tax burden may have a material negative impact on our results of operations and cash flows. Other provisions of this legislation, 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 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 or reduce medical procedure volumes could adversely affect our business and results of operations.

Results of Operations

Net Sales

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 foreign exchange 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 currency exchange, we convert current period and prior period net sales from local currency to U.S. dollars using current period 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 P Segment Reporting* to our 2010 consolidated financial statements included in Item 8 of this Annual Report. As of December 31, 2010, 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. The reportable segments represent an aggregate of all operating divisions within each segment.

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

				2010 versus 2009		2009 versus 2008	
	Year Ended December 31,			As Reported Currency Basis	Constant Currency Basis	As Reported Currency Basis	Constant Currency Basis
(in millions)	2010	2009	2008				
United States	**$ 4,335**	**$ 4,675**	**$ 4,487**	**(7) %**	**(7) %**	**4 %**	**4 %**
EMEA	1,759	1,837	1,960	(4) %	(1) %	(6) %	1 %
Japan	968	988	861	(2) %	(8) %	15 %	4 %
Inter-Continental	740	677	673	9 %	1 %	1 %	8 %
International	**3,467**	**3,502**	**3,494**	**(1) %**	**(3) %**	**0 %**	**3 %**
Subtotal	**7,802**	**8,177**	**7,981**	**(5) %**	**(5) %**	**2 %**	**4 %**

Divested Businesses	4	11	69	N/A	N/A	N/A	N/A
Worldwide	**$ 7,806**	**$ 8,188**	**$ 8,050**	**(5) %**	**(5) %**	**2 %**	**3 %**

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

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(in millions)	Year Ended December 31, 2010	2009	2008	2010 versus 2009 As Reported Currency Basis	2010 versus 2009 Constant Currency Basis	2009 versus 2008 As Reported Currency Basis	2009 versus 2008 Constant Currency Basis
Cardiac Rhythm Management	**$ 2,180**	**$ 2,413**	**$ 2,286**	**(10) %**	**(10) %**	**6 %**	**7 %**
Interventional Cardiology	2,602	2,859	2,879	(9) %	(10) %	(1) %	0 %
Peripheral Interventions	669	661	684	1 %	0 %	(3) %	(2) %
Cardiovascular Group	**3,271**	**3,520**	**3,563**	**(7) %**	**(8) %**	**(1) %**	**0 %**
Electrophysiology	**147**	**149**	**153**	**(2) %**	**(2) %**	**(2) %**	**(1) %**
Neurovascular	**340**	**348**	**360**	**(2) %**	**(4) %**	**(3) %**	**(2) %**
Endoscopy	**1,079**	**1,006**	**943**	**7 %**	**6 %**	**7 %**	**8 %**
Urology/Women s Health	**481**	**456**	**431**	**5 %**	**5 %**	**6 %**	**6 %**
Neuromodulation	**304**	**285**	**245**	**7 %**	**7 %**	**17 %**	**17 %**
Subtotal	**7,802**	**8,177**	**7,981**	**(5) %**	**(5) %**	**2 %**	**4 %**
Divested Businesses	4	11	69	N/A	N/A	N/A	N/A
Worldwide	**$ 7,806**	**$ 8,188**	**$ 8,050**	**(5) %**	**(5) %**	**2 %**	**3 %**

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. Please see *Additional Information* for further information regarding management s use of these non-GAAP measures.

	2010 Net Sales as compared to 2009 Change			2009 Net Sales as compared to 2008 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

Cardiac Rhythm Management	**$ (233)**	**$ (230)**	**$ (3)**	**$ 127**	**$ 168**	**$ (41)**
Interventional Cardiology	(257)	(295)	38	(20)	2	(22)
Peripheral Interventions	8	2	6	(23)	(13)	(10)
Cardiovascular Group	**(249)**	**(293)**	**44**	**(43)**	**(11)**	**(32)**
Electrophysiology	**(2)**	**(3)**	**1**	**(4)**	**(3)**	**(1)**
Neurovascular	**(8)**	**(15)**	**7**	**(12)**	**(8)**	**(4)**
Endoscopy	**73**	**64**	**9**	**63**	**74**	**(11)**
Urology/ Women s Health	**25**	**21**	**4**	**25**	**27**	**(2)**
Neuromodulation	**19**	**19**	**0**	**40**	**41**	**(1)**
Subtotal	**(375)**	**(437)**	**62**	**196**	**288**	**(92)**
Divested Businesses	(7)	(7)	0	(58)	(58)	0
Worldwide	**$ (382)**	**$ (444)**	**$ 62**	**$ 138**	**$ 230**	**$ (92)**

