BOSTON SCIENTIFIC CORP
Form 10-K
February 27, 2009

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

For the fiscal year ended December 31, 2008 Commission File No. 1-11083

BOSTON SCIENTIFIC CORPORATION
(Exact Name Of Company As Specified In Its Charter)

DELAWARE	04-2695240
(State of Incorporation)	(I.R.S. Employer Identification No.)

ONE BOSTON SCIENTIFIC PLACE, NATICK, MASSACHUSETTS 01760-1537
(Address Of Principal Executive Offices)

(508) 650-8000
(Company'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 Class)	(Name of Exchange on Which Registered)

Securities registered pursuant to Section 12(g) of the Act:
NONE

Indicate by check mark if the Company is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes: x No o

Indicate by check mark if the Company is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes: o No x

Indicate by check mark whether the Company (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 Company was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes: x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Company'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 as defined in Rule 12b-2 of the Exchange Act. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer x	Accelerated Filer o	Non-Accelerated Filer o	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 x

The aggregate market value of the Company's common stock held by non-affiliates of the Company was approximately $16.8 billion based on the closing price of the Company's common stock on June 30, 2008, the last business day of the Company's most recently completed second fiscal quarter.

The number of shares outstanding of the Company's common stock as of January 31, 2009 was 1,502,237,400.

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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 including interventional cardiology, cardiac rhythm management, peripheral interventions, electrophysiology, neurovascular intervention, endoscopy, urology, gynecology and neuromodulation. When used in this report, the terms “we,” “us,” “our” and “the Company” mean Boston Scientific Corporation and its divisions and subsidiaries.

Since we were formed in 1979, we have advanced the practice of less-invasive medicine by helping physicians and other medical professionals treat a variety of diseases and improve patients’ quality of life by providing alternatives to surgery and other medical procedures that are typically traumatic to the body. Some of the uses of our products include: enlarging narrowed blood vessels to prevent heart attack and stroke; clearing passages blocked by plaque to restore blood flow; detecting and managing fast, slow or irregular heart rhythms; mapping electrical problems in the heart; performing biopsies and intravascular ultrasounds; placing filters to prevent blood clots from reaching the lungs, heart or brain; treating urological, gynecological, renal, pulmonary, neurovascular and gastrointestinal diseases; and modulating nerve activity to treat chronic pain.

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. Medi-tech introduced its initial products in 1969, 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, our net sales have increased substantially, growing from $2 million in 1979 to approximately $8.1 billion in 2008.

Our growth has been fueled in part by strategic acquisitions and alliances designed to improve our ability to take advantage of growth opportunities in the medical device industry. On April 21, 2006, we consummated our acquisition of Guidant Corporation. With this acquisition, we became a major provider in the cardiac rhythm management (CRM) market, enhancing our overall competitive position and long-term growth potential and further diversifying our product portfolio. This acquisition has established us as one of the world’s largest cardiovascular device companies and a global leader in microelectronic therapies. This and other strategic acquisitions have helped us to add promising new technologies to our pipeline and to offer one of the broadest product portfolios in the world for use in less-invasive procedures. We believe that the depth and breadth of our product portfolio has also enabled us to compete more effectively in, and better absorb the pressures of, the current healthcare environment of cost containment, managed care, large buying groups, government contracting and hospital consolidation and will generally assist us in navigating the current turmoil in the global economic markets.

Information including revenues, measures of profits or losses and total assets for each of our geographic segments, as well as net sales by business unit, appears in Note P – Segment Reporting to our 2008 consolidated financial statements included in Item 8 of this Annual Report.

The Cardiac Rhythm Management (CRM) Opportunity

As a result of our 2006 acquisition of Guidant, we now develop, manufacture and market products that focus on the treatment of cardiac arrhythmias and heart failure. These products accounted for 28 percent of our net sales in 2008 and 25 percent in 2007. Natural electrical impulses stimulate the heart’s chambers to pump blood. In healthy

individuals, the electrical current causes the heart to beat at an appropriate rate and in synchrony. We manufacture a variety of implantable devices that monitor the heart and deliver electricity to

treat cardiac abnormalities, including:

- Implantable cardiac 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.

Tachycardia (abnormally fast or chaotic heart rhythms) prevents the heart from pumping blood efficiently and can lead to sudden cardiac death. Our ICD systems (defibrillators, leads, programmers, our LATITUDE® Patient Management System and accessories) monitor the heart and deliver electrical energy, restoring a normal rhythm. Our defibrillators deliver tiered therapy—a staged progression from lower intensity pacing pulses designed to correct the abnormal rhythm to more aggressive shocks to restore a heartbeat. In 2008, we successfully launched our COGNIS® CRT-D and TELIGEN® ICD implantable defibrillators, which are small, thin, high-energy devices, in the U.S. and our EMEA (Europe/Middle East/Africa) region, as well as in certain Inter-Continental countries.

Heart failure (the heart's inability to pump effectively) is a debilitating, progressive condition, with symptoms including shortness of breath and extreme fatigue. Statistics show that one in five persons die within the first year of a heart failure diagnosis, and patients with heart failure suffer sudden cardiac death at six to nine times the rate of the general population. The condition is pervasive, with approximately five million people in the U.S. affected.

Bradycardia (slow or irregular heart rhythms) often results in a heart rate insufficient to provide adequate blood flow throughout the body, creating symptoms such as fatigue, dizziness and fainting. Our cardiac pacemaker systems (pulse generators, leads, programmers and accessories) deliver electrical energy to stimulate the heart to beat more frequently and regularly. Pacemakers range from conventional single-chamber devices to more sophisticated adaptive-rate, dual-chamber devices.

Our remote monitoring system, the LATITUDE® Patient Management System, may be placed in a patient's home (at their bedside) and reads implantable device information at times specified by the patient's physician. The communicator then transmits the data to a secure Internet server where the physician or other qualified third party can access this medical information anytime, anywhere. In addition to automatic device data uploads, the communicator enables a daily confirmation of the patient's device status, providing assurance the device is operating properly. The LATITUDE® Weight Scale and Blood Pressure Monitor is available as an optional component to the system. Weight and blood pressure data is captured by the communicator and sent to the secure server for review by the patient's physician or other qualified third party. In addition, this weight and blood pressure information is available immediately to patients in their home to assist their compliance with the day-to-day and home-based heart failure instructions prescribed by their physician.

The Drug-Eluting Stent Opportunity

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 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. Drug-eluting stent

systems accounted for 20 percent of our net sales in 2008 and 21 percent in 2007. Since our entry into the drug-eluting stent market with the launch of our proprietary polymer-based paclitaxel-eluting stent technology for reducing coronary restenosis, the TAXUS® Express²® coronary stent system, in the majority of our international markets in 2003 and in the U.S. in 2004, we have become the worldwide leader in the drug-eluting coronary stent market. In 2008, we launched our second-generation drug-eluting stent system, the TAXUS® Liberté® stent system; as well as the PROMUS® everolimus-eluting stent system, supplied to us by Abbott Laboratories, in the U.S. following our earlier launches in our EMEA and Inter-Continental markets. In January 2009, we received approval from the Japanese Ministry of Health, Labor and Welfare to market our TAXUS® Liberté® stent system in Japan, and are planning to launch the TAXUS® Liberté® stent system in Japan during the first quarter of 2009. We expect to launch the PROMUS® stent system in Japan in the second half of 2009, subject to regulatory approval. We are the only company to offer two distinct drug-eluting stent platforms, which has enabled us to sustain our leadership position in the worldwide drug-eluting stent market.

We continue to develop and enhance our product offerings in the drug-eluting stent market. In late 2008, we launched our TAXUS® Express²® Atom™ paclitaxel-eluting coronary stent system, a highly deliverable drug-eluting stent designed for treating small coronary vessels. We expect to launch an internally developed and manufactured next-generation everolimus-based stent system, the PROMUS® Element™ platinum chromium coronary stent, in our EMEA region, as well as in certain Inter-Continental countries, in late 2009 and in the U.S. and Japan in mid-2012, subject to regulatory approval. Additionally, we are conducting clinical trials for our third-generation paclitaxel-eluting stent, the TAXUS® Element™ platinum chromium coronary stent system.

Business Strategy

Our business strategy is to lead global markets for less-invasive medical devices by developing and delivering products and therapies that address unmet patient needs, provide superior clinical outcomes and demonstrate compelling economic value. We intend to achieve leadership, drive profitable sales growth and increase shareholder value by focusing on the following key elements:

- Customers
- Innovation
- Quality
- People
- Financial Strength

Customers

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 close professional 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. Active participation in the medical community contributes to physician understanding and adoption of less-invasive techniques and the expansion of these techniques into new therapeutic and diagnostic areas.

Innovation

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.

We are committed to harnessing technological innovation through a mixture of tactical and strategic initiatives that are designed to offer sustainable growth in the near and long term. Combining internally developed products and technologies with those obtained through our strategic acquisitions and alliances allows us to focus on and deliver products currently in our own research and development pipeline as well as to strengthen our technology portfolio by accessing third-party technologies.

Our commitment to innovation is demonstrated further by our clinical capabilities. Our clinical groups focus on driving innovative therapies aimed at transforming the practice of medicine. Our clinical teams are organized by therapeutic specialty to better support our research and development pipeline. During 2008, our clinical organization planned, initiated and conducted an expanding series of focused clinical trials that support regulatory and reimbursement requirements and demonstrated the safe and effective clinical performance of critical products and technologies.

Quality

Our commitment to quality and the success of our quality objectives are designed to build customer trust and loyalty. This commitment to provide quality products to our customers runs throughout our organization and is one of our most critical business objectives. In order to strengthen our corporate-wide quality controls, we established Project Horizon, a cross-functional initiative to improve and harmonize our overall quality processes and systems. Under Project Horizon, we made significant improvements to our quality systems, including in the areas of field action decision-making, corrective and preventative actions, management controls, process validations and complaint management systems. At the end of 2007, we formally ended our Project Horizon program and transferred all open projects to sustaining organizations. In 2008, we implemented the Quality Master Plan to drive continuous improvement in compliance and quality performance. In addition, our Compliance and Quality Committee of our Board of Directors monitors our compliance and quality initiatives. Our efforts on our quality systems were recognized during the year with the approval of several new products by the U.S. Food and Drug Administration (FDA) and, in October 2008, the FDA informed us that our quality system is now in substantial compliance with its Quality System Regulations. Our quality policy, applicable to all employees, is “I improve the quality of patient care and all things Boston Scientific.” This personal commitment connects our people with our quality strategy.

People

We believe that success and leadership evolve from a motivating corporate culture that rewards achievement; respects and values individual employees and customers; and focuses on quality, patient care, integrity, technology and service. This high performance culture has embraced an intense focus on quality and doing business with integrity as an important part of our success. Being honest and fair with each other reflects on everything we do, especially as we take our quality commitment to new heights. Our Code of Conduct, applicable to all employees, officers and directors, is the cornerstone of our Corporate Integrity Program. We believe that our success is attributable in large part to the high caliber of our employees and our commitment to respecting the values on which we have based our success.

Financial Strength

We are focused on driving profitable sales growth, generating strong cash flow and actively managing our balance sheet. In 2008, we completed, continued or commenced several initiatives designed to increase our profitability and provide better focus on our core businesses and priorities, including:

- Completed the sale of non-strategic businesses, consisting of our Auditory, Cardiac Surgery, Vascular Surgery, Venous Access and Fluid Management businesses, as well as our TriVascular Endovascular Aortic Repair (EVAR) program;

- Substantially completed the sale of non-strategic investments;

- Continued the restructuring of several businesses and product franchises in order to leverage resources, strengthen competitive positions, and create a more simplified and efficient business model;

- Continued execution of significant expense and head count reductions; and

- Commenced our Plant Network Optimization plan, a complement to our previously announced expense and head count reduction plan, which is intended to simplify our plant network, reduce our manufacturing costs and improve gross margins.

Our goal was, and continues to be, to better align expenses with revenues, while preserving our ability to make needed investments in quality, research and development projects, capital and our people that are essential to our long-term success. Each of these initiatives are described more fully in our Management's Discussion and Analysis included in Item 7 of this Annual Report.

Research and Development

Our investment in research and development is critical to driving our future growth. We have directed our development efforts toward regulatory compliance and innovative technologies designed to expand current markets or enter new markets. We believe that streamlining, prioritizing and coordinating our technology pipeline and new product development activities are essential to our ability to stimulate growth and maintain leadership positions in our markets. 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 bring them to market in a timely manner. In 2009, we expect to see the benefits of manufacturing value improvement programs as our manufacturing engineers, many of whom have been focused on quality remediation over the last few years, are now once again focused on driving significant manufacturing cost improvement programs. 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. In 2008, we expended more than $1 billion on research and development, representing approximately 12 percent of our 2008 net sales. Our investment in research and development reflects:

- regulatory compliance and clinical research, particularly relating to our next-generation stent and CRM platforms and other internal development programs, as well as others obtained through our strategic acquisitions; and

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

Acquisitions and Alliances

Since 1995, we have undertaken a strategic acquisition program 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. Our 2008 acquisitions included the following:

- Labcoat, Ltd., a development-stage company that is developing a proprietary drug-eluting stent coating technology designed to reduce the amount of polymer and drug that comes in contact with the wall of the treated vessel, while eliminating polymer and drug on the inner surface of the stent where endothelial cell growth is required for healing; and

- CryoCor, Inc., a developer and manufacturer of a disposable catheter system based on proprietary cryoablation technology for the minimally invasive treatment of cardiac arrhythmias.

We expect that we will continue to focus selectively on strategic acquisitions and alliances in order to provide new products and technology platforms to our customers, including making additional investments in several of our existing strategic relationships.

Products

Our products are offered for sale principally by three dedicated business groups—CRM; Cardiovascular, including our Cardiovascular, and Neurovascular businesses; Endosurgery, including our Endoscopy and Urology/Gynecology businesses; and Neuromodulation. Our Cardiovascular organization focuses on products and technologies for use in interventional cardiology, cardiac rhythm management, peripheral interventions, electrophysiology and neurovascular. During 2008, we derived 79 percent of our net sales from our Cardiovascular businesses (76 percent in 2007), approximately 17 percent from our Endosurgery businesses (15 percent in 2007) and approximately three percent from our Neuromodulation business (two percent in 2007). The remaining one percent of our 2008 net sales (seven percent in 2007) was derived from businesses divested in the first quarter of 2008, some from which we continue to generate net sales as a result of post-separation transition services agreements.

The following section describes certain of our CRM, Cardiovascular, Endosurgery and Neuromodulation offerings:

Cardiac Rhythm Management (CRM)

We offer a variety of implantable devices that monitor the heart and deliver electrical impulses to treat cardiac rhythm abnormalities, including tachycardia (abnormally fast heartbeats), which can put patients at risk of sudden cardiac death and bradycardia (abnormally slow heartbeats), which impairs the ability to live a full life. We also offer cardiac resynchronization devices that treat heart failure by delivering electrical impulses to help the heart beat in a more coordinated fashion. A key component of many of our implantable device systems is our remote LATITUDE® Patient Management System, which provides clinicians with information about a patient's device and clinical status non-invasively via the Internet, allowing for more frequent monitoring in order to guide treatment decisions.

