

BOSTON SCIENTIFIC CORP
Form 10-K
February 17, 2012
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

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

For the fiscal year ended December 31, 2011

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 (I.R.S. Employer Identification No.)
organization)

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: No

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: No

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: No

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 shorter period that the registrant was required to submit and post such files). Yes: No

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.

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 <input checked="" type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>
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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes: No

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The aggregate market value of the registrant's common stock held by non-affiliates was approximately \$10.4 billion based on the closing price of the registrant's common stock on June 30, 2011, 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, 2012 was 1,451,346,240.

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 2012 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 its divisions and subsidiaries.

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

Our net sales have increased substantially since our formation over thirty years ago. Our growth has been fueled in part by strategic acquisitions designed to improve our ability to take advantage of growth opportunities in the medical device industry. 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 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 the current healthcare environment of cost containment, managed care, large buying groups, government contracting, hospital consolidation, and international expansion and will generally assist us in navigating through the complexities of the global healthcare market, including healthcare reform.

Business Strategy

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. 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. We have defined 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.

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. We have several restructuring initiatives designed to strengthen and position us for long-term success. We believe these programs will increase our profitability while strengthening our operational effectiveness and enhancing our

competitiveness. We are simplifying our manufacturing plant structure by transferring certain production lines among facilities and by closing other facilities. We are relocating select administrative and functional activities; standardizing and automating certain processes and activities; rationalizing organizational reporting structures; and expanding our ability to deliver best-in-class global business services. We are improving both the efficiency and focus of our corporate research and development to strengthen our innovation efforts, and are organizing our clinical organization to take full

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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 are transforming the way we conduct research and development and are scrutinizing our cost structure, which we expect will enhance our cost efficiency and effectiveness.

- 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 are re-aligning our International regions to be more effective in executing our business strategy and are renewing our focus on selling in order to maximize our opportunities in countries whose economies and healthcare sectors are growing rapidly. We recently created a new Asia-Pacific regional organization under new leadership to further increase our capabilities and strengthen our position in the world's fastest growing region. We also significantly increased sales in China, Brazil and India and continued investments in infrastructure in those countries.

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 actively managing and realigning our business portfolio to 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. In the first quarter of 2011, we closed several acquisitions targeting several of our priority growth areas, and closed the sale of our Neurovascular business to Stryker Corporation.

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

Products

During 2011, our products were offered for sale by seven core businesses - Interventional Cardiology, CRM, Endoscopy, Peripheral Interventions, Urology/Women's Health, Neuromodulation, and Electrophysiology. In January 2011, we closed the sale of our Neurovascular business to Stryker Corporation.

During 2011, we derived 33 percent of our sales from our Interventional Cardiology business, 27 percent of our sales from our CRM business, 16 percent of our sales from our Endoscopy business, 10 percent of our sales from our Peripheral Interventions business, six percent of our sales from our Urology/Women's Health business, four percent of our sales from our Neuromodulation business, and two percent of our sales from our Electrophysiology business. Two percent of our 2011 sales were derived from the Neurovascular business that we sold to Stryker Corporation. We continue to generate sales from the Neurovascular business pursuant to our supply and distribution agreements with Stryker; however, these sales are at significantly lower levels and at reduced gross profit margins as compared to periods prior to the divestiture. The following section describes certain of our product offerings:

Interventional Cardiology

Coronary Stent Systems

Our broad, innovative product offerings have enabled us to become a leader in the interventional cardiology market. This leadership is due in large part to our coronary stent product offerings. Coronary stents are tiny, mesh tubes used in the treatment of coronary artery disease, which are implanted in patients to prop open arteries and facilitate blood

flow to and from the heart. We have further

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enhanced the outcomes associated with the use of coronary stents, particularly the processes that lead to restenosis (the growth of neointimal tissue within an artery after angioplasty and stenting), through dedicated internal and external product development, strategic alliances and scientific research of drug-eluting stent systems. We are the only company in the industry to offer a two-drug platform strategy with our paclitaxel-eluting and everolimus-eluting stent system offerings, and we offer a broad range of stent sizes. We currently market our next-generation internally-developed and self-manufactured PROMUS® Element™ stent system in the U.S., our Europe/Middle East/Africa (EMEA) region and certain Inter-Continental countries, including China and India. We market the PROMUS® everolimus-eluting stent system, supplied to us by Abbott Laboratories, in Japan. We also market our TAXUS® paclitaxel-eluting stent line, including our third-generation TAXUS® Element™ paclitaxel-eluting stent system in the U.S., Japan, EMEA and certain Inter-Continental countries. We expect to launch our PROMUS® Element™ stent system in Japan at or before mid-2012.

