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

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

For the fiscal year ended December 31, 2012

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

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

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

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

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

Securities registered pursuant to Section 12(g) of the Act:
NONE
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes: þ No o
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: o No þ
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: þ No o
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorted period that the registrant was required to submit and post such files). Yes: þ No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

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

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

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

Documents Incorporated by Reference

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

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PART I

ITEM 1. BUSINESS

The Company

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

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

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

Business Strategy

The following are our five strategic imperatives:

- Strengthen Execution to Grow Share

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

- Expand into High Growth Adjacencies

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

- Drive Global Expansion

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

- Fund the Journey to Fuel Growth

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

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- Develop Key Capabilities

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

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

Products

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

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

The following section describes certain of our product offerings:

Endoscopy

Gastroenterology

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

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Interventional Bronchoscopy

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

Peripheral Interventions (PI)

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

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

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

Neuromodulation

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

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

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

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

Urology/Women’s Health

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

Electrophysiology

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

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

Cardiac Rhythm Management

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

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

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

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

Interventional Cardiology

Coronary Stent Systems

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

Core Coronary Technology

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

Intraluminal Ultrasound Imaging

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

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Structural Heart Therapy

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

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

Innovation

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

Research and Development

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

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

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

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

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

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Marketing and Sales

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

International Operations

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

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

Manufacturing and Raw Materials

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

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

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

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

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

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

Quality Assurance

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

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

Competition

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

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

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

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Regulatory Environment

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

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

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

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

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

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

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

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

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

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

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

Government Affairs

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

Healthcare Reform

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

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

Third-Party Coverage and Reimbursement

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

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

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