U.S. Net Sales

During 2010, our U.S. net sales decreased $340 million, or seven percent, as compared to 2009. The decrease was driven primarily by lower U.S. CRM net sales of $237 million, due primarily to the ship hold and product removal actions impacting our ICD and CRT-D systems discussed above, as well as a decline in U.S. coronary stent system net sales of $119 million, due primarily to a decline in our share of the U.S. drug-eluting stent market as well as lower average selling prices. In addition, U.S. net sales of our Interventional Cardiology (excluding coronary stent systems) business decreased $15 million in 2010, as compared to the prior year. These decreases were partially offset by increases of U.S. net sales in 2010 from our Endoscopy business of $24 million, $12 million attributable to our Urology/Women s Health business, and $17 million of growth in our Neuromodulation

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business, as compared to 2009. Refer to the *Business and Market Overview* section for further discussion of our net sales.

During 2009, our U.S. net sales increased $188 million, or four percent, as compared to 2008. The increase was driven primarily by an increase in U.S. CRM net sales of $125 million and an increase of $47 million in U.S. net sales of our coronary stent systems. In addition, U.S. net sales in 2009 from our Endoscopy business grew $40 million, our Urology/Women s Health net sales increased $18 million, and our Neuromodulation division increased U.S. net sales $37 million in 2009, as compared to 2008. These increases were partially offset by declines in U.S. net sales from our Interventional Cardiology (excluding coronary stent systems) business of $52 million and a decrease of $16 million in Peripheral Interventions U.S. net sales in 2009, as compared to the prior year.

International Net Sales

During 2010, our international net sales decreased $35 million, or one percent, as compared to 2009. Foreign currency fluctuations contributed $62 million to our international net sales in 2010, as compared to the prior year. Excluding the impact of foreign currency fluctuations, net sales in our EMEA region decreased $21 million, or one percent, in 2010, as compared the prior year. Our net sales in Japan decreased $81 million, or eight percent, excluding the impact of foreign currency fluctuations in 2010, as compared to 2009, due primarily to competitive launches of drug-eluting stent system technology and clinical trial enrollment limiting our access to certain drug-eluting stent system customers, as well as reductions in average selling prices. Net sales in our Inter-Continental region, excluding the impact of foreign currency fluctuations, increased $5 million, or one percent, in 2010, as compared to the prior year. Refer to the *Business and Market Overview* section for further discussion of our net sales.

During 2009, our international net sales increased $8 million, or less than one percent, as compared to 2008. Foreign currency fluctuations contributed a negative $92 million to our international net sales, as compared to the prior year. Excluding the impact of foreign currency fluctuations, net sales in our EMEA region increased $11 million, or one percent, in 2009, as compared to 2008. Our net sales in Japan increased $37 million, or four percent, excluding the impact of foreign currency fluctuations in 2009, as compared to 2008, due primarily to an increase in coronary stent system sales following the launch of our second-generation TAXUS® Liberté® stent system in that region. Net sales in our Inter-Continental region increased $52 million, or eight percent, excluding the impact of foreign currency fluctuations, in 2009, as compared to the prior year.

Gross Profit

Our gross profit was $5.207 billion in 2010, $5.612 billion in 2009, and $5.581 billion in 2008. As a percentage of net sales, our gross profit decreased to 66.7 percent in 2010, as compared to 68.5 percent in 2009 and 69.3 percent in 2008. 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,			
	2010		**2009**	
Gross profit - prior year	**68.5**	**%**	**69.3**	%
Drug-eluting stent system sales mix and pricing	(1.7)	%	(1.4)	%
Impact of CRM ship hold	(0.4)	%		
Net impact of foreign currency	0.1	%	0.9	%
All other	0.2	%	(0.3)	%
Gross profit - current year	**66.7**	**%**	**68.5**	%