In 2008, we launched several new CRM products, including the following:

ICD and CRT-D Systems

In 2008, we launched our first Boston Scientific-branded ICD and CRT-D devices, the CONFIENT® ICD and LIVIAN® CRT-D product lines, in the U.S. We also launched our COGNIS® CRT-D and TELIGEN® ICD products, which are small, thin high energy devices, in the U.S., EMEA and certain Inter-Continental countries. These full-featured pulse generators are based on a new common platform that offers clinicians innovative options for

customizing therapy to address the needs of individual patients. We received regulatory approval in January 2009 to launch our CONFIENT® ICD in Japan and expect to launch our

COGNIS® and TELIGEN® devices in Japan in 2009, subject to regulatory approval.

In May 2008, our global launch of the ACUITY™ Spiral lead, a left ventricular lead, added to our left ventricular leads portfolio enabling us to offer physicians greater fixation options for delivering cardiac resynchronization therapy to patients with various venous anatomies.

Pacemaker Systems

In May 2008, we launched our first new pacemaker system globally under the Boston Scientific brand, the ALTRUA™ pacing system. The minute ventilation sensor in these pacemakers allows restoration of chronotropic competence to patients who lack the ability to moderate their heart rates appropriately in response to physiologic stress. We expect to launch our ALTRUA™ pacing system in Japan in 2009, subject to regulatory approval.

Remote Patient Monitoring System

To support our ICD and CRT-D product lines, we launched two new enhancements to our LATITUDE® remote patient monitoring system in the U.S. These enhancements include an improved LATITUDE® web site and a smaller in-home communicator featuring touch-screen technology. We plan to begin introducing our LATITUDE® system in our EMEA region in 2009, subject to regulatory approval.

Electrophysiology

We offer medical devices for the diagnosis and treatment of cardiac arrhythmias. Included in our product offerings are RF generators, intracardiac ultrasound and steerable ablation catheters, and diagnostic catheters. Our leading brands include the Blazer™ cardiac ablation catheter, the Chilli II®™ cooled ablation catheter and the MAESTRO 3000® Cardiac Ablation System. Our electrophysiology products are distributed globally.

Interventional Cardiology

Drug-Eluting Stent Systems

We are the market leader in the worldwide drug-eluting stent market. We market our second-generation coronary stent, the TAXUS® Liberté® stent system; as well as the PROMUS® everolimus-eluting coronary stent system, supplied to us by Abbott, in our EMEA and Inter-Continental markets, and, in 2008, launched both products in the U.S. market, expanding our drug-eluting stent portfolio to include two distinct drug platforms. As of the closing of Abbott's acquisition of Guidant's vascular intervention and endovascular solutions businesses, we obtained a perpetual license to use the intellectual property used in Guidant's drug-eluting stent system program purchased by Abbott. In 2008, we also initiated the U.S. launch of our TAXUS® Express²® Atom™ paclitaxel-eluting coronary stent system, a highly deliverable drug-eluting stent designed for treating small coronary vessels.

We expect to launch our TAXUS® Liberté® stent system in Japan in the first quarter of 2009. We plan to launch the PROMUS® everolimus-eluting coronary stent system in Japan in the second half of 2009, subject to regulatory approval. We are also incurring incremental costs and expending incremental resources in order to develop and commercialize additional products utilizing everolimus-eluting stent technology and to support an internally developed and manufactured next-generation everolimus-eluting stent system. We expect to launch an internally developed and manufactured next-generation everolimus-based stent system,

the PROMUS® Element™ stent system, in our EMEA region, as well as certain Inter-Continental countries, in late 2009 and in the U.S. and Japan in mid-2012. In addition, we are conducting clinical trials for our third-generation paclitaxel-eluting stent, the TAXUS® Element™ platinum chromium coronary stent system, which we expect to launch in EMEA and certain Inter-Continental countries during the fourth quarter of 2009, and in the U.S. and Japan in mid-2011.

Bare-Metal Stent Systems

We offer our Liberté® bare-metal coronary stent system globally. The Liberté® coronary stent system serves as the platform for our second-generation paclitaxel-eluting stent system, the TAXUS® Liberté® coronary stent system. The Liberté® bare-metal coronary stent system is designed to enhance deliverability and conformability, particularly in challenging lesions. We are also developing a bare-metal version of the TAXUS® Element coronary stent system.

Coronary Revascularization

We market a broad line of products used to treat patients with atherosclerosis. Atherosclerosis, a principal cause of coronary artery obstructive disease, is characterized by a thickening of the walls of the coronary arteries and a narrowing of arterial lumens (openings) caused by the progressive development of deposits of plaque. The majority of our products in this market are used in percutaneous transluminal coronary angioplasty (PTCA) procedures and include bare-metal and drug-eluting stent systems; PTCA balloon catheters, such as the Maverick® balloon catheter; the Cutting Balloon® microsurgical dilatation device; rotational atherectomy systems; guide wires; guide catheters and diagnostic catheters.

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, available in the U.S., Japan and other international markets, continues as our flagship console and is compatible with our full line of imaging catheters. This system enhances the diagnosis and treatment of blocked vessels and heart disorders.

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 vascular access products, balloon catheters, stents and peripheral vascular catheters, wires and accessories. In 2009, we will begin integrating certain products used for peripheral embolization procedures into our Peripheral Interventions business. We also sell products designed to treat patients with non-vascular disease (disease which appears outside the blood system). Our non-vascular suite of products includes biliary stents, drainage catheters, biopsy devices and micro-puncture sets, designed to treat, diagnose and palliate various forms of benign and malignant tumors. We market the PolarCath™ peripheral dilatation system used in CryoPlasty® Therapy, an innovative approach to the treatment of peripheral artery disease in the lower extremities. In December 2008, we received FDA approval for our Express® SD Renal Monorail® premounted stent system for use as an adjunct to percutaneous transluminal renal angioplasty in certain lesions of the renal arteries. In October 2008, we received FDA approval for our Carotid WALLSTENT® Monorail® Endoprosthesis for the treatment of patients with carotid artery disease who are at high risk for surgery.

Neurovascular Intervention

We market a broad line of detachable coils (coated and uncoated), micro-delivery stents, micro-guidewires, micro-catheters, guiding catheters and embolics to neuro-interventional radiologists and neurosurgeons to

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treat diseases of the neurovascular system. We market the GDC® Coils (Guglielmi Detachable Coil) and Matrix® systems to treat brain aneurysms. We plan to launch a next-generation family of detachable coils, including an enhanced delivery system, in the U.S. in the second half of 2009. We also offer the NeuroForm® stent for the treatment of wide neck aneurysms and the Wingspan® Stent System with Gateway® PTA Balloon Catheter, each under a Humanitarian Device Exemption approval granted by the FDA. The Wingspan Stent System is designed to treat atherosclerotic lesions or accumulated plaque in brain arteries. Designed for the brain's fragile vessels, the Wingspan Stent System is a self-expanding, nitinol stent sheathed in a delivery system that enables it to reach and open narrowed arteries in the brain. The Wingspan Stent System is currently the only device available in the U.S. for the treatment of intracranial atherosclerotic disease (ICAD) and is indicated for improving cerebral artery lumen diameter in patients with ICAD who are unresponsive to medical therapy.

Embolic Protection

Our FilterWire EZ™ Embolic Protection System is a low profile filter designed to capture embolic material that may become dislodged during a procedure, which could otherwise travel into the microvasculature where it could cause a heart attack or stroke. It is commercially available in the U.S., EMEA 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.

Endosurgery

Esophageal, Gastric and Duodenal (Small Intestine) Intervention

We market a broad range of products to diagnose, treat and palliate a variety of gastrointestinal diseases and conditions, including those affecting the esophagus, stomach and colon. Common disease states include esophagitis, portal hypertension, peptic ulcers and esophageal cancer. Our product offerings in this area include disposable single and multiple biopsy forceps, balloon dilatation catheters, hemostasis catheters and enteral feeding devices. We also market a family of esophageal stents designed to offer improved dilatation force and greater resistance to tumor in-growth. 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.

Colorectal Intervention

We market a line of hemostatic catheters, polypectomy snares, biopsy forceps, enteral stents and dilatation catheters for the diagnosis and treatment of polyps, inflammatory bowel disease, diverticulitis and colon cancer.

Pancreatico-Biliary Intervention

We sell a variety of products to diagnose, treat and palliate benign and malignant strictures of the pancreatico-biliary system (the gall bladder, common bile duct, hepatic duct, pancreatic duct and the pancreas) and to remove stones found in the common bile duct. Our product offerings include diagnostic catheters used with contrast media, balloon dilatation catheters and sphincterotomes. We also market self-expanding metal and temporary biliary stents for palliation and drainage of the common bile duct. In addition, we market the Spyglass® Direct Visualization System for direct imaging of the bile duct system. The Spyglass system is the first single-operator cholangioscopy device that offers clinicians a direct visualization of the bile duct system and includes supporting devices for tissue acquisition, stone management and lithotripsy.

Pulmonary Intervention

We market devices to diagnose, treat and palliate diseases of the pulmonary system. Our product offerings include pulmonary biopsy forceps, transbronchial aspiration needles, cytology brushes and tracheobronchial stents used to dilate strictures or for tumor management.

Urinary Tract Intervention and Bladder Disease

We sell a variety of products designed primarily to treat patients with urinary stone disease, including: ureteral dilatation balloons used to dilate strictures or openings for scope access; stone baskets used to manipulate or remove stones; intracorporeal shock wave lithotripsy devices and holmium laser systems used to disintegrate stones; ureteral stents implanted temporarily in the urinary tract to provide short-term or long-term drainage; and a wide variety of guidewires used to gain access to specific sites. We have also developed other devices to aid in the diagnosis and treatment of bladder cancer and bladder obstruction.

Prostate Intervention

We market electro-surgical resection devices designed to resect large diseased tissue sites for the treatment of benign prostatic hyperplasia (BPH). We also market disposable needle biopsy devices, designed to take core prostate biopsy samples. We also market the Prolieve® Thermodilatation System, a transurethral microwave thermotherapy system for the treatment of BPH. In addition, we distribute and market the DuoTome™ SideLite™ holmium laser treatment system for treatment of symptoms associated with BPH.

Pelvic Floor Reconstruction and Urinary Incontinence

We market a line of less-invasive devices to treat female pelvic floor conditions in the areas of stress urinary incontinence and pelvic organ prolapse. These devices include a full line of mid-urethral sling products, sling materials, graft materials, pelvic floor reconstruction kits, suturing devices and injectables. We have exclusive U.S. distribution rights to the Coaptite® Injectable Implant, a next-generation bulking agent, for the treatment of stress urinary incontinence.

Gynecology

We also market other products in the area of women’s health. Our Hydro ThermAblator® System offers a less-invasive technology for the treatment of excessive uterine bleeding by ablating the lining of the uterus, the tissue responsible for menstrual bleeding.

Neuromodulation

We market the Precision® Spinal Cord Stimulation (SCS) system for the treatment of chronic pain of the lower back and legs. This system delivers advanced pain management by applying a small electrical signal to mask pain signals traveling from the spinal cord to the brain. The Precision System utilizes a rechargeable battery and features a patient-directed fitting system for fast and effective programming. The Precision System is also being assessed for use in treating other sources of peripheral pain.

Marketing and Sales

A dedicated sales force of approximately 2,300 individuals in approximately 40 countries internationally, and over 3,200 individuals in the U.S. marketed our products worldwide as of December 31, 2008. The majority of our net sales are derived from countries in which we have direct sales organizations. A network of distributors and dealers

who offer our products worldwide accounts for our remaining sales. We will continue to leverage our infrastructure in markets where commercially appropriate and use third parties in those markets where it is not economical or strategic to establish or maintain a direct presence. We also have

a dedicated corporate sales organization in the U.S. focused principally on selling to major buying groups and integrated healthcare networks.

In 2008, we sold our products to over 10,000 hospitals, clinics, outpatient facilities and medical offices. We are not dependent on any single institution and no single institution accounted for more than ten percent of our net sales in 2008. 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.

Certain products are manufactured for us by third parties, such as the PROMUS® everolimus-eluting coronary stent system, introducer sheaths and certain guidewires, and pneumatic and laser lithotripters. Employing our sales and marketing strength, we expect to continue to seek new opportunities for distributing complementary products as well as new technologies.

International Operations

In the first quarter of 2008, we began operating through two international business units: EMEA, consisting of Europe, Middle East and Africa; and Inter-Continental, consisting of Japan, Asia Pacific, Canada and Latin America. This reorganization is designed to allow for better leverage of infrastructure and resources, as well as restored competitiveness. 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. After our acquisition of Guidant, we integrated Guidant's international sales operations into our geographic regions. We have moved from a distributor model to a direct sales force, utilizing a dealer network, for our CRM products in Japan, which has negatively impacted our net sales and market share there and may continue to do so until we fully implement this model.

International net sales accounted for approximately 43 percent of our net sales in 2008. Net sales and operating income attributable to our 2008 geographic regions are presented in Note P—Segment Reporting to our 2008 consolidated financial statements included in Item 8 of this Annual Report.

We have five international manufacturing facilities in Ireland, two in Costa Rica and one in Puerto Rico. Approximately 32 percent of our products sold worldwide are manufactured at these facilities. Additionally, we maintain international research and development capabilities in Ireland, and Miyazaki, Japan, as well as physician training centers in Paris, France and Tokyo, Japan. In connection with certain of our restructuring initiatives, we intend to close two of our manufacturing plants in Ireland.

Manufacturing and Raw Materials

We are focused on continuously improving our supply chain effectiveness, strengthening our manufacturing processes and increasing operational efficiencies within our organization. By shifting global manufacturing along product lines, we are able to leverage our existing resources and concentrate on new product development, including the enhancement of existing products, and their commercial launch. We are implementing new systems designed to provide improved quality and reliability, service, greater efficiency and lower supply chain costs. We 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 2008, we continued to focus on examining our operations and general business activities to identify cost-improvement opportunities in order to enhance our operational effectiveness. In early 2009, we announced our Plant Network Optimization plan as a complement to our previously initiated expense and head count reductions. The plan calls for reducing the number of our manufacturing plants from 17 to 12 over the next three years and relocating approximately 15 percent of our current value of production to different facilities.

We design and manufacture the majority of our products in technology centers around the world. 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. However, in certain cases, we may not be able to quickly establish additional or replacement suppliers for specific components or materials, 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 or components could adversely affect our operations and financial condition, particularly materials or components related to our TAXUS® drug-eluting stent system and our CRM products. In addition, our products require sterilization prior to sale and we rely primarily on third party vendors to perform this service. To the extent our third party sterilizers are unable to process our products, whether due to raw material, 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.

We are reliant on Abbott for our supply of PROMUS® stent systems. Any production or capacity issues that affect Abbott's manufacturing capabilities or the process for forecasting, ordering and receiving shipments may impact our ability to increase or decrease the level of supply to us in a timely manner; therefore, our supply of PROMUS® stent systems may not align with customer demand, which could have an adverse effect on our operating results. At present, we believe that our supply of PROMUS® stent systems from Abbott is sufficient to meet customer demand. Our supply agreement with Abbott for PROMUS® stent systems extends through the middle of the fourth quarter of 2009 in Europe, and is currently being reviewed by the European Commission for possible extension, and through the end of the second quarter of 2012 in the U.S. and Japan. We expect to launch an internally developed and manufactured next-generation everolimus-eluting stent system, the PROMUS® Element™ stent system, in our EMEA region and certain Inter-Continental countries in late 2009 and in the U.S. and Japan in mid-2012.