Coronary Revascularization

We market a broad line of products used to treat patients with atherosclerosis, a principal cause of coronary artery obstructive disease which is characterized by a thickening of the walls of the coronary arteries and a narrowing of arterial openings caused by the progressive development of deposits of plaque. Our product offerings include balloon catheters, rotational atherectomy systems, guide wires, guide catheters, embolic protection devices, and diagnostic catheters used in percutaneous transluminal coronary angioplasty (PTCA).

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 transcatheter aortic valve replacement (TAVR) to treat patients with severe aortic stenosis. The Lotus™ Valve System consists of a stent-mounted tissue valve prosthesis and catheter delivery system for guidance and placement of the valve. The low-profile delivery system and introducer sheath are designed to enable accurate positioning, repositioning and retrieval at any time prior to release of the aortic valve implant. TAVR is one of the fastest growing medical device markets.

In addition, in March 2011, we completed the acquisition of Atritech, Inc. 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. We expect to complete enrollment in our U.S. clinical trial by the end of 2012 and expect to receive FDA approval in 2013.

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 the fourth quarter of 2011, we began the U.S. launch of 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, and delivers excellent longevity, which combined with our advantage in size, makes it highly attractive to physicians and patients. Additionally, this next-generation of defibrillators includes models with our 4-SITE lead delivery system which is built off our highly reliable RELIANCE platform. We expect to launch the INGENIO™ family of pacemaker systems in EMEA and in the U.S. during the first half of 2012.

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Endoscopy

Gastroenterology

We market a broad range of products to diagnose, treat and ease a variety of digestive diseases, including those affecting the esophagus, stomach, liver, pancreas, duodenum, and colon. Common disease states include esophagitis, portal hypertension, peptic ulcers as well as esophageal, biliary, pancreatic and colonic cancer. We offer the Radial Jaw® 4 Single-Use Biopsy Forceps, which are designed to enable collection of large high-quality tissue specimens without the need to use large channel therapeutic endoscopes. Our exclusive line of RX Biliary System™ devices are designed to provide greater access and control for physicians to diagnose and treat challenging conditions of the bile ducts, such as removing gallstones, opening obstructed bile ducts and obtaining biopsies in suspected tumors. We also market the Spyglass® Direct Visualization System for direct imaging of the pancreatico-biliary system. The Spyglass® System is the first single-operator cholangioscopy device that offers clinicians a direct visualization of the pancreatico-biliary system and includes supporting devices for tissue acquisition, stone management and lithotripsy. Our products also include the WallFlex® family of stents, in particular, the WallFlex® Biliary line and WallFlex® Esophageal line; and in 2011, we launched our Advanix Biliary Plastic Stent System and the Expect Endoscopic Ultrasound Aspiration Needle in the U.S. and certain international markets. In addition, we continue to see increased adoption of our Resolution® Clip Device, an endoscopic mechanical clip designed to treat gastrointestinal bleeding.

Interventional Bronchoscopy

We market devices to diagnose, treat and ease pulmonary disease systems within the airway and lungs. Our products are designed to help perform biopsies, retrieve foreign bodies from the airway, open narrowings of an airway, stop internal bleeding, and ease symptoms of some types of airway cancers. Our product line includes pulmonary biopsy forceps, transbronchial aspiration needles, cytology brushes and tracheobronchial stents used to dilate narrowed airway passages or for tumor management. In 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.

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, wires, peripheral embolization devices and vena cava filters. In 2010 and 2011, we launched several of our market-leading products internationally, including the EPIC™ self-expanding nitinol stent system in certain international markets, and the Carotid WALLSTENT® stent system in Japan. We launched three new peripheral angioplasty balloons in 2011, including our next-generation Mustang™ percutaneous transluminal angioplasty (PTA) balloon, our Coyote™ balloon catheter, a highly deliverable and ultra-low profile balloon dilatation catheter designed for a wide range of peripheral angioplasty procedures and our Charger™ PTA Balloon Catheter, a 0.035" percutaneous transluminal angioplasty balloon catheter designed for post-stent dilatation as well as conventional balloon angioplasty to open blocked peripheral arteries. With our Coyote, Mustang and Charger devices, we now offer best-in-class balloons across all size platforms, which has enabled us to regain the number one PTA balloon position in the U.S. In addition, we expect to receive FDA approval of the EPIC™ self-expanding nitinol stent system during 2012, which will allow us to offer a complete line of advanced iliac solutions in the U.S.