The primary factor contributing to the reduction in our gross profit margin during 2010 and 2009, as compared to the prior years, was, in each year, a further decrease in sales of our higher-margin TAXUS® drug-eluting stent systems and an increasing shift towards the PROMUS® stent system, as well as declines in the average selling prices of drug-eluting stent systems. Sales of the PROMUS® stent system represented approximately 52 percent of our worldwide drug-eluting stent system sales in 2010, 40 percent in 2009, and 19 percent in 2008. As a result of the terms of our supply arrangement with Abbott, the gross profit margin of a PROMUS® stent system, supplied to us by

Abbott, is significantly lower than that of our TAXUS® stent system. In the fourth quarter of 2009, we launched our next-generation internally-developed and manufactured PROMUS® Element everolimus-eluting

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stent system in our EMEA region and certain Inter-Continental countries. This product generates gross profit margins more favorable than the PROMUS® stent system, and has positively affected our overall gross profit and operating profit margins. We expect to launch our PROMUS® Element stent system in the U.S. and Japan in mid-2012. In addition, the average selling prices of drug-eluting stent systems have decreased, including an estimated nine percent decline in the U.S., in 2010, as compared to 2009. Our gross profit margin in 2010 was also negatively impacted by the ship hold and product removal actions associated with our U.S. CRM business previously discussed.

We expect our gross profit, as a percentage of net sales, will continue to be negatively impacted by declines in average selling prices across our businesses. In addition, our 2011 gross profit percentage will be negatively impacted as a result of our expected low-margin sales of Neurovascular product to Stryker under the terms of our transitional supply agreements.

Operating Expenses

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

	Year Ended December 31,					
	2010		2009		2008	
(in millions)	$	% of Net Sales	$	% of Net Sales	$	% of Net Sales
Selling, general and administrative expenses	2,580	33.1	2,635	32.2	2,589	32.2
Research and development expenses	939	12.0	1,035	12.6	1,006	12.5
Royalty expense	185	2.4	191	2.3	203	2.5

Selling, General and Administrative (SG&A) Expenses

In 2010, our SG&A expenses decreased $55 million, or two percent, as compared to 2009. This decrease was related primarily to savings from our restructuring initiatives driven by lower head count and lower consulting and travel spending, as compared to the prior year. These decreases were partially offset by an $11 million unfavorable impact from foreign currency fluctuations. As a percentage of net sales, our SG&A expenses were slightly higher than 2009 due to the impact of maintaining compensation levels for our U.S. CRM sales force, despite the reduction in our net sales of our CRM products in the U.S. We plan to increase our investment in SG&A in 2011 to introduce new products; strengthen our sales organization in emerging markets such as Brazil, China and India; and to support our acquired businesses; as a result, our SG&A expenses are likely to increase slightly as a percentage of net sales in 2011, as compared to 2010.

In 2009, our SG&A expenses increased by $46 million, or two percent, as compared to 2008. This increase was related primarily to the addition of direct selling expenses and head count, including expanding our global sales force and an increase in costs associated with various litigation-related matters. These increases were partially offset by a benefit from foreign currency fluctuations of approximately $22 million.

Research and Development (R&D) Expenses

In 2010, our R&D expenses decreased $96 million, or nine percent, as compared to 2009. This decrease was due to the on-going re-prioritization of R&D projects and the re-allocation of spending as part of our efforts to focus on products with higher returns, as well as the delay of certain of our clinical trials. We remain committed 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 2009, our R&D expenses increased $29 million, or three percent, as compared to 2008. As a percentage of net sales, our R&D expenses in 2009 were relatively flat with the prior year.

Royalty Expense

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In 2010, our royalty expense decreased $6 million, or three percent, as compared to 2009. This decrease was due primarily to lower sales of our drug-eluting coronary stent systems, partially offset by the continued shift in the mix of our drug-eluting stent system sales towards the PROMUS® and PROMUS® Element stent systems. The royalty rate applied to sales of these stent systems is, on average, higher than that associated with sales of our TAXUS® stent systems.