Under the terms of our supply arrangement with Abbott, the gross profit and operating profit margin of a PROMUS® stent system is significantly lower than that of our TAXUS® stent system. Therefore, if sales of our PROMUS® stent system continue to increase in relation to our total drug-eluting stent system sales, our profit margins will continue to decrease. Further, the price we pay Abbott for our supply of PROMUS® stent systems is determined by our contracts with them. Our cost is based, in part, on previously fixed estimates of Abbott's manufacturing costs for PROMUS® stent systems and third-party reports of our average selling price of PROMUS® stent systems. Amounts paid pursuant to this pricing arrangement are subject to a retroactive adjustment at pre-determined intervals based on Abbott's actual costs to manufacture these stent systems for us and our average selling price of PROMUS® stent systems. During 2009, we may make a payment to or receive a payment from Abbott based on the differences between their actual manufacturing costs and the contractually stipulated manufacturing costs and differences between our actual average selling price and third-party reports of our average selling price, in each case, with respect to our purchases of PROMUS® stent systems from Abbott during 2008, 2007 and 2006. As a result, during 2009, our profit margins on the PROMUS® stent system may increase or decrease.

Quality Assurance

In January 2006, legacy Boston Scientific received a corporate warning letter from the FDA notifying us of serious regulatory problems at three of our facilities and advising us that our corporate-wide corrective action plan relating to three site-specific warning letters issued to us in 2005 was inadequate. We have identified solutions to the quality system issues cited by the FDA and have made significant progress in transitioning our organization to implement those solutions. We implemented and continue to use the Quality Master Plan to drive continuous improvement in compliance and quality performance. In addition, the Compliance and Quality Committee of our Board of Directors monitors our compliance and quality initiatives. During 2008, the FDA reinspected a number of our facilities and, in October 2008, informed us that our quality system is now in substantial compliance with its Quality System Regulations. The FDA has approved all of our requests for final approval of Class III product submissions previously on hold due to the corporate warning letter and has approved all currently eligible requests for Certificates to Foreign Governments (CFGs). The corporate warning letter remains in place pending final remediation of certain Medical Device Report (MDR) filing issues, which we are actively working with the FDA to resolve.

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 policy, applicable to all employees, is “I improve the quality of patient care and all things Boston Scientific.” This personal commitment connects our people with the vision and mission of Boston Scientific. Our quality system starts with the initial product specification and continues through the design of the product, component specification process and the manufacturing, sales 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 ISO 13485:2003 quality system standard 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.

We maintain an on-going initiative to seek ISO 14001 certification at our plants around the world. ISO 14001, the environmental management system standard in the ISO 14000 series, provides a voluntary framework to identify key environmental aspects associated with our businesses. We engage in continuous environmental performance improvement around these aspects. At present, ten of our manufacturing and distribution facilities have attained ISO 14001 certification. We expect to continue this initiative until each of our manufacturing facilities, including those we acquire, becomes certified.

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 have historically included Johnson & Johnson (including its subsidiary, Cordis Corporation) and Medtronic, Inc. (including its subsidiary, Medtronic AVE, Inc.), as well as a wide range of companies that sell a single or limited number of competitive products or participate in only a specific market segment. Since we acquired Guidant, Abbott has become a primary competitor of ours in the interventional cardiology market and we now compete with St. Jude Medical, Inc. in the CRM and neuromodulation markets. We also face competition from non-medical device companies, such as pharmaceutical companies, which may offer alternative therapies for disease states intended to be treated using our products.

We believe that our products compete primarily on their ability to safely and effectively perform diagnostic and therapeutic procedures in a less-invasive manner, including ease of use, 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, clinical outcomes, reliability and efficiency. We believe the current global economic conditions could put additional competitive pressure on us, including on our average selling prices, overall procedure rates and market sizes. We believe that our continued competitive success will depend upon our ability to create or acquire 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 development 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 program be conducted before a device receives approval for commercial distribution.

In the U.S., permission 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 descriptive data and, when necessary, performance data to establish that the device is substantially equivalent to a predicate device. In some instances, data from human clinical trials must also be submitted in support of a 510(k) Submission. If so, these data must be collected in a manner that conforms to the applicable Investigational Device Exemption (IDE) regulations. The FDA must issue an order finding substantial equivalence before commercial distribution can occur. Changes to existing devices covered by a 510(k) Submission that do not raise new questions of safety or effectiveness can generally be made without additional 510(k) Submissions. More significant changes, such as new designs or materials, may require a separate 510(k) with data to support that the modified device remains substantially equivalent.

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

The third process requires that an application for a Humanitarian Device Exemption (HDE) be made to the FDA for the use of a Humanitarian Use Device (HUD). A HUD is intended to benefit patients by treating or diagnosing a disease or condition that affects, or is manifested in, fewer than 4,000 individuals in the U.S. per year. The application submitted to the FDA for an HDE is similar in both form and content to a PMA application, but is exempt from the effectiveness requirements of a PMA. This approval process demonstrates 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 small patient populations.

The FDA can ban certain medical devices; detain or seize adulterated or misbranded medical devices; order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations. International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. to take advantage of differing regulatory requirements. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

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In the European Union, we are required to comply with the Medical Devices Directive and obtain CE Mark certification in order to market medical devices. The CE Mark certification, granted following approval from an independent notified body, is an international symbol of adherence to quality assurance standards and compliance with applicable European Medical Devices Directives. We are also required to comply with other foreign regulations such as the requirement that we obtain Ministry of Health, Labor and Welfare approval before we can launch new products in Japan. The time required to obtain these foreign approvals to market our products may vary from U.S. approvals, and requirements for these approvals may differ from those required by the FDA.

We are also subject to various environmental laws, directives and regulations both in the U.S. and abroad. Our operations, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe that compliance with environmental laws will not have a material impact on our capital expenditures, earnings or competitive position. Given the scope and nature of these laws, however, 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 quarterly basis. At present, we are not aware of any such liabilities that would have a material impact on our business. We are also certified with respect to the enhanced environmental FTSE4Good criteria and are a constituent member of the London Stock Exchange's FTSE4Good Index, which recognizes companies that meet certain corporate responsibility standards. In 2008, we were recognized for environmental stewardship, winning a Leadership in Energy and Environmental Design (LEED) award for the renovation of our research and development facility in Marlborough, Massachusetts.

We are members of the U.S. Climate Action Partnership (USCAP). USCAP is a diverse group of 27 major businesses and six environmental non-governmental organizations with a commitment to work with Congress and the President to rapidly enact legislation that would significantly slow, stop and reverse the growth of greenhouse gas emissions.

Government Affairs

We maintain a global Government Affairs presence in Washington D.C. to actively monitor and influence a myriad of legislative and administrative policies impacting us, both on a domestic and an international basis. The Government Affairs office works closely with members of Congress, key Congressional committee staff and White House and Administration staff, which facilitates our active engagement on issues affecting our business. Our proactive approach and depth of political and policy expertise are aimed at having our positions heard by federal, state and global decision-makers, while also advancing our business objectives by educating policymakers on our positions, key priorities and the value of our technologies.

The Government Affairs office also manages the Company's political action committee and works closely with trade groups on issues affecting our industry and healthcare generally.

Community Outreach

We have developed a program to assist to "close the gap" in addressing disparities in cardiovascular care for women, black Americans, and Hispanic/Latino Americans. In 2006, a team of physicians and health care professionals from across the United States came together to look at ways to address these disparities by creating a "Proof of Principle" pilot in ten test market cities. The committee facilitated the development of educational tools and community events, to help healthcare professionals improve outcomes for specific underserved patient populations.

We believe that healthcare professionals can provide enhanced service, and ensure better communications with patients when they are skilled in engaging women and other minority patients. This is especially

important as these underserved patient populations continue to grow.

Third-Party Coverage and Reimbursement

Our products are purchased principally by hospitals, physicians and other healthcare providers around the world that typically bill various third-party payors, including governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care programs, for the healthcare services provided to their patients. Third-party payors may provide or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Reimbursement by third-party payors for these services is based on a wide range of methodologies that may reflect the services' assessed resource costs, clinical outcomes and economic value. These reimbursement methodologies confer different, and sometimes conflicting, levels of financial risk and incentives to healthcare providers and patients, and these methodologies are subject to frequent refinements. Third-party payors are also increasingly adjusting reimbursement rates and challenging the prices charged for medical products and services. There can be no assurance that our products will be covered automatically by third-party payors, that reimbursement will be available or, if available, that the third-party payors' coverage policies will not adversely affect our ability to sell our products profitably.

Initiatives to limit the growth of healthcare costs, including price regulation, are also underway in many countries in which we do business including the U.S. under the new administration. 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. Spending on health care in some countries, including the U.S., may also be affected by the global economic slowdown.

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. At December 31, 2008, we held approximately 6,500 U.S. patents, many of which have foreign counterparts, and had more than 10,000 patent applications pending worldwide that cover various aspects of our technology. In addition, we hold exclusive and non-exclusive licenses to a variety of third-party technologies covered by patents and patent applications. There can be no assurance that pending patent applications will result in the issuance of patents, that patents issued to or licensed by us will not be challenged or circumvented by competitors, or that these patents will be found to be valid or sufficiently broad to protect our technology or to provide us with a competitive advantage.

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 have defended, and will continue to defend, ourself 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. Settlement may include cross licensing of the patents that are the subject of the litigation as well as our other intellectual property and may involve monetary payments to or from third parties.

See Item 3. Legal Proceedings and Note L—Commitments and Contingencies to our 2008 consolidated financial statements included in Item 8 of this Annual Report for a further discussion of patent and other litigation and proceedings in which we are involved. In management's opinion, we are not currently involved in any legal proceeding other than those specifically identified in Note L, which, individually or in the aggregate, could have a material effect on our financial condition, results of operations and liquidity.

Risk Management

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

Employees

As of December 31, 2008, we had approximately 24,800 employees, including approximately 12,700 in operations; 1,800 in administration; 4,200 in clinical, regulatory and research and development; 5,500 in selling and marketing; and 600 in distribution. Of these employees, we employed approximately 8,900 outside the U.S., approximately 5,600 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. In October 2007, we committed to an expense and head count reduction plan, which resulted in the elimination of approximately 2,300 positions worldwide. We also eliminated 2,000 positions in connection with divestiture of our non-strategic businesses, which were completed in early 2008. We added 500 positions during 2008, primarily in direct sales-related positions. In early 2009, we announced our Plant Network Optimization plan, aimed at simplifying our plant network, reducing our manufacturing costs and improving gross margins, which we estimate will result in the reduction of approximately 300 positions by the end of 2011.

Seasonality

Our worldwide sales do not reflect any significant degree of seasonality; however, customer purchases have been lighter in the third quarter of prior years than in other quarters. This reflects, among other factors, lower demand during summer months, particularly in European countries.

Available Information

Copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and

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amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge on our website (www.bostonscientific.com) as soon as reasonably practicable after we electronically file the material with or furnish it to the SEC. Our Corporate Governance Guidelines and Code of Conduct, which applies to all of our directors, officers and employees, including our Board of Directors, Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and Corporate Controller, are also available on our website, along with any amendments to those documents. Any amendments to or waivers for executive officers or directors of our Code of Conduct will be disclosed on our website promptly after the date of any such amendment or waiver. Printed copies of these posted materials are also available free of charge to shareholders who request them in writing from Investor Relations, One Boston Scientific Place, Natick, MA 01760-1537. Information on our website or connected to our website is not incorporated by reference into this Annual Report.

Safe Harbor for Forward-Looking Statements

Certain statements that we may make from time to time, including statements contained in this report and information incorporated by reference into this report, constitute "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words and include, among other things, statements regarding our financial performance; our growth strategy; the effectiveness of our restructuring, expense, head count reduction and plant network optimization initiatives; timing of regulatory approvals and plant certifications; our regulatory and quality compliance; expected research and development efforts; product development and iterations; new product launches and launches of our existing products in new geographies; our market position in the marketplace for our products and our sales and marketing strategy; the effect of new accounting pronouncements; the outcome of matters before taxing authorities; intellectual property and litigation matters; our ability to finance our capital needs and expenditures; the ability of our suppliers and third-party sterilizers to meet our requirements; 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; and our strategy regarding acquisitions, divestitures and strategic investments, as well as integration execution. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at this time and are not intended to be guarantees of future events or performance. 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, investors 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 below even if new information becomes available or other events occur in the future. We have identified these forward-looking statements below, which are based on certain risks and uncertainties, including the risk factors described in Item 1A under the heading "Risk Factors." Factors that could cause actual results to differ materially from those expressed in forward-looking statements are contained below and in the risk factors described in Item 1A under the heading "Risk Factors."

CRM

- Our estimates for the worldwide CRM market, the increase in the size of the CRM market above existing levels and our ability to increase CRM net sales;

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

- The results of CRM clinical trials undertaken by us, our competitors or other third parties;
- Our ability to successfully launch next-generation products and technology features, including the INGENIO™ pacemaker system;
- Our ability to grow sales of both new and replacement implant units;
- Our ability to retain key members of our CRM sales force and other key personnel;
- Competitive offerings in the CRM market and the timing of receipt of regulatory approvals to market existing and anticipated CRM products and technologies;
- Our ability to successfully and timely implement a direct sales model for our CRM products in Japan; and
- Our ability to avoid disruption in the supply of certain components or materials or to quickly secure additional or replacement components or materials on a timely basis.

Coronary Stents

- Volatility in the coronary stent market, our estimates for the worldwide coronary stent market, the recovery of the coronary stent market and our ability to increase coronary stent net sales, competitive offerings and the timing of receipt of regulatory approvals to market existing and anticipated drug-eluting stent technology and other stent platforms;
- Our ability to successfully launch next-generation products and technology features;
- Our ability to maintain or expand our worldwide market positions through reinvestment in our two drug-eluting stent programs;
- Our ability to manage the mix of our PROMUS® stent system net sales relative to our total drug-eluting stent net sales and to launch on-schedule a next-generation everolimus-eluting stent system with gross profit margins more comparable to our TAXUS® stent system;
- Our share of the worldwide drug-eluting stent market, the distribution of share within the coronary stent market in the U.S. and around the world, the average number of stents used per procedure and average selling prices, and the penetration rate of drug-eluting stent technology in the U.S. and international markets;
- The overall performance of, and continued physician confidence in, our and other drug-eluting stent systems, our ability to adequately address concerns regarding the perceived risk of late stent thrombosis, and the results of drug-eluting stent clinical trials undertaken by us, our competitors or other third parties;
- Abbott’s ability to obtain approval for its XIENCE V™ everolimus-eluting coronary stent system in Japan and Abbott’s payment to us of the associated milestone obligation;
- Our reliance on Abbott’s manufacturing capabilities and supply chain, and our ability to align our PROMUS® stent system supply from Abbott with customer demand through our forecasting and ordering processes;

- 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;

- Our ability to manage inventory levels, accounts receivable, gross margins and operating expenses and to react effectively to worldwide economic and political conditions; and

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

Litigation and Regulatory Compliance

- Any conditions imposed in resolving, or any inability to resolve, our corporate warning letter or other FDA matters, as well as 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 FDA warning letters or field actions relating to our products and the on-going inherent risk of potential physician advisories or field actions related to medical devices;

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

- The impact of 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 next-generation products and technologies within our drug-eluting stent and CRM businesses, as well as our ability to develop products and technologies successfully in our other businesses;

- Our ability to fund and achieve benefits from our focus on internal research and development and external alliances 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;
- Our ability to integrate the strategic acquisitions we have consummated;
- Our ability to fund with cash or common stock any acquisitions or alliances, or to fund contingent payments associated with these alliances;
- Our ability to prioritize our internal research and development project portfolio and our external investment portfolio to keep expenses in line with expected revenue levels, or our decision to sell, discontinue, write down or reduce the funding of any of these projects;
- The timing, size and nature of strategic initiatives, market opportunities and research and development platforms available to us and the ultimate cost and success of these initiatives; and
- Our ability to successfully identify, develop and market new products or the ability of others to develop products or technologies that render our products or technologies noncompetitive or obsolete.