In February 2011, we announced the acquisitions of S.I. Therapies and ReVascular Therapeutics, Inc., which add to our PI portfolio a re-entry catheter and intraluminal chronic total occlusion (CTO) crossing device, enabling endovascular treatment in cases that typically cannot be treated with standard endovascular devices. We have commenced a limited market release of our OFFROAD™ re-entry catheter system in certain international markets, and in February 2012, we launched our TRUEPATH™ intraluminal CTO device in the U.S. We expect to launch our TRUEPATH™ device in EMEA during the first half of 2012, and to expand the launch of our OFFROAD™ system in our international markets throughout 2012. We believe that offering these devices will enhance our position in assisting physicians in addressing the challenges of treating complex peripheral lesions.

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

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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.

Urology/Women's Health

Our Urology/Women's Health division develops, manufactures and sells 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 market our Genesys Hydro ThermAblator® (HTA) system, a next-generation endometrial ablation system designed to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia. The Genesys HTA System features a smaller and lighter console, simplified set-up requirements, and an enhanced graphic user interface and is designed to improve operating performance.

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 2011, we launched our Clik™ Anchor for our Precision® Plus™ SCS System, the world's first rechargeable SCS device for chronic pain management. In the fourth quarter of 2011, we received FDA approval for and launched the Infinion™ 16 Percutaneous Lead, the world's first and only 16-contact percutaneous lead. We also market the Linear™ 3-4 and Linear 3-6 Percutaneous Leads for use with our SCS systems, which are designed to provide physicians more treatment options for their chronic pain patients. These leads provide the broadest range of percutaneous lead configurations in the industry. 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. We are looking to strengthen the clinical evidence with spinal cord stimulation and are committed to studies designed to demonstrate cost effectiveness or demonstrate the value of proprietary features in our SCS system. We expect to complete our VANTAGE Study, a European clinical trial for the treatment of Parkinson's Disease using our Vercise™ Deep Brain Stimulation (DBS) System, in 2013. We believe we have an exciting opportunity in DBS with our ability to customize the field designed to precisely stimulate the target without extraneous stimulation of adjacent areas that may cause unwanted side effects. In addition, in January 2011, we completed the acquisition of Intellect Medical, Inc., a development-stage company developing advanced visualization and programming for the Vercise™ system. We believe this acquisition leverages the core architecture of our Vercise™ platform and will advance our technology in the field of deep-brain stimulation.

Electrophysiology

Within our Electrophysiology business, we develop less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart. Included in our product offerings are radio frequency (RF) generators, steerable RF ablation catheters, intracardiac ultrasound catheters, diagnostic catheters, delivery sheaths, and other accessories. Our leading products include the Blazer® and Blazer Prime® line of temperature ablation catheters, designed to deliver enhanced performance, responsiveness, and durability. Our cooled ablation portfolio includes the only closed-loop irrigated catheter on the market, the Chilli II® cooled ablation catheter, and the newly launched Blazer™ Open-Irrigated ablation catheter with a unique Total Tip Cooling™ Design.

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. We have closed several acquisitions targeting several of these areas. In 2010, we

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completed the acquisition of Asthmatx, Inc., and in 2011, we completed the acquisitions of Sadra Medical, Inc., Intellect Medical, Inc., and 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 \$895 million on research and development in 2011, \$939 million in 2010 and \$1.035 billion in 2009, 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 other programs 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 transforming the way we conduct research and development and are scrutinizing our cost structure, which we expect will enhance our cost efficiency and effectiveness. Our approach to new product design and development is through focused, cross-functional teams. We believe that our formal process for technology and product development aids in our ability to offer innovative and manufacturable products in a consistent and timely manner. Involvement of the research and development, clinical, quality, regulatory, manufacturing and marketing teams early in the process is the cornerstone of our product development cycle. This collaboration allows these teams to concentrate resources on the most viable and clinically relevant new products and technologies, and focus on bringing them to market in a timely and cost-effective manner. In addition to internal development, we work with hundreds of leading research institutions, universities and clinicians around the world to develop, evaluate and clinically test our products. We believe our future success will depend upon the strength of these development efforts.

Marketing and Sales

During 2011, we marketed our products to over 13,000 hospitals, clinics, outpatient facilities and medical offices in nearly 98 countries worldwide. The majority of our net sales are derived from countries in which we have direct sales organizations. We also have a network of distributors and dealers who offer our products in certain countries and markets, which accounts for our remaining sales. We expect to continue to leverage our infrastructure in markets where commercially appropriate and use third parties in those markets where it is not economical or strategic to establish or maintain a direct presence. We are not dependent on any single institution and no single institution accounted for more than ten percent of our net sales in 2011 or 2010; 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 approximately 50 percent of our net sales in 2011. Net sales and operating income attributable to our 2011 geographic regions are presented in Note O – Segment Reporting to our 2011 consolidated financial statements included in Item 8 of this Annual Report, incorporated by reference herein. Our

international structure operates through three international business units: EMEA, consisting of Europe, the Middle East and Africa; Japan; and Inter-Continental, consisting of our Asia Pacific and the Americas reporting units. Maintaining and expanding our international presence is an important component of our long-term growth plan. Through our international presence, we seek to increase net sales and market share, leverage our relationships with leading physicians and their clinical research programs, accelerate the time to bring new products to market, and gain access to worldwide technological developments that we can implement across our product lines. We are investing in infrastructure in emerging markets such as China and India in order to introduce new products and strengthen our sales capabilities in these countries. A discussion of the risks associated with our international operations is included in Item 1A of this Annual Report.