In 2009, our royalty expense decreased $12 million, or six percent, as compared to 2008. The decrease was primarily the result of a reduction in royalty expense of $29 million attributable to the expiration of a CRM royalty agreement during the first quarter of 2009. Partially offsetting this decrease was an increase in royalty expense of $20 million as a result of an increase in sales of our drug-eluting stent systems, as well as the shift in the mix of our drug-eluting stent system sales towards the PROMUS® stent system, following its launch in the U.S. in mid-2008.

Loss on Program Termination

In the second quarter of 2009, we discontinued one of our internal R&D programs in order to focus on those with a higher likelihood of success. As a result, we recorded a pre-tax loss of $16 million, in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 420, *Exit or Disposal Cost Obligations* (formerly FASB Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*), associated with future payments that we believe we remain contractually obligated to make. We continue to focus on developing new technologies that we believe will contribute to profitable sales growth in the future and do not believe that the cancellation of this program will have a material adverse impact on our future results of operations or cash flows.

Amortization Expense

Amortization expense was $513 million in 2010, as compared to $511 million in 2009, an increase of $2 million, or less than one percent. This non-cash charge is excluded by management for purposes of evaluating operating performance and assessing liquidity.

Amortization expense was $511 million in 2009, as compared to $543 million in 2008, a decrease of $32 million, or six percent. This decrease was due primarily to the impact of certain Interventional Cardiology-related intangible assets reaching the end of their accounting useful life during 2008, as well as the write-down of certain intangible assets to their fair values in 2009 and 2008, described in *Other Intangible Asset Impairment Charges* below.

Goodwill Impairment Charges

We test our April 1 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. The 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 expected corresponding financial impact on our operations created an indication of potential impairment of the goodwill balance attributable to our U.S. CRM reporting unit. Therefore, we performed an interim impairment test in accordance with our accounting policies and recorded a goodwill impairment charge of $1.817 billion, on both a pre-tax and after-tax basis, associated with our U.S. CRM reporting unit. This charge does not impact our compliance with our debt covenants or our cash flows, and is excluded by management for purposes of evaluating operating performance and assessing liquidity.

At the time we performed our interim goodwill impairment test, we estimated that our U.S. defibrillator market share would decrease approximately 400 basis points exiting 2010 as a result of the ship hold and product removal actions, as compared to our market share exiting 2009, and that these actions would negatively impact our 2010 U.S. CRM revenues by approximately $300 million. In addition, we expected that, our on-going U.S. CRM net sales and profitability would likely continue to be adversely impacted as a result of the ship hold and product removal actions. Therefore, as a result of these product actions, as well as lower expectations of market growth in new areas and increased competitive and other pricing pressures, we lowered our estimated average U.S. CRM net sales growth rates within our 15-year discounted cash flow (DCF) model, as well as our terminal

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value growth rate, by approximately a couple of hundred basis points to derive the fair value of the U.S. CRM reporting unit. The reduction in our forecasted 2010 U.S. CRM net sales, the change in our expected sales growth rates thereafter and the reduction in profitability as a result of the recently enacted excise tax on medical device manufacturers were several key factors contributing to the impairment charge. Partially offsetting these factors was a 50 basis point reduction in our estimated market-participant risk-adjusted weighted-average cost of capital (WACC) used in determining our discount rate.

In the second quarter of 2010, we performed our annual goodwill impairment test for all of our reporting units. We updated our U.S. CRM assumptions to reflect our market share position at that time, our most recent operational budgets and long range strategic plans. In conjunction with our annual test, the fair value of each reporting unit exceeded its carrying value, with the exception of our U.S. CRM reporting unit. Based on the remaining book value of our U.S. CRM reporting unit following the goodwill impairment charge, the carrying value of our U.S. CRM business unit continues to exceed its fair value, due primarily to the book value of amortizable intangible assets allocated to this reporting unit. The book value of our amortizable intangible assets which have been allocated to our U.S. CRM reporting unit is approximately $3.5 billion as of December 31, 2010. We tested these amortizable intangible assets for impairment on an undiscounted cash flow basis as of March 31, 2010, and determined that these assets were not impaired, and there have been no impairment indicators related to these assets subsequent to that test. The assumptions used in our annual goodwill impairment test related to our U.S. CRM reporting unit were substantially consistent with those used in our first quarter interim impairment test; therefore, it was not deemed necessary to proceed to the second step of the impairment test in the second quarter of 2010.