International Markets

- Dependency on international net sales to achieve growth;
- Risks associated with international operations, including compliance with local legal and regulatory requirements as well as changes in reimbursement practices and policies; and
- The potential effect of foreign currency fluctuations and interest rate fluctuations on our net sales, expenses and resulting margins.

Capital Management

- Our ability to implement, fund, and achieve sustainable cost improvement measures, including our plant network optimization plan, intended to improve overall gross profit margins, and sustaining our other expense and head count reduction initiatives and restructuring program;
- Our ability to generate sufficient cash flow to fund operations, capital expenditures, and strategic investments, as well as to effectively manage our debt levels and covenant compliance and to minimize the impact of interest rate fluctuations on our earnings and cash flows;
- 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 recover substantially all of our deferred tax assets; and
- The impact of examinations and assessments by domestic and international taxing authorities on our tax provision, financial condition or results of operations.

Other

- Risks associated with significant changes made or to be made to our organizational structure, or to the membership of our executive committee or Board of Directors;

- Risks associated with our acquisition of Guidant, including, among other things, the indebtedness we have incurred and the integration challenges we will continue to face;

- Our ability to retain our key employees and avoid business disruption and employee distraction as we execute our expense and head count reduction and plant network optimization initiatives; and

- Our ability to maintain management focus on core business activities while also concentrating on resolving the corporate warning letter and implementing strategic initiatives, including expense and head count reductions and our restructuring program and our plant network optimization plan, in order to streamline our operations, reduce our debt obligations and improve our gross margins.

Several important factors, in addition to the specific factors discussed in connection with each forward-looking statement individually and the risk factors described in Item 1A under the heading "Risk Factors," could affect our future results and growth rates and could cause those results and rates to differ materially from those expressed in the forward-looking statements and the risk factors contained in this report. These additional factors include, among other things, future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; 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 report.

ITEM 1A. RISK FACTORS

In addition to the other information contained in this Annual Report and the exhibits hereto, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition 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 or results of operations.

We derive a significant portion of our net sales from the sale of drug-eluting coronary stent systems and cardiac rhythm management (CRM) products in the United States. A decline in market size, a failure of market growth rates to return to historic levels, increased competition, supply interruption or product launch delays may materially adversely affect our results of operations, our financial position, including our goodwill balances, or financial condition.

Net sales from drug-eluting coronary stent systems represented approximately 20 percent of our consolidated net sales during the year ended December 31, 2008. Our U.S. TAXUS® sales declined in 2008 relative to prior years, due largely to recent competitive launches. In addition, the U.S. market size for drug-eluting stents has declined due to uncertainty regarding the perceived risk of late stent thrombosis following the use of drug-eluting stents. Late stent thrombosis is the formation of a clot, or thrombus, within the stented area one year or more after implantation of the stent. There can be no assurance that these concerns will be alleviated in the near term or that the size of the U.S.

drug-eluting stent market will return to previous levels. In 2007, our

TAXUS® stent system and Johnson & Johnson's CYPHER® stent system were the only two drug-eluting stents available in the U.S. market. In 2008, Medtronic launched its Endeavor® drug-eluting stent system and Abbott launched its XIENCE V™ everolimus-eluting stent system in the U.S.

The manufacture of our TAXUS® coronary stent system involves the integration of multiple technologies, critical components, raw materials and complex processes. Significant favorable or unfavorable changes in forecasted demand, as well as disruptions associated with our TAXUS® stent manufacturing process, may impact our inventory levels. Variability in expected demand or the timing of the launch of next-generation products may result in excess or expired inventory positions and future inventory charges, which may adversely impact our results from operations. We share with Abbott rights to everolimus-eluting stent technology, including its XIENCE V™ everolimus-eluting stent program. As a result of our sharing arrangements, we are reliant on Abbott's regulatory and clinical activities and on their continued supply of both PROMUS® everolimus-eluting stent systems and certain components utilized in our drug-eluting stent research and development programs. Delays in receipt of regulatory approvals for the XIENCE V™ stent system in Japan, receipt of insufficient quantities of the PROMUS® stent system from Abbott, changing acceptance of these stents in the marketplace, or disruption in our supply of components (including everolimus) for research and development could adversely affect our results of operations, as well as our ability to effectively differentiate ourselves from our competitors in the drug-eluting stent market as the leading competitor with two drug-eluting stent programs.

We expect to launch an internally developed and manufactured next-generation everolimus-based stent system, the PROMUS® Element™ platinum chromium coronary stent, in Europe and certain Inter-Continental countries in late 2009 and in the United States and Japan in mid-2012. Our supply of the existing PROMUS® stent system from Abbott extends through the middle of the fourth quarter of 2009 in Europe, and is currently being reviewed by the European Commission for possible extension, and through the end of the second quarter of 2012 in the U.S. and Japan. If we are unable to obtain regulatory approval and timely launch our PROMUS® Element stent system, the absence of an everolimus-eluting stent in our product pipeline may materially adversely affect our results of operations, our financial position, or financial condition.

Worldwide CRM market growth rates over the past three years, including the U.S. ICD market, have been below those experienced in prior years, resulting primarily from previous industry field actions and from a lack of new indications for use. The U.S. ICD market represents approximately 40 percent of the worldwide CRM market. 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. Net sales from our CRM products represented approximately 28 percent of our consolidated net sales during the year ended December 31, 2008 and there can be no assurance of continued acceptance of our new products. Therefore, decreases in net sales from our CRM products could have a significant impact on our results of operations. In addition, our inability to increase our CRM net sales, particularly in the U.S., could result in additional goodwill and intangible asset impairment charges.

The profit margin of a PROMUS® stent system is significantly lower than that of our TAXUS® system and an increase of PROMUS® sales relative to TAXUS® sales may adversely impact our gross profit and operating profit margins. The price we pay Abbott for our supply of PROMUS® stent systems is further impacted by our contractual arrangement with Abbott and is subject to retroactive adjustment, which may also negatively impact our profit margins. In addition, we are reliant on Abbott for supply of PROMUS® and any disruption to that supply could adversely effect our operating results.

Under the terms of our supply arrangement with Abbott, the gross profit and operating profit margin of a PROMUS® stent system is significantly lower than that of our TAXUS® stent system. Therefore, if sales of our PROMUS® stent system continue to increase in relation to our total drug-eluting stent system sales, our profit margins will continue to decrease. Further, the price we pay Abbott for our supply of PROMUS® stent systems is determined by our contracts with them. Our cost is based, in part, on previously fixed

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estimates of Abbott's manufacturing costs for PROMUS® stent systems and third-party reports of our average selling price of PROMUS® stent systems. Amounts paid pursuant to this pricing arrangement are subject to a retroactive adjustment at pre-determined intervals based on Abbott's actual costs to manufacture these stent systems for us and our average selling price of PROMUS® stent systems. During 2009, we may make a payment to or receive a payment from Abbott based on the differences between their actual manufacturing costs and the contractually stipulated manufacturing costs and differences between our actual average selling price and third-party reports of our average selling price, in each case, with respect to our purchases of PROMUS® stent systems from Abbott during 2008, 2007 and 2006. As a result, during 2009, our profit margins on the PROMUS® stent system may increase or decrease.

In addition, we are reliant on Abbott for our supply of PROMUS® stent systems. Any production or capacity issues that affect Abbott's manufacturing capabilities or our process for forecasting, ordering and receiving shipments may impact our ability to increase or decrease the level of supply to us in a timely manner; therefore, our supply of PROMUS® stent systems may not align with customer demand, which could have an adverse effect on our operating results.

Recent deterioration in the economy and credit markets may adversely affect our future results of operations.

As widely reported, the global credit markets and financial services industry have been experiencing a period of upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions, severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, uncertainty about economic stability and an unprecedented level of intervention from the United States federal government. There can be no assurance that there will not be further deterioration in the global economy, credit and financial markets and confidence in economic conditions. While the ultimate outcome of these events cannot be predicted, it may have a material adverse effect on us and our ability to borrow money in the credit markets and potentially to draw on our revolving credit facility or otherwise. Similarly, our customers and suppliers 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.

Our share price will fluctuate, and accordingly, the value of our investment may be unpredictable.

Stock markets in general and our common stock in particular have experienced significant price and volume volatility over the past year. The market price and trading volume of our common stock may continue to be subject to significant fluctuations due not only to general stock market conditions but also to variability in the prevailing sentiment regarding our operations or business prospects, as well as, among other things, potential further sales of our common stock to satisfy the financial commitments of our historical shareholders.

New competitors have entered the drug-eluting stent market, which has impacted our market share and may continue to negatively affect our net sales.

Until 2008, our TAXUS® paclitaxel-eluting coronary stent system was one of only two drug-eluting stent products available in the U.S. Additional competitors have recently entered the U.S. drug-eluting stent market, including the introduction of the Endeavor® Zotarolimus-Eluting Coronary Stent by Medtronic, Inc. and the launch of Abbott Laboratories' XIENCE V™ drug-eluting stent system, which has put increased pressure on our U.S. drug-eluting stent system sales and may negatively impact our market share and average selling prices. Our share of the U.S. drug-eluting stent market, as well as unit prices, may continue to be impacted as the market has become more competitive.

Our industry is experiencing greater scrutiny and regulation by governmental authorities, which has led to certain costs and business distractions as we respond to inquiries and comply with new regulations, and may lead to greater governmental regulation in the future.

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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. Recently, we have received inquiries from Congress and other government agencies regarding, among other things, the conduct of clinical trials, conflicts of interests and financial arrangements with health care providers and consultants, and product promotional practices. We are cooperating with the requests, which cooperation involves document production costs, human resources costs and diversion of management and employee focus. In addition, certain states, including Massachusetts, where we are headquartered, have recently passed or are considering legislation restricting our interactions with health care providers and requiring disclosure of many payments to them, compliance with which will require significant human resource and financial costs as well as complex information technology systems. The Federal government has recently introduced similar legislation, which may or may not preempt state laws. Recent Supreme Court case law has clarified that the FDA's authority over medical devices preempts state tort laws, but legislation has been introduced at the Federal level to allow state intervention, which could lead to increased and inconsistent regulation at the state level. We anticipate that the government will continue to scrutinize our industry closely and that we will be subject to more rigorous regulation by governmental authorities in the future.

Because we derive a significant amount of our net sales from our cardiovascular businesses, changes in market or regulatory conditions that impact those businesses or our inability to develop non-cardiovascular products, could have a material adverse effect on our business, financial condition or results of operations.

During 2008, we derived approximately 79 percent of our net sales from our Cardiovascular group, which includes our CRM, Cardiovascular and Neurovascular businesses. As a result, our sales growth and profitability from our cardiovascular businesses may be limited by risks and uncertainties related to market or regulatory conditions that impact those businesses. If the worldwide CRM market and the U.S. ICD market do not return to their historical growth rates or we are unable to regain CRM market share or further increase CRM net sales, it may adversely affect our business, financial condition or results of operations. Net sales from drug-eluting coronary stent systems represented approximately 20 percent of our consolidated net sales for 2008. Although we have seen a recent uptick in overall percutaneous coronary intervention (PCI) volumes, there can be no assurance that percutaneous coronary intervention procedures or the overall drug-eluting stent market will recover to previous levels, which may have a material adverse effect on our business. Similarly, our inability to develop products and technologies successfully in addition to our drug-eluting stent and CRM technologies could further expose us to fluctuations and uncertainties in these markets.

Should we be unable to resolve the remaining outstanding issues related to our FDA warning letters in a timely manner, our business, financial condition and results of operations, and physician perception of our products could be materially adversely affected.

We are currently taking remedial action in response to certain deficiencies of our quality systems as cited by the FDA in its warning letters to us. In January 2006, legacy Boston Scientific received a corporate warning letter from the FDA notifying us of serious regulatory problems at three of our facilities and advising us that our corrective action plan relating to three site-specific warning letters issued to us in 2005 was inadequate. During 2008, the FDA reinspected a number of our facilities and, in October 2008, informed us that our quality system is now in substantial compliance with its Quality System Regulations. The FDA has approved all of our requests for final approval of Class III product submissions previously on hold due to the corporate warning letter, and has approved all of our currently eligible requests for Certificates to Foreign Governments (CFGs). The corporate warning letter remains in place pending final remediation of certain Medical Device Report (MDR) filing issues. This remediation has resulted and may continue to result in medical device and vigilance reporting, which could adversely impact physician perception of our products.

We may face enforcement actions in connection with these FDA warning letters, including injunctive relief, consent decrees or civil fines. While we are working with the FDA to resolve the remaining outstanding

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issues, this work has required and will continue to require the dedication of significant incremental internal and external resources and has resulted in adjustments to the product launch schedules of certain products and the decision to discontinue certain other product lines over time. There can be no assurances regarding the length of time or cost it will take us to resolve these issues to the satisfaction of the FDA. In addition, if our remedial actions are not satisfactory to the FDA, we may have to devote additional financial and human resources to our efforts and the FDA may take further regulatory actions against us including, but not limited to, seizing our product inventory, obtaining a court injunction against further marketing of our products, assessing civil monetary penalties or imposing a consent decree on us, which could result in further regulatory constraints, including the governance of our quality system by a third party. If we, or our manufacturers, fail to adhere to quality system regulations or ISO requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

We are subject to extensive 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, development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA pursuant to the Federal Food, Drug, and Cosmetic Act (FDC Act), by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDC Act, medical devices must receive FDA clearance or approval before they can be commercially marketed in the U.S. In 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 that have added or are expected to add to the delays and uncertainties associated with new product releases, as well as the clinical and regulatory costs of supporting those releases. Even after products have received marketing approval or clearance, product approvals and clearances by the FDA can be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. There can be no assurance that we will receive the required clearances for new products or modifications to existing products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post-market study requirements.

In addition, regulations regarding the development, manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, those changes might have on our business. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances, seizures or recalls of products, operating restrictions and/or criminal prosecution. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products or the withdrawal of product approval by the FDA could have a material adverse effect on our business, financial

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condition or results of operations.

We may not meet regulatory quality standards applicable to our manufacturing and quality processes, which could have an adverse effect on our business, financial condition and results of operations.

As a medical device manufacturer, we are required to register with the FDA and are subject to periodic inspection by the FDA for compliance with its Quality System Regulation (QSR) requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the Federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications.

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

The medical device market in which we primarily participate is in large part technology driven. Physician customers, particularly in interventional cardiology, have historically moved quickly to new products and new technologies. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. However, intellectual property litigation to defend or create market advantage is inherently complex and unpredictable. Furthermore, appellate courts frequently overturn lower court patent decisions.

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

Several third parties have asserted that our current and former stent systems or other products infringe patents owned or licensed by them. We have similarly asserted that stent systems or other products sold by our competitors infringe patents owned or licensed by us. Adverse outcomes in one or more of these proceedings against us could limit our ability to sell certain stent products in certain jurisdictions, or reduce our operating margin on the sale of these products. In addition, damage awards related to historical sales could be material.