As of December 31, 2011, we had six international manufacturing facilities, including three in Ireland, two in Costa Rica and one

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in Puerto Rico. Approximately 53 percent of our products sold worldwide during 2011 were manufactured at these facilities. Additionally, we maintain international research and development capabilities in Ireland, as well as physician training centers in France and Japan.

Manufacturing and Raw Materials

We are focused on continuously improving our supply chain effectiveness, strengthening our manufacturing processes and increasing operational efficiencies within our organization. By shifting global manufacturing along product lines, we are able to leverage our existing resources and concentrate on the development and commercial launch of new products and the enhancement of existing products. We 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.

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

Many components used in the manufacture of our products are readily fabricated from commonly available raw materials or off-the-shelf items available from multiple supply sources. 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 Japan. Our supply agreement with Abbott for everolimus-eluting stent systems extends through June 30, 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 self-manufactured next-generation PROMUS® Element™ everolimus-eluting stent system in Japan, currently expected at or before mid-2012, will be sufficient to meet our customer demand. However, any changes in anticipated timing of regulatory approval or launch of our PROMUS® Element™ stent system in Japan could result in an inability to meet our customer demand for everolimus-eluting stent systems. We received FDA approval and launched our next-generation internally-developed and self-manufactured PROMUS® Element™ Plus stent system in the U.S. in the fourth quarter of 2011, as discussed in Item 7 of this Annual Report.

Quality Assurance

We are committed to providing high quality products to our customers. To meet this commitment, we have implemented updated quality systems and concepts throughout our organization. Our quality system starts with the initial product specification and continues through the design of the product, component specification process and the

manufacturing, sale and servicing of the product. Our quality system is intended to build in quality and process control and to utilize continuous improvement concepts throughout the product life. These systems are designed to enable us to satisfy the various international quality system regulations, including those of the FDA with respect to products sold in the U.S. All of our manufacturing facilities, including our U.S. and European distribution centers, are certified under the ISO13485:2003 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.

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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, 11 of our 15 manufacturing and distribution facilities have attained ISO14001 certification. We are committed to achieving ISO14001 certification at all of our major manufacturing facilities and Tier I distribution centers worldwide.

Competition

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

We believe that our products compete primarily on their ability to safely and effectively perform diagnostic and therapeutic procedures in a less-invasive manner, as well as clinical outcomes, ease of use, comparative effectiveness, reliability and physician familiarity. In the current environment of managed care, economically-motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price, value, reliability and efficiency. We believe the current global economic conditions and healthcare reform measures could put additional competitive pressure on us, including on our average selling prices, overall procedure rates and market sizes. We recognize that our continued competitive success will depend upon our ability to offer products with differentiated clinical outcomes; create or acquire innovative, scientifically advanced technology; apply our technology cost-effectively and with superior quality across product lines and markets; develop or acquire proprietary products; attract and retain skilled personnel; obtain patent or other protection for our products; obtain required regulatory and reimbursement approvals; continually enhance our quality systems; manufacture and successfully market our products either directly or through outside parties; and supply sufficient inventory to meet customer demand.

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 commercial distribution under a 510(k) Submission. Applicants must submit 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 a decision 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 2011, the FDA released numerous draft proposals on the 510(k) process. Several of the FDA’s proposals could increase the regulatory burden on our industry,

including those that could increase the frequency of 510(k) submissions, as well as their complexity and cost, and therefore could delay time to market for certain high-risk Class II medical devices.

The second process requires the submission of a PMA application to the FDA to demonstrate that the device is safe and effective for its intended use. This approval process applies to most Class III devices. 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.

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The third process requires that an application for a Humanitarian Device Exemption (HDE) be made to the FDA for the use of a Humanitarian Use Device (HUD). An HUD is intended to benefit patients by treating or diagnosing a disease or condition that affects, or is manifested in, fewer than 4,000 individuals in the U.S. per year. The application submitted to the FDA for an HDE is similar in both form and content to a PMA application, but is exempt from the effectiveness requirements of a PMA. 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 a company for certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations. International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin first. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

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 applied following approval from an independent notified body or declaration of conformity, is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. We are also required to comply with foreign regulations in each country where we commercialized products, such as the requirement that we obtain approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) before we can launch new products in Japan.