In the fourth quarter of 2010, we performed an interim impairment test on our international reporting units as a result of the announced divestiture of our Neurovascular business. We allocated a portion of our goodwill from our each of our international reporting units to the Neurovascular business. We then tested each of our international reporting units for impairment in accordance with ASC Topic 350, *Intangibles Goodwill and Other*. Our testing did not identify any reporting units whose carrying values exceeded their calculated fair values. Refer to *Critical Accounting Estimates* for a discussion of our goodwill balances as of December 31, 2010, including our assessment of reporting units with a higher risk of future impairment.

During the fourth quarter of 2008, the decline in our stock price and our market capitalization created an indication of potential impairment of our goodwill balance. Therefore, we performed an interim impairment test and recorded a $2.613 billion goodwill impairment charge associated with our U.S. CRM reporting unit. The impact of economic conditions, and the related increase in volatility in the equity and credit markets, on our risk-adjusted weighted-average cost of capital, along with reductions in market demand for products in our U.S. CRM reporting unit relative to our assumptions at the time of our acquisition of Guidant, were the key factors contributing to the impairment charge.

Intangible Asset Impairment 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 the 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 $65 million of intangible asset impairment charges during 2010 to write down the balance of these intangible assets to their fair value. We do not believe that these impairments, or the factors causing these impairments, will have a material impact on our future operations or cash flows.

In 2009, we recorded intangible asset impairment charges of $12 million, associated primarily with lower than anticipated market penetration of one of our Urology technology offerings. We do not believe that these impairments will have a material impact on our future operations or cash flows.

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In 2008, we recorded intangible asset impairment charges of $177 million, including a $131 million write-down of certain of our Peripheral Interventions-related intangible assets, and a $46 million write-down of certain Urology-related intangible assets. We do not believe that the write-down of these assets will have a material impact on future operations or cash flows.

These non-cash charges are excluded by management for purposes of evaluating operating performance and assessing liquidity. Refer to *Critical Accounting Estimates* and *Note D - Goodwill and Other Intangible Assets* to our 2010 consolidated financial statements included in Item 8 of this Annual Report for more information on our intangible asset impairment charges.

Purchased Research and Development

On January 1, 2009, we adopted the provisions of FASB Statement No. 141(R), *Business Combinations* (codified within ASC Topic 805, *Business Combinations*). Among other changes to accounting for business combinations, Statement No. 141(R) superseded FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, which required research and development assets acquired in a business combination that had no alternative future use to be measured at their fair values and expensed at the acquisition date. Statement No. 141(R) now requires that purchased research and development acquired in a business combination be recognized as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Accordingly, we have accounted for purchased research and development acquired in connection with our 2010 business combinations as intangible assets in our 2010 consolidated financial statements included in Item 8 of this Annual Report.

Our policy is to record certain costs associated with strategic investments outside of business combinations as purchased research and development. Our adoption of Statement No. 141(R) (Topic 805) did not change this policy with respect to asset purchases. In accordance with this policy, we recorded purchased research and development charges of $21 million in 2009, associated with entering certain licensing and development arrangements. Since the technology purchases did not involve the transfer of processes or outputs as defined by Statement No. 141(R) (Topic 805), the transactions did not qualify as business combinations.

In 2008, we recorded $43 million of purchased research and development charges, including $17 million associated with our acquisition of Labcoat, Ltd., $8 million attributable to our acquisition of CryoCor, Inc., and $18 million associated with entering certain licensing and development arrangements. These acquisition-related charges are excluded by management for purposes of evaluating operating performance and assessing liquidity.

Contingent Consideration Expense

In connection with our 2010 acquisitions, we may be required to pay future consideration that is contingent upon the achievement of certain revenue-based milestones. As of the respective acquisition dates, we recorded total contingent liabilities of $69 million, representing the estimated fair value of the contingent consideration we expect to pay to the former shareholders of the acquired businesses. In accordance with ASC Topic 805, 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. During 2010, we recorded expense of $2 million representing the increase in the estimated fair value of this obligation. This acquisition-related charge is excluded by management for purposes of evaluating operating performance and assessing liquidity.

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

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milestone payment from Abbott, which we recorded as a $250 million pre-tax gain. This non-recurring acquisition-related credit is excluded by management for purposes of evaluating operating performance and assessing liquidity.