Patents and other proprietary rights are and will continue to be essential to our business, and our ability to compete effectively with other companies will be dependent upon the proprietary nature of our technologies. We rely upon trade secrets, know-how, continuing technological innovations, strategic alliances and licensing opportunities to develop, maintain and strengthen our competitive position. We pursue a policy of generally obtaining patent protection in both the U.S. and abroad for patentable subject matter in our proprietary devices and attempt to review third-party patents and patent applications to the extent publicly available in order to develop an effective patent strategy, avoid infringement of third-party patents, identify licensing opportunities and monitor the patent claims of others. We currently own numerous U.S. and foreign patents and have numerous patent applications pending. We also are party to various license agreements pursuant to which patent rights have been obtained or granted in consideration for cash, cross-licensing rights or royalty payments. No assurance can be made that any pending or future patent applications will result in the issuance of patents, that any current or future patents issued to, or licensed by, us will not be challenged or circumvented by our competitors, or that our patents will not be found invalid.

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In addition, we may have to take legal action in the future to protect our patents, trade secrets or know-how or to assert them against claimed infringement by others. Any legal action of that type could be costly and time consuming and no assurances can be made that any lawsuit will be successful. We are generally involved as both a plaintiff and a defendant in a number of patent infringement and other intellectual property-related actions. We are involved in numerous patent-related claims with our competitors, including Johnson & Johnson.

The invalidation of key patents or proprietary rights that we own, or an unsuccessful outcome in lawsuits to protect our intellectual property, could have a material adverse effect on our business, financial position or results of operations.

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

We operate in an industry that is susceptible to significant intellectual property litigation and, in recent years, it has been common for companies in the medical device field to aggressively challenge the patent rights of other companies in order to prevent the marketing of new devices. We are currently the subject of various patent litigation proceedings and other proceedings described in more detail under Item 3. Legal Proceedings. Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. Pending or future patent litigation may result in significant royalty or other payments or injunctions that can prevent the sale of products and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, we may be required to obtain a license on terms which may not be favorable to us, if at all. If we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected.

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

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

We are currently the subject of numerous product liability claims and other litigation, including private securities litigation and shareholder derivative suits including, but not limited to, the claims and litigation described under Item 3. Legal Proceedings. Our efforts to settle product liability cases, including Guidant litigation, may not be successful.

The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, including not only actual damages, but also punitive damages. The magnitude of the potential losses relating to these lawsuits may remain unknown for substantial periods of time. In addition, the cost to defend against any future litigation may be significant. Further, we are substantially self-insured with respect to product liability claims. We maintain insurance policies providing limited coverage against securities claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims and adverse decisions. Product liability claims, product recalls, securities litigation and other litigation in the future,

regardless of the outcome, could have a material adverse effect on our financial position, results of operations or liquidity.

We may not be successful in our strategic acquisitions of, investments in or alliances with, other companies and businesses, which have been a significant source of historical growth for us.

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 continue to grow our business significantly or may record asset impairment charges in the future. These acquisitions, investments and alliances have been significant sources of growth for us. The success of any acquisition, investment or alliance that we may undertake 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;
- the strength of the other companies' underlying technology and ability to execute;
- regulatory approvals and reimbursement levels of the acquired products and related procedures;
- intellectual property and litigation related to these technologies; and
- our ability to successfully integrate the acquired company or business with our existing business, including the ability to adequately fund acquired in-process research and development projects.

If we are unsuccessful in our acquisitions, investments and alliances, we may be unable to continue to grow our business significantly or may record asset impairment charges in the future.

We may not realize the expected benefits from our 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 early 2009, we announced our Plant Network Optimization plan, aimed at simplifying our plant network, reducing our manufacturing costs and improving gross margins. Activities under the plan 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 in connection with our plant network optimization efforts or a material decrease in employee morale or productivity could negatively affect our business, 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 plant network optimization program will result in charges and expenses that will 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.

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

We had total debt of $6.745 billion at December 31, 2008, attributable in large part to our acquisition of Guidant. We expect to use a significant portion of our operating cash flows to reduce our outstanding debt obligations over the next several years. We are examining all of our operations in order to identify cost improvement measures that will better align operating expenses with expected revenue levels and cash

flows, and have sold certain non-strategic assets and have implemented other strategic initiatives to generate proceeds that would be available for debt repayment. There can be no assurance that these initiatives will be effective in reducing expenses sufficiently to enable us to repay our indebtedness. 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, particularly in light of the current tightening in the credit markets.

Our credit ratings are currently below investment grade, which could have an adverse impact on our ability to borrow funds or issue debt securities in the public capital markets.

Our current credit ratings from Standard & Poor's Rating Services (S&P) and Fitch Ratings are BB+, and our credit rating from Moody's Investor Service is Ba1. All of these are below investment grade ratings and the ratings outlook by S&P and Moody's is currently negative. Our inability to regain investment grade credit ratings could impact our ability to obtain financing on terms reasonably acceptable to us, and increase the cost of borrowing funds in the future.

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 a commercially viable product.

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 divisions, particularly in our drug-eluting stent and CRM programs. We expect to launch our next-generation everolimus-based stent system, the PROMUS® Element™ platinum chromium coronary stent, in Europe in late 2009 and in the United States in mid-2012, subject to regulatory approval. In addition, we expect to continue to invest in our CRM technologies, including our LATITUDE® Patient Management System and our next-generation products and technologies. If we are unable to develop and launch these and other products as anticipated, our ability to maintain or expand our market position in the drug-eluting stent and CRM markets may be materially adversely impacted.

Further, we expect to invest selectively in areas outside of drug-eluting stent and CRM technologies. There can be no assurance that these or other technologies will achieve technological feasibility, obtain regulatory approval or gain market acceptance. A delay in the development or approval of these technologies or our decision to reduce funding of these projects may adversely impact the contribution of these technologies to our future growth.

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

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 market is 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 have historically included Johnson & Johnson (including its subsidiary, Cordis Corporation) and Medtronic, Inc. (including its subsidiary, Medtronic AVE, Inc.). Through our acquisition of Guidant, Abbott has become a primary competitor of ours in the interventional cardiology market and we now compete with St. Jude

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Medical, Inc. in the CRM and neuromodulation markets. In addition, we face competition from 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, as well as from non-medical device companies, including pharmaceutical companies, which may offer alternative therapies for disease states intended to be treated using our products.

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

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

Sales outside the U.S. accounted for approximately 43 percent of our net sales in 2008. Additionally, a significant percentage of our future growth is expected to come from international operations. As a result, our sales growth and profitability from our international operations may be limited by risks and uncertainties related to economic conditions in these regions, foreign currency fluctuations, interest rate fluctuations, regulatory and reimbursement approvals, competitive offerings, infrastructure development, rights to intellectual property and our ability to implement our overall business strategy. Further, international markets are also being affected by economic pressure to contain reimbursement levels and healthcare costs; and international markets may also be impacted by foreign government efforts to understand healthcare practices and pricing in other countries, which could result in increased pricing transparency across geographies and pressure to harmonize reimbursement and ultimately reduce the selling prices of our products. The trend in countries around the world, including Japan, toward more stringent regulatory requirements for product clearance, changing reimbursement models and more rigorous inspection and enforcement activities has generally caused or may cause medical device manufacturers to experience more uncertainty, delay, risk and expense. In addition, most international jurisdictions have adopted regulatory approval and periodic renewal requirements for medical devices, and we must comply with these requirements in order to market our products in these jurisdictions. Any significant changes in the competitive, political, legal, regulatory, reimbursement or economic environment where we conduct international operations may have a material impact on our business, financial condition or results of operations.

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 could have a material adverse effect on our business, financial condition or results of operations.

Major third-party payors for hospital services in the U.S. and abroad continue to work to contain healthcare costs. The introduction of cost containment incentives, combined with closer scrutiny of healthcare expenditures by both private health insurers and employers, has resulted in increased discounts and contractual adjustments to hospital charges for services performed and has shifted services between inpatient and outpatient settings. Initiatives to limit the increase of healthcare costs, including price regulation, are also underway in several countries in which we do business. Hospitals or physicians may respond to these cost-containment pressures by substituting lower cost products or other therapies for our products. In connection with Guidant's product recalls, certain third-party payors have sought, and others may seek, recourse against us for amounts previously reimbursed.

Consolidation in the healthcare industry could lead to 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 in turn has resulted in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to consolidate purchasing decisions for some of our hospital customers. We expect that market demand, government regulation, third-party reimbursement policies, government contracting requirements, and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers and competitors, which may reduce competition, exert further downward pressure on the prices of our products and adversely impact our business, financial condition or results of operations.

We rely on external manufacturers to supply us with materials and components used in our products and external providers to sterilize our products, and any disruption in sources of supply or any ability to sterilize our products could adversely impact our production efforts and could materially adversely affect our business, financial condition or results of operations.

We vertically integrate operations where integration provides significant cost, supply or quality benefits. However, we purchase many of the materials and components used in manufacturing our products, some of which are custom made. Certain supplies are purchased from single-sources due to quality considerations, expertise, costs or constraints resulting from regulatory requirements. We may not be able to establish additional or replacement suppliers for certain components or materials in a timely manner largely due to the complex nature of our and many of our suppliers' manufacturing processes. Production issues, including capacity constraint; quality issues affecting us or our suppliers; an inability to develop and validate alternative sources if required; or a significant increase in the price of materials or components could adversely affect our operations and financial condition.

In addition, our products require sterilization prior to sale and we rely primarily on third party vendors to perform this service. To the extent our third party sterilizers are unable to process our products, whether due to raw material, 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

There are no unresolved written comments that were received from the SEC staff 180 days or more before the end of our fiscal year relating to our periodic or current reports under the Securities Exchange Act of 1934.

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ITEM 2. PROPERTIES

Our world headquarters are located in Natick, Massachusetts, with additional support provided from regional headquarters located in Tokyo, Japan and Paris, France. As of December 31, 2008, our manufacturing, research, distribution and other key facilities totaled approximately 10 million square feet, seven million of which are owned by us, with the balance under lease arrangements. As of December 31, 2008, our principal manufacturing and technology centers were located in Minnesota, California, Florida, Indiana, Utah, Washington, Ireland, Costa Rica and Puerto Rico. Our products are distributed internationally from customer fulfillment centers in Massachusetts, The Netherlands and Japan. As of December 31, 2008, we maintained 17 manufacturing facilities; nine in the U.S.; one in Puerto Rico; five in Ireland; and two in Costa Rica; as well as various distribution and technology centers. Many of these facilities produce and manufacture products for more than one of our divisions and include research facilities.

The following is a summary of our facilities (in square feet):

	Owned	Leased	Total
Domestic	5,486,831	1,542,026	7,028,857
Foreign	1,385,599	1,418,694	2,804,293
	6,872,430	2,960,720	9,833,150

ITEM 3. LEGAL PROCEEDINGS

See Note L—Commitments and Contingencies to our 2008 consolidated financial statements included in Item 8 of this Annual Report.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

PART II

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

Our common stock is traded on the New York Stock Exchange (NYSE) under the symbol "BSX." Our annual CEO certification for the previous year has been submitted to the NYSE.

The following table provides the market range for our common stock for each of the last eight quarters based on reported sales prices on the NYSE.

	High	Low
2008		
First Quarter	$ 13.21	$ 10.98
Second Quarter	14.11	12.23
Third Quarter	13.89	11.75
Fourth Quarter	11.47	5.48
2007		
First Quarter	$ 18.59	$ 14.22
Second Quarter	16.67	14.59
Third Quarter	15.72	12.16
Fourth Quarter	15.03	11.47

We did not pay a cash dividend in 2008, 2007 or 2006. We currently do not intend to pay dividends, and intend to retain all of our earnings to repay indebtedness and invest in the continued growth of our business. We may consider declaring and paying a dividend in the future; however, there can be no assurance that we will do so.

At February 20, 2009, there were 16,934 record holders of our common stock.

The closing price of our common stock on February 20, 2009 was $8.18.

We did not repurchase any of our common stock in 2008, 2007 or 2006. There are approximately 37 million remaining shares authorized for purchase under our share repurchase program. We currently do not anticipate material repurchases in 2009.

Stock Performance Graph

The graph below compares the five-year total return to stockholders on our common stock with the return of the Standard & Poor's 500 Stock Index and the Standard & Poor's Healthcare Equipment Index. The graph assumes $100 was invested in our common stock and in each of the named indices on January 1, 2004, and that all dividends were reinvested.

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ITEM 6. SELECTED FINANCIAL DATA

FIVE-YEAR SELECTED FINANCIAL DATA
(in millions, except per share data)

Operating Data

Year Ended December 31,	2008	2007	2006	2005	2004
Net sales	$ 8,050	$ 8,357	$ 7,821	$ 6,283	$ 5,624
Gross profit	5,581	6,015	5,614	4,897	4,332
Selling, general and administrative expenses	2,589	2,909	2,675	1,814	1,742
Research and development expenses	1,006	1,091	1,008	680	569
Royalty expense	203	202	231	227	195
Amortization expense	543	620	474	142	112
Goodwill and intangible asset impairment charges	2,790	21	56	10	
Acquisition-related milestone	(250)				
Purchased research and development	43	85	4,119	276	65
Gain on divestitures	(250)				
Loss on assets held for sale		560			
Restructuring charges	78	176			
Litigation-related charges	334	365		780	75
Total operating expenses	7,086	6,029	8,563	3,929	2,758
Operating (loss) income	(1,505)	(14)	(2,949)	968	1,574
(Loss) income before income taxes	(2,031)	(569)	(3,535)	891	1,494
Net (loss) income	(2,036)	(495)	(3,577)	628	1,062
Net (loss) income per common share:					
Basic	$ (1.36)	$ (0.33)	$ (2.81)	$ 0.76	$ 1.27
Assuming dilution	$ (1.36)	$ (0.33)	$ (2.81)	$ 0.75	$ 1.24
Weighted-average shares outstanding — basic	1,498.5	1,486.9	1,273.7	825.8	838.2
Weighted-average shares outstanding — assuming dilution	1,498.5	1,486.9	1,273.7	837.6	857.7

Balance Sheet Data

As of December 31,	2008	2007	2006	2005	2004
Cash, cash equivalents and marketable securities	$ 1,641	$ 1,452	$ 1,668	$ 848	$ 1,640
Working capital*	2,219	2,691	3,399	1,152	684
Total assets	27,139	31,197	30,882	8,196	8,170
Borrowings (long-term and short-term)	6,745	8,189	8,902	2,020	2,367
Stockholders' equity	13,174	15,097	15,298	4,282	4,025
Book value per common share	$ 8.77	$ 10.12	$ 10.37	$ 5.22	$ 4.82

*In 2008 and 2007, we reclassified certain assets and liabilities to the "Assets held for sale" and "Liabilities associated with assets held for sale" captions in our consolidated balance sheets. These assets and liabilities are labeled as 'current' to give effect to the short term nature of those assets and liabilities that were divested in the first quarter of 2008 in connection with the sale of certain of our businesses, or assets that are expected to be sold in 2009. We have reclassified 2007 balances for comparison purposes on the face of the consolidated balance sheets, and restated both

2007 and 2006 in the working capital metric above. We have not restated working capital for 2005 or 2004, as we did not have assets and liabilities held for sale prior to 2006, nor are they presented on the face of the consolidated balance sheets.