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

We are also subject to various environmental laws, directives and regulations both in the U.S. and abroad. Our operations, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We do not believe that compliance with environmental laws will have a material impact on our capital expenditures, earnings or competitive position. However, given the scope and nature of these laws, there can be no assurance that environmental laws will not have a material impact on our results of operations. We assess potential environmental contingent liabilities on a regular basis. At present, we are not aware of any such liabilities that would have a material impact on our business.

We believe that sound environmental, health and safety performance contributes to our competitive strength while benefiting our customers, shareholders and employees. We are committed to continuous improvement in these areas by reducing pollution, the depletion of natural resources, and our overall environmental footprint. Specifically, we are working to optimize energy and resource usage, ultimately reducing greenhouse gas emissions and waste. We are certified to the FTSE4Good Corporate Social Responsibility Index, managed by The Financial Times and the London

Stock Exchange, which measures the performance of companies that meet globally recognized standards of corporate responsibility. This certification recognizes our dedication to those standards, and it places us in a select group of companies with a demonstrated commitment to responsible business practices and sound environmental policies.

Government Affairs

We maintain a global Government Affairs presence, headquartered in Washington D.C., to actively monitor and advocate on a myriad of legislation and policies impacting us, both on a domestic and an international front. The Government Affairs office

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works closely with members of Congress and committee staff, the White House and Administration office, state legislatures and regulatory agencies, and governments overseas on issues affecting our business. Our proactive approach and depth of political and policy expertise are aimed at having our positions heard by federal, state and global decision-makers, while also advancing our business objectives by educating policymakers on our positions, key priorities and the value of our technologies. The Government Affairs office also manages our political action committee and works closely with trade groups on issues affecting our industry and healthcare in general.

Healthcare Reform

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives to limit the growth of healthcare costs (including price regulation); competitive pricing; coverage and payment policies; comparative effectiveness of therapies; technology assessments; and health care delivery structure reforms, are continuing in many countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. Although we believe our less-invasive products and technologies generate favorable clinical outcomes, value and cost efficiency, the resources necessary to demonstrate value to our customers, patients, payers, and other stakeholders may be significant. In addition, uncertainty remains regarding the continued implementation of the Affordable Care Act (ACA) and impact to our business.

Further, the federal government, as part of the ACA, and certain state governments have enacted laws aimed at increasing transparency in relationships between medical device, biologics and pharmaceutical companies and healthcare professionals (HCPs). As a result, we are required by law to report many types of payments made and items of value provided to HCPs licensed by certain states. We also expect to be required to make similar reports at the federal level starting in 2013. We have devoted substantial time and financial resources in order to develop and implement enhanced structure, policies, systems and processes in order to comply with these U.S. federal and state legal and regulatory requirements. In addition, certain foreign jurisdictions are currently acting to implement similar laws. Failure to adhere to our policies, comply with required laws or implement adequate policies and practices to address changes to legal and regulatory requirements could have a negative impact on our results of operations.

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. We expect that pricing of medical devices will remain under pressure as alternative payment models such as bundling, value-based purchasing and accountable care organizations (ACOs) begin to take shape. In addition, patients and clinicians are becoming more informed on the risks and benefits of alternative treatments as comparative effectiveness research findings are beginning to be disseminated. Therefore, we believe that compelling clinical and economic data will become increasingly important to demonstrate efficacy and justify the economic benefits of technology purchases.

Third-party payors 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 automatically covered by third-party payors, that reimbursement will be available or, if available, that the third-party payors' coverage policies will not adversely affect our ability to sell our products profitably.

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, 2011, we held more than 15,000 patents, and had approximately 8,500 patent applications pending worldwide that cover various aspects of our technology. In addition, we hold exclusive and non-exclusive licenses to a

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variety of third-party technologies covered by patents and patent applications. There can be no assurance that pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage. In the aggregate, these intellectual property assets and licenses are of material importance to our business; however, we believe that no single patent, technology, trademark, intellectual property asset or license, except for those relating to our drug-eluting coronary stent systems, is material in relation to our business as a whole.

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

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

We are substantially self-insured with respect to intellectual property infringement claims, among other types of claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims or adverse decisions. See Item 3 and Note K – Commitments and Contingencies to our 2011 consolidated financial statements included in Item 8 of this Annual Report for a discussion of intellectual property and other litigation and proceedings in which we are involved. In management's opinion, we are not currently involved in any legal proceeding other than those specifically identified in Note K, which, individually or in the aggregate, could have a material effect on our financial condition, results of operations or liquidity.