Gain on Divestitures

During 2008, we recorded a $250 million gain in connection with the sale of our Fluid Management and Venous Access businesses and our TriVascular EVAR program. This divestiture-related gain is excluded by management for purposes of evaluating operating performance and assessing liquidity. Refer to *Note C Divestitures and Assets Held for Sale* to our 2010 consolidated financial statements included in Item 8 of this Annual Report for more information on these transactions.

Restructuring Charges and Restructuring-related Activities

In October 2007, our Board of Directors approved, and we committed to, an expense and head count reduction plan (the 2007 Restructuring plan). The plan was intended to bring expenses in line with revenues as part of our initiatives to enhance short- and long-term shareholder value. Key activities under the plan included the restructuring of several businesses, corporate functions and product franchises in order to better utilize resources, strengthen competitive positions, and create a more simplified and efficient business model; the elimination, suspension or reduction of spending on certain research and development projects; and the transfer of certain production lines among facilities. The execution of this plan enabled us to reduce research and development and selling, general and administrative expenses by an annualized run rate of approximately $500 million exiting 2008. We have partially reinvested our savings from these initiatives into targeted head count increases, primarily in customer-facing positions. In addition, the plan has reduced annualized run-rate reductions of manufacturing costs by approximately $35 million exiting 2010 as a result of transfers of certain production lines. We initiated activities under the plan in the fourth quarter of 2007. The transfer of certain production lines contemplated under the 2007 Restructuring plan was completed as of December 31, 2010; all other major activities under the plan, with the exception of final production line transfers, were completed as of December 31, 2009.

The execution of this plan resulted in total pre-tax expenses of $427 million and required cash outlays of $380 million, of which we have paid $370 million to date. We recorded a portion of these expenses as restructuring charges and the remaining portion through other lines within our consolidated statements of operations. The following provides a summary of total costs associated with the plan by major type of cost:

Type of cost	Total amount incurred
Restructuring charges:	
Termination benefits	$204 million
Fixed asset write-offs	$31 million
Other (1)	$67 million
Restructuring-related expenses:	
Retention incentives	$66 million
Accelerated depreciation	$16 million
Transfer costs (2)	$43 million
	$427 million

(1) Consists primarily of consulting fees, contractual cancellations, relocation costs and other costs.

(2)

Consists primarily of costs to transfer product lines among facilities, including costs of transfer teams, freight and product line validations.

In January 2009, our Board of Directors approved, and we committed to, a Plant Network Optimization program, which is intended to simplify our manufacturing plant structure by transferring certain production lines among facilities and by closing certain other facilities. The program is a complement to our 2007 Restructuring plan, discussed above, and is intended to improve overall gross profit margins. We estimate that the program will result in annualized run-rate reductions of manufacturing costs of approximately $65 million exiting 2012. These savings are in addition to the estimated $35 million of annual reductions of manufacturing

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costs from activities under our 2007 Restructuring plan. Activities under the Plant Network Optimization program were initiated in the first quarter of 2009 and are expected to be substantially complete by the end of 2012. Activities under the Plant Network Optimization program were initiated in the first quarter of 2009 and are expected to be substantially complete by the end of 2012.

We expect that the execution of the Plant Network Optimization program will result in total pre-tax charges of approximately $135 million to $150 million, and that approximately $115 million to $125 million of these charges will result in cash outlays, of which we have made payments of $40 million to date. We have recorded related costs of $79 million since the inception of the 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. The following provides a summary of our estimates of costs associated with the Plant Network Optimization program by major type of cost:

Type of cost	Total estimated amount expected to be incurred
Restructuring charges:	
Termination benefits	$30 million to $35 million
Restructuring-related expenses:	
Accelerated depreciation	$20 million to $25 million
Transfer costs (1)	$85 million to $90 million
	$135 million to $150 million

(1) Consists primarily of costs to transfer product lines among facilities, including costs of transfer teams, freight, idle facility and product line validations.