See also the notes to our consolidated financial statements included in Item 8 of this Annual Report.

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

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

Introduction

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 business strategy is to lead global markets for less-invasive medical devices by developing and delivering products and therapies that address unmet patient needs, provide superior clinical outcomes and demonstrate compelling economic value. We intend to achieve leadership, drive profitable sales growth and increase shareholder value by focusing on:

- Customers
- Innovation
- Quality
- People
- Financial Strength

In the first quarter of 2008, we completed the divestiture of certain non-strategic businesses. Our operating results for the years ended December 31, 2007 and 2006 include a full year of results of these businesses. Our operating results for the year ended December 31, 2008 include the results of these businesses through the date of separation. We are involved in several post-closing separation activities through transition service agreements, some from which we continue to generate net sales. These transition service agreements expire throughout 2009 and the first half of 2010. Refer to the Strategic Initiatives section and Note F – Divestitures and Assets Held for Sale to our consolidated financial statements contained in Item 8 of this Annual Report for a description of these business divestitures.

On April 21, 2006, we consummated the acquisition of Guidant Corporation. With this acquisition, we became a major provider in the cardiac rhythm management (CRM) market, enhancing our overall competitive position and long-term growth potential, and further diversifying our product portfolio. We also now share certain drug-eluting stent technology with Abbott Laboratories, which gives us access to a second drug-eluting stent program, and complements our TAXUS® stent system program. See Note D- Acquisitions to our 2008 consolidated financial statements included in Item 8 of this Annual Report for further details on the Guidant acquisition and Abbott transaction. Our operating results for the years ended December 31, 2008 and 2007 include a full year of results of our CRM business that we acquired from Guidant. Our operating results for the year ended December 31, 2006 include the results of the CRM business beginning on the date of acquisition. We have included supplemental pro forma financial information in Note D – Acquisitions to our 2008 consolidated financial statements included in Item 8 of this Annual Report which gives effect to the acquisition as though it had occurred at the beginning of 2006.

Executive Summary

Financial Highlights and Trends

Net sales in 2008 were $8.050 billion, which included sales from divested businesses of $69 million, as compared to net sales of $8.357 billion in 2007, which included sales from divested business of $553 million, a decrease of $307 million or four percent. Foreign currency fluctuations increased our net sales by $213 million in 2008, as compared to 2007. Excluding the impact of foreign currency and sales from divested businesses, our net sales were flat with the prior year.

Worldwide net sales of our CRM products increased eight percent in 2008, including an eight percent

increase in our U.S. CRM net sales and a seven percent increase in international CRM product net sales. These increases were driven by multiple product launches in both our U.S. and international markets, highlighted by the launch of our COGNIS® cardiac resynchronization therapy defibrillator (CRT-D) system and our TELIGEN® implantable cardioverter defibrillator (ICD) system. In addition, net sales from our Endosurgery businesses grew eight percent and our Neuromodulation division increased net sales by twenty percent in 2008, as compared to 2007. Partially offsetting these increases, was a decline in worldwide net sales from our Cardiovascular division of four percent during 2008, due principally to the impact of new competition in the U.S. drug-eluting stent market. However, we realized increased U.S. drug-eluting stent market share in the fourth quarter of 2008, as compared to the third quarter of 2008, and exited the year with an estimated 49 percent share of the U.S. drug-eluting stent market for the month of December.

Our reported net loss for 2008 was $2.036 billion, or $1.36 per share, on approximately 1.5 billion weighted-average shares outstanding, as compared to a net loss for 2007 of $495 million, or $0.33 per share, also on 1.5 billion weighted-average shares outstanding. Our reported results for 2008 included goodwill and intangible asset impairment charges and acquisition-, divestiture-, litigation- and restructuring-related net charges; and discrete tax items of $2.796 billion (after-tax), or $1.87 per share, consisting of:

- $2.756 billion ($2.790 billion pre-tax) of goodwill and intangible asset impairment charges, associated primarily with a write-down of goodwill;
- a $184 million gain ($250 million pre-tax) related to the receipt of an acquisition-related milestone payment from Abbott;
- $44 million ($43 million pre-tax) of net purchased research and development charges, associated primarily with the acquisitions of Labcoat, Ltd. and CryoCor, Inc.;
- $100 million of costs ($133 million pre-tax) associated with our on-going expense and head count reduction initiatives;
- a $185 million gain ($250 million pre-tax), associated with the sale of certain non-strategic businesses;
- $54 million of net losses ($80 million pre-tax) in connection with the sale of certain non-strategic investments;
- $238 million of litigation-related charges ($334 million pre-tax) resulting primarily from a ruling by a federal judge in a patent infringement case brought against us by Johnson & Johnson; and
- $27 million of discrete tax benefits related to certain tax positions associated with prior period acquisition-, divestiture-, litigation- and restructuring-related charges.

During the fourth quarter of 2008, we recorded a $2.613 billion goodwill impairment charge associated with our acquisition of Guidant. The decline in our stock price and our market capitalization during the fourth quarter created an indication of potential impairment of our goodwill balance; therefore, we performed an interim impairment test. Key factors contributing to the impairment charge included disruptions in the credit and equity markets, and the resulting impacts to weighted-average costs of capital, and changes in CRM market demand relative to our original assumptions at the time of acquisition. Refer to Note E – Goodwill and Other Intangible Assets to our consolidated financial statements contained in Item 8 of this Annual Report for more information.

Our reported results for 2007 included goodwill and intangible asset impairment charges and acquisition-, divestiture-, litigation- and restructuring-related charges of $1.110 billion (after-tax), or $0.74 per share. Refer to Liquidity and Capital Resources for a discussion of these charges.

We continued to generate substantial cash flow during 2008. Cash provided by operating activities was $1.216 billion in 2008 as compared to $934 million in 2007. At December 31, 2008, we had total debt of $6.745 billion, cash and cash equivalents of $1.641 billion and working capital of $2.219 billion. During 2008, we prepaid $1.425 billion of debt under our term loan and our credit facility secured by our U.S. trade receivables and, in February 2009, prepaid an additional $500 million. As a result, our next scheduled debt maturity is $325 million due in April 2010.

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Strategic Initiatives

In 2007, we announced several new initiatives designed to enhance short- and long-term shareholder value, including the restructuring of several of our businesses and product franchises; the sale of non-strategic businesses and investments; and significant expense and head count reductions. Our goal was, and continues to be, to better align expenses with revenues, while preserving our ability to make needed investments in quality, research and development (R&D), capital improvements and our people that are essential to our long-term success. These initiatives have helped to provide better focus on our core businesses and priorities, which we believe will strengthen Boston Scientific for the future and position us for increased, sustainable and profitable sales growth. The execution of this plan enabled us to reduce R&D and selling, general and administrative (SG&A) expenses by an annualized run rate of approximately $500 million exiting 2008.

Restructuring

In October 2007, our Board of Directors approved, and we committed to, an expense and head count reduction plan, which resulted in the elimination of approximately 2,300 positions worldwide. We initiated activities under the plan in the fourth quarter of 2007 and expect to be substantially complete worldwide in 2010. Refer to Results of Operations and Note H – Restructuring-related Activities to our consolidated financial statements included in Item 8 of this Annual Report for information on restructuring-related activities and estimated costs.

Plant Network Optimization

On January 27, 2009, our Board of Directors approved, and we committed to, a plant network optimization plan, which is intended to simplify our manufacturing plant structure by transferring certain production lines from one facility to another and by closing certain facilities. The plan is a complement to our previously announced expense and head count reduction plan, and is intended to improve overall gross profit margins. Activities under the plan will be initiated in 2009 and are expected to be substantially completed by the end of 2011. Refer to Results of Operations and Note H – Restructuring-related Activities to our consolidated financial statements included in Item 8 of this Annual Report for information on restructuring-related activities and estimated costs.

Divestitures

During 2007, we determined that our Auditory, Vascular Surgery, Cardiac Surgery, Venous Access and Fluid Management businesses were no longer strategic to our on-going operations. Therefore, we initiated the process of selling these businesses in 2007, and completed their sale in the first quarter of 2008, as discussed below. We received pre-tax proceeds of approximately $1.3 billion from the sale of these businesses and our TriVascular Endovascular Aortic Repair (EVAR) program, and eliminated 2,000 positions in connection with these divestitures.

In January 2008, we completed the sale of a controlling interest in our Auditory business and drug pump development program, acquired with Advanced Bionics Corporation in 2004, to entities affiliated with the principal former shareholders of Advanced Bionics for an aggregate purchase price of $150 million in cash. In connection with the sale, we recorded a loss of $367 million (pre-tax) in 2007, attributable primarily to the write-down of goodwill. In addition, we recorded a tax benefit of $7 million during 2008 in connection with the closing of the transaction. Also in January 2008, we completed the sale of our Cardiac Surgery and Vascular Surgery businesses for net cash proceeds of approximately $700 million. In connection with the sale, we recorded a pre-tax loss of $193 million in 2007, representing primarily a write-down of goodwill. In addition, we recorded a tax expense of $19 million during 2008 in connection with the closing of the transaction. In February 2008, we completed the sale of our Fluid Management and Venous Access businesses for net cash proceeds of approximately $400 million. We recorded a pre-tax gain of $234 million ($161 million after-tax) during 2008 associated with this transaction.

Further, in March 2008, we sold our EVAR program obtained in connection with our 2005 acquisition of TriVascular, Inc. for $30 million in cash. We discontinued our EVAR program in 2006. In connection with the sale, we recorded a pre-tax gain of $16 million ($36 million after-tax) during 2008.

During 2007, in connection with our strategic initiatives, we announced our intent to sell the majority of our investment portfolio in order to monetize those investments determined to be non-strategic. In June 2008, as part of our initiative to monetize non-strategic investments, we signed separate definitive agreements with Saints Capital and Paul Capital Partners to sell the majority of our investments in, and notes receivable from, certain publicly traded and privately held entities for gross proceeds of approximately $140 million. In connection with these agreements, we received proceeds of $95 million during 2008. In addition, we received $54 million of proceeds from other transactions to monetize certain other non-strategic investments and notes receivable. We recorded net pre-tax losses of approximately $80 million during 2008 related to these monetization initiatives and the write-down of certain non-strategic investments. We expect to receive $45 million of remaining proceeds from the Saints and Paul transactions during 2009, and do not expect to record significant gains or losses in 2009 related to these definitive agreements. Refer to our Other, net discussion, as well as Note G – Investments and Notes Receivable to our consolidated financial statements included in Item 8 of this Annual Report for more information on our investment portfolio activity.

Corporate Warning Letter

In January 2006, legacy Boston Scientific received a corporate warning letter from the U.S. Food and Drug Administration (FDA) notifying us of serious regulatory problems at three of our facilities and advising us that our corporate-wide corrective action plan relating to three site-specific warning letters issued to us in 2005 was inadequate. We have identified solutions to the quality system issues cited by the FDA and have made significant progress in transitioning our organization to implement those solutions. During 2008, the FDA reinspected a number of our facilities and, in October 2008, informed us that our quality system is now in substantial compliance with its Quality System Regulations. The FDA has approved all of our requests for final approval of Class III product submissions previously on hold due to the corporate warning letter and has approved all currently eligible requests for Certificates to Foreign Governments (CFGs). Since October 2008, we have received approval to market the following new products in the U.S.:

- our TAXUS® Express2® Atom™ paclitaxel-eluting coronary stent system, designed for treating small coronary vessels;
- our TAXUS® Liberté® paclitaxel-eluting coronary stent system, our second-generation drug-eluting stent system;
- our Carotid WALLSTENT® Monorail® Endoprosthesis, a less-invasive alternative to surgery for treating carotid artery disease;
- our Apex™ Percutaneous Transluminal Coronary Angioplasty (PTCA) dilatation catheter, for treating the most challenging atherosclerotic lesions;
- our Express® SD Renal Monorail® stent system, the first low-profile, pre-mounted stent approved in the U.S. for use in renal arteries; and
- our Sterling™ Monorail® and Over-the-Wire balloon dilatation catheter for use in the renal and lower extremity arteries.

The FDA also approved the use of our TAXUS® Express2® paclitaxel-eluting coronary stent system for the treatment of in-stent restenosis1 (ISR) in bare-metal stents, the first ISR approval granted by the FDA.

The corporate warning letter remains in place pending final remediation of certain Medical Device Report (MDR) filing issues, which we are actively working with the FDA to resolve. This remediation has resulted and may continue to result in incremental medical device and vigilance reporting, which could adversely impact physician perception of our products.

1 In-stent restenosis is re-narrowing of the vessel inside a stent.

Business and Market Overview

Cardiac Rhythm Management

We estimate that the worldwide CRM market approximated $10.8 billion in 2008, as compared to approximately $10.0 billion in 2007, and estimate that U.S. ICD system sales represented approximately 40 percent of the worldwide CRM market in both years. Worldwide CRM market growth rates over the past three years, including the U.S. ICD market, have been below those experienced in prior years, resulting primarily from previous industry field actions and from a lack of new indications for use. In 2008, however, we began to see renewed growth of the worldwide CRM market with steadily increasing implant volumes.

Net sales of our CRM products represented approximately 28 percent of our consolidated net sales for 2008 and 25 percent in 2007. The following are the components of our worldwide CRM product sales:

(in millions)	Year Ended December 31, 2008			Year Ended December 31, 2007		
	U.S.	International	Total	U.S.	International	Total
ICD systems	$ 1,140	$ 541	$ 1,681	$ 1,053	$ 489	$ 1,542
Pacemaker systems	340	265	605	318	264	582
	$ 1,480	$ 806	$ 2,286	$ 1,371	$ 753	$ 2,124

Our U.S. sales of CRM products in 2008 increased $109 million, or eight percent, as compared to 2007. Our U.S. sales benefited from growth in the U.S. CRM market and from the successful launch of our next-generation COGNIS® CRT-D and TELIGEN® ICD systems, as well as the launches of our CONFIENT® ICD system, the LIVIAN® CRT-D system, and the ALTRUA™ family of pacemaker systems. We experienced ten percent growth in U.S. CRM sales during each of the second, third and fourth quarters of 2008, largely as a result of these new product launches.

Our international CRM product sales increased $53 million, or seven percent in 2008, as compared to 2007, due primarily to an increase in the size of the international ICD market. However, our net sales and market share in Japan have been negatively impacted as we move to a direct sales model for our CRM products in Japan and, until we fully implement this model, our net sales and market share in Japan may continue to be negatively impacted.

During 2008, we received more than a dozen new CRM product approvals. We will continue to execute on our product pipeline and expect to begin offering our LATITUDE® Patient Management System in certain European countries in 2009. This technology, which enables physicians to monitor device performance remotely while patients are in their homes, is a key component of many of our implantable device systems. We also plan to launch our next-generation pacemaker, the INGENIO™ pacemaker system, in the U.S., our EMEA (Europe/Middle East/Africa) region and certain Inter-Continental countries in the first half of 2011. We believe that these launches position us for sustainable growth within the worldwide CRM market.