Risk Management

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

Current Economic Climate

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

Employees

As of December 31, 2011, we had approximately 24,000 employees, including approximately 12,000 in operations; 6,000 in selling, marketing and distribution; 4,000 in clinical, regulatory and research and development; and 2,000 in administration. Of these employees, we employed approximately 10,000 outside the U.S., approximately 6,000 of whom are in the manufacturing operations function. We believe that the continued success of our business will depend, in part, on our ability to attract and retain qualified personnel, and we are committed to developing our people and providing them with opportunities to contribute to our growth and success.

Community Outreach

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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 (CV) 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. By sponsoring programs to help educate healthcare professionals on disparities in CV care and by working via partnerships in the community, these messages reached over one million people.

Through the Boston Scientific Foundation, established in 2001, we fund non-profit organizations in our local communities. Our community grants focus on increasing access to quality healthcare and improving educational opportunities, particularly with regards to science, technology, engineering and math (STEM). Additionally, Boston Scientific has committed to contributing \$15 million to our Close the Gap program and STEM education through 2013.

Seasonality

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

Available Information

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

Safe Harbor for Forward-Looking Statements

Certain statements that we may make from time to time, including statements contained in this 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 similar words. Forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our financial performance; our business and growth strategy, including our priority growth initiatives; integration of acquired businesses and technologies; 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; use of our cash flow; investments in our business; goodwill impairment analysis and charges; changes in the market and our market share; product performance; product development and iterations; the strength of our technologies and pipeline; 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; our sales and marketing strategy and our investments in our sales organization; reimbursement practices; our emerging markets strategy and investments; 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 healthcare reform legislation and the new medical device excise tax; the effect of proposed tax laws; the outcome of matters before taxing authorities; our tax position; intellectual property,

governmental proceedings and litigation matters; adequacy of our reserves; 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. Except as required by law, we do not intend to update any forward-looking statements even if new information becomes available or other events occur in the future. The forward-looking statements here and elsewhere in this Annual Report are based on certain

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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 elsewhere in this Annual Report, including in Item 1A.

CRM Business

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 next-generation INCEPTA™, ENERGEN™ and PUNCTUA™ defibrillators in additional geographies 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;

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; and

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

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 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;

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The overall performance of, and continued physician confidence in, our and other drug-eluting stent systems, including our PROMUS® Element™ stent systems;

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;

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• 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.

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 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 and realize anticipated benefits of 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

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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, including our newly created Asia-Pacific regional organization;

• 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;

• Our ability to execute and realize anticipated benefits from our investments in emerging markets, including our plan to build a manufacturing facility in China to serve local market needs;

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

• Risks and uncertainties related to political and economic conditions in international markets, including emerging markets.

Liquidity

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

• The impact of the European sovereign debt crisis on our ability to collect outstanding and future receivables and/or transfer receivables to third parties.

Strategic Initiatives

• Our ability to implement, fund, and achieve timely and sustainable restructuring, efficiency and cost improvement measures consistent with our expectations, including our 2011 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;

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Risks associated with significant changes made or to be made to our organizational structure, including as a result of the realignment of our international structure, pursuant to our 2011 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, including under Project Transformation;

• The successful separation of divested businesses, including the performance of related supply, manufacturing and 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

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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 cause actual results to vary materially from the expectations and projections expressed or implied by our forward-looking statements and affect our future results and growth rates. These additional factors include, among other things, future political, 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.

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ITEM 1A. RISK FACTORS

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

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

We have experienced pricing pressures across many of our businesses due to competitive activity, increased market power of our customers as the healthcare industry consolidates, economic pressures experienced by our customers, and the impact of managed care organizations and other third-party payors. Competitive pricing pressures, 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 seven percent in 2011 as compared to the prior year. Continued declines in average selling prices of our products due to pricing pressures may have an adverse impact on our results of operations.

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

Net sales from drug-eluting coronary stent systems represented approximately 20 percent of our consolidated net sales during 2011. In 2011, 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. There can be no assurance that these and other factors will not further impact our share of the U.S. or worldwide drug-eluting stent markets, that we will regain or gain share of the U.S. or worldwide drug-eluting stent markets, or that the size of the U.S. drug-eluting stent market will reach previous levels or will not decline further, all of which could materially adversely affect our results of operations or financial condition. In addition, we expect to launch our internally-developed and manufactured next-generation everolimus-eluting stent system, the PROMUS® Element™ platinum chromium coronary stent system, in Japan at or before mid-2012. A delay in the timing of the launch of next-generation products, the overall performance of, and continued physician confidence in, those products may result in a further decline in our market share and have an adverse impact on our results of operations.

Net sales from our CRM group represented approximately 27 percent of our consolidated net sales in 2011.