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 include the integration of our Cardiovascular and CRM businesses, as well as the restructuring of certain other businesses and corporate functions; the centralization of our research and development organization; 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 our product portfolio. We estimate that the execution of this plan will result in gross reductions in pre-tax operating expenses of approximately $200 million to $250 million, once completed in 2012. We expect to reinvest a portion of the savings into customer-facing and other activities to help drive future sales growth and support the business. Activities under the 2010 Restructuring plan were initiated in the first quarter of 2010 and are expected to be substantially complete by the end of 2012. We expect the execution of the 2010 Restructuring plan will result in the elimination of approximately 1,000 to 1,300 positions worldwide by the end of 2012.

We estimate that the 2010 Restructuring plan will result in total pre-tax charges of approximately $180 million to $200 million, and that approximately $165 million to $175 million of these charges will result in cash outlays, of which we have made payments of $69 million to date. We have recorded related costs of $110 million since the inception of the 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. The following provides a summary of our expected total costs associated with the plan by major type of cost:

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Type of cost	Total estimated amount expected to be incurred
Restructuring charges:	
Termination benefits	$95 million to $100 million
Fixed asset write-offs	$10 million to $15 million
Other (1)	$55 million to $60 million
Restructuring-related expenses:	
Other (2)	$20 million to $25 million
	$180 million to $200 million

(1) Includes primarily consulting fees and costs associated with contractual cancellations.

(2) Comprised of other costs directly related to restructuring plan, including accelerated depreciation and infrastructure-related costs.

We recorded restructuring charges pursuant to our restructuring plans of $116 million during 2010, $63 million during 2009, and $78 million during 2008. In addition, we recorded expenses within other lines of our accompanying consolidated statements of operations related to our restructuring initiatives of $53 million during 2010, $67 million during 2009, and $55 million during 2008. The following presents these costs by major type and line item within our 2010 consolidated statements of operations included in Item 8 of this Annual Report, as well as by program:

Year Ended December 31, 2010

(in millions)	Termination Benefits	Retention Incentives	Accelerated Depreciation	Transfer Costs	Fixed Asset Write-offs	Other	Total
Restructuring charges	**$ 70**				**$ 11**	**$ 35**	**$ 116**
Restructuring-related expenses:							
Cost of products sold			$ 7	$ 41			48
Selling, general and administrative expenses						5	5
Research and development expenses							
			7	**41**		**5**	**53**
	$ 70		**$ 7**	**$ 41**	**$ 11**	**$ 40**	**$ 169**

(in millions)	Termination Benefits	Retention Incentives	Accelerated Depreciation	Transfer Costs	Fixed Asset Write-offs	Other	Total

2010 Restructuring plan	$ 66				$ 11	$ 33	$ 110
Plant Network Optimization program	4	$ 7	$ 28				39
2007 Restructuring plan			13			7	20
	$ 70	**$ 7**	**$ 41**	**$ 11**	**$ 40**	**$ 169**	

Year Ended December 31, 2009

(in millions)	**Termination Benefits**	**Retention Incentives**	**Accelerated Depreciation**	**Transfer Costs**	**Fixed Asset Write-offs**	**Other**	**Total**
Restructuring charges	**$ 34**				**$ 13**	**$ 16**	**$ 63**
Restructuring-related expenses:							
Cost of products sold		$ 5	$ 8	$ 37			50
Selling, general and administrative expenses		10	3			1	14
Research and development expenses		3					3
		18	**11**	**37**		**1**	**67**
	$ 34	**$ 18**	**$ 11**	**$ 37**	**$ 13**	**$ 17**	**$ 130**

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(in millions)	Termination Benefits	Retention Incentives	Accelerated Depreciation	Transfer Costs	Fixed Asset Write-offs	Other	Total
Plant Network Optimization program	$ 22		$ 6	$ 12			$ 40
2007 Restructuring plan	12	$ 18	5	25	$ 13	$ 17	90
	$ 34	**$ 18**	**$ 11**	**$ 37**	**$ 13**	**$ 17**	**$ 130**

Year Ended December 31, 2008

(in millions)	Termination Benefits	Retention Incentives	Accelerated Depreciation	Transfer Costs	Fixed Asset Write-offs	Other	Total
Restructuring charges	**$ 34**				**$ 10**	**$ 34**	**$ 78**
Restructuring-related expenses:							
Cost of products sold		$ 9	$ 4	$ 4			17
Selling, general and administrative expenses		27	4				31
Research and development expenses		7					