Net sales from our CRM products represent a significant source of our overall net sales. Therefore, increases or decreases in net sales from our CRM products could have a significant impact on our results of operations. While we believe that the size of the CRM market will increase above existing levels, there can be no assurance as to the timing or extent of this increase. We believe we are well positioned within the CRM market; however, the following variables may impact the size of the CRM market and/or our share of that market:

- our continued ability to improve the trust and confidence of the implanting physician community, the referring physician community and prospective patients in our technology;

- future product field actions or new physician advisories by us or our competitors;

- our ability to successfully launch next-generation products and technology;
- the successful conclusion and positive outcomes of on-going clinical trials that may provide opportunities to expand indications for use;
- variations in clinical results, reliability or product performance of our and our competitors' products;
- delayed or limited regulatory approvals and unfavorable reimbursement policies;
- our ability to retain key members of our sales force and other key personnel;
- new competitive launches; and
- average selling prices and the overall number of procedures performed.

Coronary Stents

The size of the coronary stent market is driven primarily by the number of percutaneous coronary intervention (PCI) procedures performed, as well as the percentage of those that are actually stented; the number of devices used per procedure; average drug-eluting stent selling prices; and the drug-eluting stent penetration rate (a measure of the mix between bare-metal and drug-eluting stents used across procedures). We estimate that the worldwide coronary stent market approximated $5.0 billion in 2008 and 2007, and estimate that drug-eluting stents represented approximately 80 percent of the dollar value of worldwide coronary stent market sales in both years. Uncertainty regarding the efficacy of drug-eluting stents, as well as the increased perceived risk of late stent thrombosis[2] following the use of drug-eluting stents, contributed to a decline in the worldwide drug-eluting stent market size during 2006 and 2007. However, data addressing this risk and supporting the safety of drug-eluting stent systems positively affected trends in the growth of the drug-eluting stent market in 2008, as referring cardiologists regained confidence in this technology.

Net sales of our coronary stent systems represented approximately 23 percent of our consolidated net sales for 2008 and 24 percent in 2007. We are the only company in the industry to offer a two-drug platform strategy with our TAXUS® paclitaxel-eluting stent system and the PROMUS® everolimus-eluting stent system. The following are the components of our worldwide coronary stent system sales:

(in millions)	Year Ended December 31, 2008			Year Ended December 31, 2007		
	U.S.	International	Total	U.S.	International	Total
TAXUS®	$ 621	$ 697	$ 1,318	$ 1,006	$ 754	$ 1,760
PROMUS®	212	104	316		28	28
Drug-eluting	833	801	1,634	1,006	782	1,788
Bare-metal	88	129	217	104	135	239
	$ 921	$ 930	$ 1,851	$ 1,110	$ 917	$ 2,027

During 2008, U.S. sales of our drug-eluting stent systems declined $173 million, or 17 percent, due primarily to an increase in competition following recent competitive launches. We believe that our average share of the

2 Late stent thrombosis is the formation of a clot, or thrombus, within the stented area one year or more after implantation of the stent.

U.S. drug-eluting stent market declined to 46 percent during 2008, as compared to 55 percent in 2007. In addition, pricing pressure resulted in a reduction in the average selling price of our TAXUS® stent system in the U.S. by approximately five percent as compared to the prior year. However, increasing penetration rates have had a positive effect on the size of the U.S. drug-eluting stent market. Average drug-eluting stent penetration rates in the U.S. were 68 percent during 2008 (exiting 2008 at 73 percent for the month of December), as compared to 65 percent during 2007 (exiting 2007 at 62 percent for the month of December). We believe this is a strong indicator that the recovery of the U.S. drug-eluting stent market is continuing and the market is strengthening. In addition, the launch of our TAXUS® Express2® Atom™ and TAXUS® Liberté® stent systems in the U.S. during the fourth quarter of 2008 had a positive effect on our market share. We believe that exiting 2008, we were the market leader with 49 percent share of the U.S. drug-eluting stent market for the month of December, and are well positioned entering 2009.

Our international drug-eluting stent system sales increased $19 million, or two percent, in 2008 as compared to 2007, due to a full year of drug-eluting stent sales in Japan and growth in the size of the international drug-eluting stent market as a result of increased PCI procedural volume and higher penetration rates. In May of 2007, we launched our TAXUS® Express2® coronary stent system in Japan, and, in January 2009, we received approval from the Japanese Ministry of Health, Labor and Welfare to market our second-generation TAXUS® Liberté® drug-eluting stent system in Japan. We are planning to launch our TAXUS® Liberté® stent system in Japan during the first quarter of 2009 and the PROMUS® everolimus-eluting coronary stent system in the second half of 2009, subject to regulatory approval.

In July 2008, Abbott launched its XIENCE V™ everolimus-eluting coronary stent system, and, simultaneously, we launched the PROMUS® everolimus-eluting coronary stent system, supplied to us by Abbott. As of the closing of Abbott's acquisition of Guidant's vascular intervention and endovascular solutions businesses, we obtained a perpetual license to use the intellectual property used in Guidant's drug-eluting stent system program purchased by Abbott. We believe that being the only company to offer two distinct drug-eluting stent platforms provides us a considerable advantage in the drug-eluting stent market and has enabled us to sustain our worldwide leadership position. However, under the terms of our supply arrangement with Abbott, the gross profit and operating profit margin of a PROMUS® stent system is significantly lower than that of our TAXUS® stent system. Our PROMUS® stent systems have operating profit margins that approximate half of our TAXUS® stent system operating profit margin. Therefore, if sales of our PROMUS® stent system continue to increase in relation to our total drug-eluting stent system sales, our profit margins will continue to decrease. Refer to our Gross Profit discussion for more information on the impact this sales mix has had on our gross profit margins. Further, the price we pay Abbott for our supply of PROMUS® stent systems is determined by our contracts with them. Our cost is based, in part, on previously fixed estimates of Abbott's manufacturing costs for PROMUS® stent systems and third-party reports of our average selling price of PROMUS® stent systems. Amounts paid pursuant to this pricing arrangement are subject to a retroactive adjustment at pre-determined intervals based on Abbott's actual costs to manufacture these stent systems for us and our average selling price of PROMUS® stent systems. During 2009, we may make a payment to or receive a payment from Abbott based on the differences between their actual manufacturing costs and the contractually stipulated manufacturing costs and differences between our actual average selling price and third-party reports of our average selling price, in each case, with respect to our purchases of PROMUS® stent systems from Abbott during 2008, 2007 and 2006. As a result, during 2009, our profit margins on the PROMUS® stent system may increase or decrease.

We are reliant on Abbott for our supply of PROMUS® stent systems. Any production or capacity issues that affect Abbott's manufacturing capabilities or the process for forecasting, ordering and receiving shipments may impact our ability to increase or decrease the level of supply to us in a timely manner; therefore, our supply of PROMUS® stent systems may not align with customer demand, which could have an adverse effect on our operating results. At present, we believe that our supply of PROMUS® stent systems from Abbott is sufficient to meet customer demand. Further, our supply agreement with Abbott for PROMUS® stent systems extends through the middle of the fourth quarter of 2009 in Europe, and is currently being reviewed by the European Commission for possible extension, and through the end of the second quarter of 2012 in the U.S. and Japan. We are incurring incremental costs and expending incremental resources in order to develop and commercialize an internally developed and manufactured next-generation everolimus-eluting stent system. We expect that this stent system, the PROMUS® Element™ stent

system, will have gross profit margins more comparable to our TAXUS® stent system and will improve our overall

gross profit and operating profit margins once launched. We expect to launch PROMUS® Element in our EMEA region and certain Inter-Continental countries in late 2009 and in the U.S. and Japan in mid-2012. We expect to launch our first-generation PROMUS® everolimus-eluting coronary stent system during the second half of 2009 in Japan. Our product pipeline also includes the TAXUS® Element™ coronary stent system. We expect to launch our TAXUS® Element stent system in EMEA and certain Inter-Continental countries during the fourth quarter of 2009 and in the U.S. and Japan in mid-2011.

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

We believe that we can sustain our leadership position within the worldwide drug-eluting stent market for a variety of reasons, including:

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

However, a further decline in net sales from our drug-eluting stent systems could have a significant adverse impact on our operating results and operating cash flows. The most significant variables that may impact the size of the drug-eluting stent market and our position within this market include:

- our ability to successfully launch next-generation products and technology features;
- physician and patient confidence in our technology and attitudes toward drug-eluting stents, including the continued abatement of prior concerns regarding the risk of late stent thrombosis;
- changes in drug-eluting stent penetration rates, the overall number of PCI procedures performed, average number of stents used per procedure, and average selling prices of drug-eluting stent systems;
- the outcome of intellectual property litigation;
- variations in clinical results or perceived product performance of our or our competitors' products;
- delayed or limited regulatory approvals and unfavorable reimbursement policies;
- our ability to retain key members of our sales force and other key personnel; and

- changes in FDA clinical trial data and post-market surveillance requirements and the associated impact on new product launch schedules and the cost of product approvals and compliance.

There continues to be significant intellectual property litigation in the coronary stent market. We are currently involved in a number of legal proceedings with certain of our existing competitors, including Johnson & Johnson, and other independent patent holders. There can be no assurance that an adverse outcome in one or more proceedings would not materially impact our ability to meet our objectives in the coronary stent market, and our liquidity and results of operations. We previously had several active lawsuits pending between us and Medtronic, Inc. However, on January 23, 2009, we reached an agreement to stop all litigation between us and Medtronic with respect to interventional cardiology and endovascular repair cases. See Note L - Commitments and Contingencies to our 2008 consolidated financial statements included in Item 8 of this Annual Report for a description of these legal proceedings.

Other Businesses

Interventional Cardiology (excluding coronary stent systems)

In addition to coronary stent systems, our Interventional Cardiology business markets balloon catheters, rotational atherectomy systems, guide wires, guide catheters, embolic protection devices, and diagnostic catheters used in percutaneous transluminal coronary angioplasty (PTCA) procedures; and ultrasound and imaging systems. Our net sales of these products increased to $1.028 billion in 2008, as compared to $989 million in 2007, an increase of $39 million or four percent. This increase was driven primarily by growth in our ultrasound and imaging system franchise; including increased sales of our iLab® Ultrasound Imaging System, which enhances the diagnosis and treatment of blocked vessels and heart disorders. In addition, in November 2008, the FDA approved our Apex™ PTCA dilatation catheter, used in treating atherosclerotic lesions.

Peripheral Interventions

Our Peripheral Interventions business product offerings include stents, balloon catheters, sheaths, wires and vena cava filters, which are used to diagnose and treat peripheral vascular disease. Our 2008 net sales of these products decreased slightly to $589 million in 2008, as compared to $597 million in 2007. The decrease was a result of U.S. sales declines of $34 million in 2008 to $294 million, from $328 million in 2007, primarily as a result of increased competition across most of the vascular interventional product categories. Our international Peripheral Interventions business grew $26 million in 2008, as compared to 2007, due primarily to foreign currency fluctuations. We continue to hold a strong worldwide position in the Peripheral Interventions market and we are the market leader in multiple product categories. Further, in the fourth quarter of 2008, we received FDA approval for three new products: our Carotid WALLSTENT® Monorail® Endoprosthesis for the treatment of patients with carotid artery disease who are at high risk for surgery; our Express® SD Renal Monorail® premounted stent system for use as an adjunct to percutaneous transluminal renal angioplasty in certain lesions of the renal arteries; and our Sterling™ Monorail® and Over-the-Wire balloon dilatation catheter for use in the renal and lower extremity arteries.

Neurovascular

We market a broad line of products used in treating diseases of the neurovascular system. Our Neurovascular net sales increased to $360 million in 2008, as compared to $352 million in 2007, an increase of $8 million or two percent. Our U.S. net sales were $131 million in 2008, as compared to $127 million in 2007, and our international net sales were $229 million in 2008, as compared to $225 million in 2007. We plan to launch a next-generation family of detachable coils, including an enhanced delivery system with reduced coil detachment times, in the U.S. in the second half of 2009. Within our product pipeline, we are also developing next-generation technologies for the treatment of aneurysms, intracranial atherosclerotic disease and acute ischemic stroke, and are involved in numerous clinical activities that are designed to expand the size of the worldwide Neurovascular market.

Endosurgery

Our Endosurgery group develops and manufactures devices to treat a variety of medical conditions, including diseases of the digestive and pulmonary systems within our Endoscopy division, and urological and gynecological disorders within our Urology division. Our Endosurgery group net sales grew eight percent in 2008 to $1.374 billion, and accounted for 17 percent of our total net sales in 2008, as compared to 15 percent in 2007. The following are the components of our worldwide Endosurgery business:

(in millions)	Year Ended December 31, 2008			Year Ended December 31, 2007		
	U.S.	International	Total	U.S.	International	Total
Endoscopy	$ 477	$ 466	$ 943	$ 453	$ 413	$ 866
Urology	335	96	431	316	87	403
	$ 812	$ 562	$ 1,374	$ 769	$ 500	$ 1,269

Our Endoscopy net sales grew nine percent in 2008 to $943 million from $866 million in 2007. Key sales growth drivers within Endoscopy included our biliary franchise, which grew $45 million, or 16 percent, to $324 million on the strength of our SpyGlass® Direct Visualization System for single-operator duodenoscope assisted cholangiopancreatoscopy, or visual examination of the bile ducts, which was launched in the second quarter of 2007. In addition, our hemostasis franchise grew $16 million, or 18 percent, to $107 million on the strength of our Resolution® Clip Device, which is the only currently-marketed mechanical clip designed to open and close (up to five times) before deployment to enable a physician to see the effects of the clip before committing to deployment. Our Urology net sales grew seven percent in 2008 to $431 million from $403 million in 2007. This growth was primarily due to our pelvic floor franchise, which grew 17 percent, or $14 million, to $95 million, led by our line of sling-based devices and kits, which are used in the treatment of a variety of stress- and age-related disorders of the lower female anatomy. The remaining Urology growth was spread across the other components of our business, including our stone management and gynecology franchises. During 2009, we intend to launch a number of new products across multiple franchises in both our Endoscopy and Urology businesses.

Neuromodulation

Despite new product launches during the year by both of our major competitors, our Neuromodulation net sales increased to $245 million in 2008, as compared to $204 million in 2007, an increase of $41 million or 20 percent. Our U.S. net sales were $234 million in 2008, as compared to $198 million in 2007, and our international net sales were $11 million in 2008, as compared to $6 million in 2007. We continued to maintain our strong position within the U.S. market with our Precision® Spinal Cord Stimulation (SCS) system, used for the treatment of chronic pain of the lower back and legs. We believe that we continue to have a technology advantage over our competitors with proprietary features such as Multiple Independent Current Control, which allows the physician to target specific areas of pain more precisely. In addition, we are currently assessing the use of our SCS system to treat other sources of pain. These factors, coupled with the move of our Neuromodulation business to a new state-of-the-art facility during 2008, position us well for continued growth in this market.

Innovation

Our approach to innovation combines internally developed products and technologies with those we 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. We expect to continue to invest in our CRM and drug-eluting stent technologies, and will also invest selectively in areas outside of these markets. We expect to continue to invest in our paclitaxel drug-eluting stent program, along with our internally developed and manufactured everolimus-eluting stent program (the PROMUS® Element™ stent system), to sustain our leadership position in the worldwide drug-eluting stent market. There can be no assurance that these technologies will achieve technological feasibility, obtain regulatory approvals or gain market acceptance. A delay in the development or approval of these technologies may adversely impact our future growth.

Our strategic acquisitions are intended to expand further our ability to offer our customers safe, effective, high-quality medical devices that satisfy their interventional needs. Management believes it has developed a sound plan to integrate acquired businesses. However, our failure to integrate these businesses successfully could impair our ability to realize the strategic and financial objectives of these transactions. Potential future acquisitions may be dilutive to our earnings and may require additional debt or equity financing, depending on their size and nature.