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 have had, and may continue to have, a negative impact on the size of the CRM market. Our U.S. ICD sales represented approximately 45 percent of our worldwide CRM net sales in 2011, 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 INGENIO family of pacemaker systems in our Europe/Middle East/Africa (EMEA) region and in the U.S. during the first half of 2012. Variability in the timing of the launch of next-generation products may result in excess or expired inventory positions and future inventory charges, or may result in a loss of market share and adversely impact our results of operations.

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

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

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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 continue to exert further downward pressure on the prices of our products and adversely impact our business, financial condition or results of operations. We face intense competition and may not be able to keep pace with the rapid technological changes in the medical devices industry, which could have an adverse effect on our business, financial condition or results of operations. The medical device markets in which we primarily participate are highly competitive. We encounter significant competition across our product lines and in each market in which our products are sold from various medical device companies, some of which may have greater financial and marketing resources than we do. Our primary competitors include Abbott Laboratories; Medtronic, Inc.; St. Jude Medical, Inc.; Johnson & Johnson (including its subsidiary, Cordis Corporation); 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 markets in which we primarily participate are characterized by extensive research and development, and rapid technological change. Developments by other companies of new or improved products, processes or technologies may make our products or proposed products obsolete or less competitive and may negatively impact our net sales. We are required to devote continued efforts and financial resources to develop or acquire scientifically advanced technologies and products, apply our technologies cost-effectively across product lines and markets, obtain patent and other protection for our technologies and products, obtain required regulatory and reimbursement approvals and successfully manufacture and market our products consistent with our quality standards. If we fail to develop new products or enhance existing products, it could have a material adverse effect on our business, financial condition or results of operations.

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

Sales outside the U.S. accounted for approximately 50 percent of our net sales in 2011. Additionally, a significant percentage of our future growth is expected to come from international operations, including from our increased sales presence and other investments in emerging markets such as Brazil, China and India. We have recently realigned our international structure, including the creation of a new Asia-Pacific regional organization, and are devoting resources to focus on increasing net sales in emerging markets. However, 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. In addition, we continue to invest in infrastructure in Brazil, China and India, including a \$150 million investment in China over a five year period through which we expect to build a local manufacturing facility focused on serving Chinese market needs, develop a world class training center for healthcare providers and invest in local research and development and clinical studies. However, risks and uncertainties related to political and economic conditions in these regions, traditional business practices, foreign currency fluctuations, interest rate fluctuations, regulatory and reimbursement approvals, competitive offerings, infrastructure development complications and intellectual property protection may adversely impact our ability to implement our business strategy in these markets and, as a result, our sales growth and operating profits from our international operations may be adversely affected. Further, international markets are increasingly being affected by economic pressure to contain reimbursement levels and healthcare costs; and certain international markets may also be impacted by foreign government efforts to understand healthcare practices and pricing in other countries, which could result in increased pricing transparency across geographies and pressure to harmonize reimbursement and ultimately reduce the selling prices of our products. Further, certain foreign governments allow favorable reimbursements for locally-manufactured products, which may put us at a competitive disadvantage and negatively affect our market share, including in China if we are unable to

executive our business strategy in that market or do so in a timely manner.

Most international jurisdictions have regulatory approval and periodic renewal requirements for medical devices, and several countries that previously did not have regulatory requirements for medical devices have adopted such requirements; we must comply with these requirements in order to market our products in these jurisdictions. In addition, the trend in countries around the world, 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 us and other medical device manufacturers to experience more uncertainty, delay, risk and expense. We expect the international regulatory environment will continue to evolve, which could impact our ability to obtain approvals for our products in those jurisdictions, which may have a material impact on our business.

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

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

As part of our strategy to increase operational leverage and continue to strengthen our financial flexibility, we reduced our total debt to \$4.261 billion as of December 31, 2011 from our total debt of \$5.438 billion as of December 31, 2010, which debt was in large part attributable to our 2006 acquisition of Guidant Corporation. In 2011, Standard & Poor's continued our credit rating as investment grade with a stable outlook, Fitch Ratings upgraded our corporate credit rating to investment grade at BBB- with a stable outlook; and in February 2012, Moody's Investors Service upgraded our corporate credit rating to investment grade at Baa3 with a stable outlook. We believe these rating improvements reflect the strength of our product portfolio and cash flows, the reduction of our debt, and our improved financial fundamentals. Our inability to maintain investment grade credit ratings at the three ratings agencies could increase our cost of borrowing funds in the future. Delays in our product development and new product launches, disruption in our cash flow or our ability to continue to effectively manage our debt levels could have an adverse effect on our cost of borrowing, financial condition or results of operations. In addition, our 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. Based on market information that became available to us toward the end of the first quarter of 2011, we concluded that there was a reduction in the estimated size of the U.S. Cardiac Rhythm Management (CRM) market, which led to lower projected U.S. CRM results compared to prior forecasts and created an indication of potential impairment of the goodwill balance attributable to our U.S. CRM business unit. Therefore, we performed an interim impairment test in accordance with U.S. GAAP and our accounting policies and recorded a non-deductible goodwill impairment charge of \$697 million, on both a pre-tax and after-tax basis, associated with this business unit during the first quarter of 2011. We continue to identify 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 reporting unit, our U.S. Cardiovascular reporting unit, our U.S. Neuromodulation reporting unit, and our Europe/Middle East/Africa (EMEA) region, which together hold approximately \$8 billion of allocated goodwill. On a quarterly basis, we monitor the key drivers of fair value for these reporting units to detect events or other changes that would warrant an interim impairment test. For each of these reporting units, relatively small declines in the future performance and cash flows of the reporting unit relative to our expectations or small changes in other key assumptions may result in the recognition of future goodwill impairment charges, which could have a material adverse impact on 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 completed several acquisitions in 2010 and 2011 in our priority growth areas and may pursue additional acquisitions in the future. Our integration of the operations of acquired businesses requires significant efforts, including the coordination of information technologies, research and development, sales and marketing, operations, manufacturing and finance. These efforts result in additional expenses and involve significant amounts of management's time. 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 and our future growth. In addition, we cannot be certain that the businesses we acquire will become profitable or remain so and if our acquisitions are not successful, we may record related asset impairment charges in the future.

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.

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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 July 2011, we announced a 2011 Restructuring plan designed to strengthen operational effectiveness and efficiencies, increase competitiveness and support new investments, thereby increasing shareholder value. Key activities under the plan include standardizing and automating certain processes and activities; relocating select administrative and functional activities; rationalizing organizational reporting structures; leveraging preferred vendors; and taking other actions aimed at increasing overall productivity. Further, in February 2010, we announced a 2010 Restructuring plan designed to strengthen and position us for long-term success. Key activities under the plan, the majority of which are complete, included the integration of our Cardiovascular and CRM businesses, as well as the restructuring of certain other businesses and corporate functions; the realignment of our international structure; and the reprioritization and diversification of our product portfolio. Additionally, in January 2009, we announced our Plant Network Optimization program, aimed at simplifying our plant network, reducing our manufacturing costs and improving gross margins. Cost reduction initiatives under these collective plans include various cost and efficiency improvement measures, which may include head count reductions; the relocation of certain resources as well as administrative and functional activities; the closure of certain facilities; the transfer of certain production lines; the sale of certain non-strategic assets and other efforts to streamline our business, among other actions. These measures could yield unintended consequences, such as distraction of our management and employees, business disruption, attrition beyond our planned reduction in workforce and reduced employee productivity. We may be unable to attract or retain key personnel. Attrition beyond our planned reduction in workforce or a material decrease in employee morale or productivity could negatively affect our business, sales, financial condition and results of operations. In addition, 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.

Our inability to effectively manage the separation activities and events with respect to the divestiture of our Neurovascular business could adversely affect our business, financial condition and operating results.

As part of our strategy to realign our business portfolio, 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, including with respect to the transfer of certain manufacturing facilities, which we now expect to occur during 2013. 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 through the end of 2012, 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 separation activities and events could adversely affect our business, financial condition and results of operations.

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

The continued global financial crisis, including the European sovereign debt 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

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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 Southern European countries and there can be no assurance that these payments will ultimately be collected. Additionally, the European sovereign debt crisis may impact our future ability to transfer receivables to third parties in certain Southern European countries as those third parties look to reduce their exposure to sovereign debt, which could result in terminations of, or changes to the costs or credit limits of our existing factoring programs which in turn could have a negative impact on our cash flow. 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 and European sovereign debt crisis may negatively impact our average selling prices, our net sales and profit margins, procedural volumes and reimbursement rates from third party payors. In addition, current economic conditions may adversely affect our suppliers, leading them to experience financial difficulties or to be unable to borrow money to fund their operations, which could cause disruptions in our ability to produce our products.

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.

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 53 percent of our worldwide net sales in 2011 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

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

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

Our products, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDCA, 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, which 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

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from existing or future clinical trials conducted by us, by our competitors or by third parties, or the market's perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects.

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

In order to develop new products and improve current product offerings, we focus our research and development programs largely on the development of next-generation and novel technology offerings across multiple programs and businesses. We expect to launch our internally-manufactured next-generation everolimus-eluting stent system, the PROMUS® Element™ platinum chromium coronary stent, in Japan at or before mid-2012, subject to regulatory approval. In addition, we expect to continue to invest in our CRM 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 priority growth areas. Expanding our focus beyond our current businesses is expensive and time-consuming. Further, there can be no assurance that we will be able to access these 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.

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

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