We have entered strategic alliances with both publicly traded and privately held companies. We enter these alliances to broaden our product technology portfolio and to strengthen and expand our reach into existing and new markets. During 2008, we monetized certain investments and alliances no longer determined to be strategic (see the Strategic Initiatives section for more information). While we believe our remaining strategic investments are within attractive markets with an outlook for sustained growth, the full benefit of these alliances is highly dependent on the strength of the other companies' underlying technology and ability to execute. An inability to achieve regulatory approvals and launch competitive product offerings, or litigation related to these technologies, among other factors, may prevent us from realizing the benefit of these strategic alliances.

Reimbursement and Funding

Our products are purchased principally by hospitals, physicians and other healthcare providers worldwide that typically bill various third-party payors, such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed-care programs for the healthcare services provided to their patients. Third-party payors may provide or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Reimbursement by third-party payors for these services is based on a wide range of methodologies that may reflect the services' assessed resource costs, clinical outcomes and economic value. These reimbursement methodologies confer different, and sometimes conflicting, levels of financial risk and incentives to healthcare providers and patients, and these methodologies are subject to frequent refinements. Third-party payors are also increasingly adjusting reimbursement rates 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. Accordingly, the outcome of these reimbursement decisions could have an adverse impact on our business. In addition, the current economic climate may impose further pressure on funds available for reimbursement of healthcare and on reimbursement levels.

Manufacturing and Raw Materials

We design and manufacture the majority of our products in technology centers around the world. 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. However, in certain cases, we may not be able to quickly establish additional or replacement suppliers for specific components or materials, 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 or components 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 rely primarily on third party vendors to perform this service. To the extent our third party sterilizers are unable to process our products, whether due to raw material, 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.

International Markets

Our profitability from our international operations may be limited by risks and uncertainties related to economic conditions in these regions, currency fluctuations, regulatory and reimbursement approvals, competitive offerings, infrastructure development, rights to intellectual property and our ability to implement our overall business strategy. Any significant changes in the competitive, political, regulatory, reimbursement or economic environment where we conduct international operations may have a material impact on our business, financial condition or results of operations. International markets, including Japan, are affected by economic pressure to contain reimbursement levels and healthcare costs. Initiatives to limit the growth of healthcare costs, including price regulation, are under way in many countries in which we do business. Implementation of cost containment initiatives and healthcare reforms in significant markets such as 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. We expect these practices to put increased pressure on reimbursement rates in these markets.

In addition, most international jurisdictions have adopted regulatory approval and periodic renewal requirements for medical devices, and we must comply with these requirements in order to market our products in these jurisdictions. Further, some emerging markets rely on the FDA's CFGs in lieu of their own regulatory approval requirements. Although the corporate warning letter has not been formally resolved, the FDA has approved all currently eligible requests for CFGs. However, any limits on our ability to market our full line of existing products and to launch new products within these jurisdictions could have an adverse impact on our business.

Results of Operations

Net Sales

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

				2008 versus 2007		2007 versus 2006	
(in millions)	2008	2007	2006	As Reported Currency Basis	Constant Currency Basis	As Reported Currency Basis	Constant Currency Basis
United States	$ 4,487	$ 4,522	$ 4,415	(1) %	(1) %	2%	2%
EMEA	1,960	1,833	1,631	7%	2%	12%	3%
Inter-Continental	1,534	1,449	1,299	6%	(2) %	12%	9%
International	3,494	3,282	2,930	6%	-%	12%	6%
Subtotal	7,981	7,804	7,345	2%	-%	6%	4%

Divested businesses	69	553	476	N/A	N/A	N/A	N/A
Worldwide	$ 8,050	$ 8,357	$ 7,821	(4) %	(6) %	7%	5%

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

(in millions)	2008	2007	2006	2008 versus 2007 As Reported Currency Basis	2008 versus 2007 Constant Currency Basis	2007 versus 2006 As Reported Currency Basis	2007 versus 2006 Constant Currency Basis
Interventional Cardiology	$ 2,879	$ 3,016	$ 3,509	(5) %	(7) %	(14) %	(15) %
Peripheral Interventions	589	597	624	(1) %	(5) %	(4) %	(8) %
Cardiovascular	3,468	3,613	4,133	(4) %	(7) %	(13) %	(14) %
Cardiac Rhythm Management	2,286	2,124	1,371	8%	5%	55%	51%
Electrophysiology	153	147	134	4%	2%	10%	8%
Cardiac Rhythm Management	2,439	2,271	1,505	7%	5%	51%	47%
Neurovascular	360	352	326	2%	(2) %	8%	4%
Peripheral Embolization	95	95	87	1%	(4) %	9%	7%
Neurovascular	455	447	413	2%	(3) %	8%	5%
Cardiovascular Group	6,362	6,331	6,051	-%	1%	5%	2%
Endoscopy	943	866	777	9%	6%	11%	9%
Urology	431	403	371	7%	6%	9%	8%
Endosurgery Group	1,374	1,269	1,148	8%	6%	11%	8%
Neuromodulation	245	204	146	20%	20%	40%	40%
Subtotal	7,981	7,804	7,345	2%	-%	6%	4%
Divested businesses	69	553	476	N/A	N/A	N/A	N/A
Worldwide	$ 8,050	$ 8,357	$ 7,821	(4) %	(6) %	7%	5%

We manage our international operating regions and divisions on a constant currency basis, and we manage market risk from currency exchange rate changes at the corporate level. To calculate net sales growth rates that exclude the impact of currency exchange, we convert actual current period net sales from local currency to U.S. dollars using constant currency exchange rates. The regional constant currency growth rates in the table above can be recalculated from our net sales by reportable segment as presented in Note P – Segment Reporting to our 2008 consolidated financial statements included in Item 8 of this Annual Report. Growth rates are based on actual, non-rounded amounts and may not recalculate precisely.

U.S. Net Sales

Our U.S. net sales, excluding sales from divested businesses, decreased $35 million, or one percent in 2008, as compared to 2007. The decrease was due primarily to a decrease in Cardiovascular division sales of $222 million, driven primarily by declines in sales of our drug-eluting stent systems due to increased competition. Partially offsetting this decrease was an increase in CRM product sales of $109 million, as a result of numerous successful product launches during the year. In addition, U.S. sales in our Endosurgery division grew $43 million in 2008, as compared to 2007, driven by strength in our biliary and hemostasis franchises, and our Neuromodulation division increased sales by $36 million, due to market growth and continued physician adoption of our Precision Plus™ spinal

cord stimulation technology. Refer to the Business and Market Overview section for a more detailed discussion of our net sales by division.

Our U.S. net sales, excluding sales from divested businesses, increased $107 million, or two percent, in 2007, as compared to 2006. The increase related primarily to an increase in U.S. CRM product sales of approximately $450 million due to a full year of consolidated operations in 2007. In addition, we achieved year-over-year U.S. sales growth of approximately $60 million in our Endosurgery businesses and $65 million in our Neuromodulation business. Offsetting these increases was a decline in our U.S. Cardiovascular division sales of approximately $500 million, driven primarily by lower sales of our TAXUS® drug-eluting stent system as a result of a decrease in the size of the U.S. drug-eluting stent market. This decrease was driven principally by declines in drug-eluting stent penetration rates resulting from on-going concerns regarding the safety and efficacy of drug-eluting stents.

International Net Sales

Our international net sales, excluding sales from divested businesses, increased $212 million, or six percent, in 2008, as compared to 2007. The increase was attributable primarily to the favorable impact of currency exchange rates, which contributed $208 million to our international net sales, excluding sales from divested businesses. Within our international business, sales in our Cardiovascular division increased $77 million and CRM product sales increased $53 million. In addition, sales in our Endosurgery franchises increased $63 million in 2008, as compared to 2007. Refer to the Business and Market Overview section for a more detailed discussion of our net sales by division.

Our international net sales, excluding sales from divested businesses, increased $352 million, or 12 percent, in 2007 as compared to 2006. Approximately $170 million was attributable to the favorable impact of currency exchange rates. Within our international business, sales of our CRM products increased $290 million, due primarily to a full year of consolidated results in 2007. Sales in our Cardiovascular division increased $50 million, due primarily to the May 2007 launch of our TAXUS® Express2® coronary stent system in Japan.

Gross Profit

In 2008, our gross profit was $5.581 billion, as compared to $6.015 billion in 2007, a decrease of $434 million or seven percent. As a percentage of net sales, our gross profit decreased to 69.3 percent for 2008, as compared to 72.0 percent for 2007. For 2007, our gross profit was $6.015 billion, as compared to $5.614 billion for 2006. As a percentage of net sales, our gross profit increased slightly to 72.0 percent in 2007, as compared to 71.8 percent in 2006. The following is a reconciliation of our gross profit percentages from 2006 to 2007 and 2007 to 2008:

	Year Ended December 31,	
	2008	2007
Gross profit - prior year	72.0%	71.8%
Shifts in product sales mix	(2.5) %	(1.8) %
Lower Project Horizion spend	0.7%	0.2%
Impact of higher inventory charges and other period expenses	(0.5) %	(1.0) %
Inventory step up charge in 2006		3.4%
All other	(0.4) %	(0.6) %
Gross profit - current year	69.3%	72.0%

The primary factor contributing to a shift in product sales mix toward lower margin products in both years was a decrease in sales of our higher margin TAXUS® drug-eluting stent system. The shift in sales away from TAXUS® stent systems during 2008 was primarily due to increased sales of PROMUS® stent systems in the U.S., following its July 2008 approval and launch. Under the terms of our supply arrangement with Abbott, the gross profit margin of a PROMUS® stent system is significantly lower than that of our TAXUS® stent system. In 2008, sales of our PROMUS® stent system represented 19 percent of our worldwide drug-eluting stent system sales, as compared to two percent in 2007.

Our gross profit margin was also negatively impacted by higher inventory charges and other period expenses during both years. In 2008, these charges consisted primarily of a $23 million inventory write-off related to an FDA warning letter received by one of our third party sterilizers, and approximately $20 million of CRM-related inventory write-offs, resulting principally from the successful launch of COGNIS® and TELIGEN®. In 2007, these charges included warranty-related and other scrap charges.

Partially offsetting these declines in our gross profit margin was lower spending associated with Project Horizon, our corporate-wide initiative to improve and harmonize our overall quality processes and systems, which ended as a formal program as of December 31, 2007. In addition, included in cost of products sold for 2006 was an adjustment of $267 million, representing the step-up value of acquired Guidant inventory sold

during the year. There were no amounts included in our 2007 or 2008 cost of products sold related to the inventory step-up and, as of December 31, 2007, we had no step-up value remaining in inventory.

Operating Expenses

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

	2008		2007		2006	
(in millions)	$	% of Net Sales	$	% of Net Sales	$	% of Net Sales
Selling, general and administrative expenses	2,589	32.2	2,909	34.8	2,675	34.2
Research and development expenses	1,006	12.5	1,091	13.1	1,008	12.9
Royalty expense	203	2.5	202	2.4	231	3.0
Amortization expense	543	6.7	620	7.4	474	6.1

Selling, General and Administrative (SG&A) Expenses

In 2008, our SG&A expenses decreased by $320 million, or 11 percent, as compared to 2007. As a percentage of our net sales, SG&A expenses decreased to 32.2 percent in 2008 from 34.8 percent in 2007. The decrease in our SG&A expenses related primarily to lower head count and spending resulting from our expense and head count reduction plan, as well as a reduction of $160 million attributable to our first quarter 2008 divestiture of certain non-strategic businesses. Refer to the Strategic Initiatives section for more discussion of these initiatives.

In 2007, our SG&A expenses increased by $234 million, or nine percent, as compared to 2006. As a percentage of our net sales, SG&A expenses increased slightly to 34.8 percent in 2007 from 34.2 percent in 2006. The increase in our SG&A expenses related primarily to $256 million in incremental SG&A expenditures associated with a full year of consolidated CRM operations, offset partially by lower head count and spending as a result of our expense and head count reduction plan, which was initiated in the fourth quarter of 2007.

Research and Development (R&D) Expenses

Our investment in R&D reflects spending on new product development programs, as well as regulatory compliance and clinical research. In 2008, our R&D expenses decreased by $85 million, or eight percent, as compared to 2007. As a percentage of our net sales, R&D expenses decreased to 12.5 percent in 2008 from 13.1 percent in 2007. The decrease related primarily to lower head count and spending of $75 million resulting from our first quarter 2008 divestiture of certain non-strategic businesses. We remain committed to advancing medical technologies and investing in meaningful research and development projects in all of our businesses in order to maintain a healthy pipeline of new products that will contribute to our short- and long-term profitable sales growth.

In 2007, our R&D expenses increased by $83 million, or 8 percent, as compared to 2006. As a percentage of our net sales, R&D expenses increased marginally to 13.1 percent in 2007 from 12.9 percent in 2006. The increase related primarily to $131 million in incremental R&D expenditures associated with a full year of consolidated CRM operations, offset partially by lower spending of approximately $37 million associated with the cancellation of our Endovations™ single-use endoscope R&D program. During the second quarter of 2007, we determined that our Endovations system would not be a commercially viable product and terminated the program. In addition, our 2006 R&D expenses included approximately $30 million in costs related to the cancellation of the TriVascular AAA stent-graft program. We do not expect these program cancellations to materially impact our future operations or cash flows.

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Royalty Expense

In 2008, our royalty expense increased by $1 million, or less than one percent, as compared to 2007. As a percentage of our net sales, royalty expense increased slightly to 2.5 percent from 2.4 percent for 2007. Royalty expense attributable to sales of our drug-eluting stent systems increased $8 million as compared to 2007, despite an overall decrease in drug-eluting stent system sales. This was due to a shift in the mix of our drug-eluting stent system sales towards the PROMUS® stent system, following its launch in 2008. The royalty rate applied to sales of the PROMUS® stent system is, on average, higher than that associated with sales of our TAXUS® stent system. Offsetting this increase was a decrease in royalty expense of $6 million attributable to our first quarter 2008 divestiture of certain non-strategic businesses.

In 2007, our royalty expense decreased by $29 million, or 13 percent, as compared to 2006, due primarily to lower sales of our TAXUS® drug-eluting stent system. As a percentage of our net sales, royalty expense decreased to 2.4 percent from 3.0 percent for 2006. Royalty expense attributable to sales of our TAXUS® stent system decreased $48 million as compared to 2006, due to a decrease in TAXUS® stent system sales. Offsetting this decrease was an increase in royalty expense attributable to Guidant-related products of $13 million, due to a full year of consolidated results, as well as increases in royalties associated with our other businesses.

Amortization Expense

In 2008, our amortization expense decreased by $77 million, or 12 percent, as compared to 2007. The decrease in our amortization expense related primarily to the disposal of $581 million of amortizable intangible assets in connection with our first quarter 2008 business divestitures, and to certain Interventional Cardiology-related intangible assets reaching the end of their accounting useful life during 2008.

In 2007, our amortization expense increased by $146 million, or 31 percent, as compared to 2006. The increase in our amortization expense related to incremental amortization associated with intangible assets obtained as part of the Guidant acquisition, due to a full year of amortization.

Goodwill and Intangible Asset Impairment Charges

In 2008, we recorded goodwill and intangible asset impairment charges of $2.790 billion, including a $2.613 billion write-down of goodwill associated with our acquisition of Guidant, a $131 million write-down of certain of our Peripheral Interventions-related intangible assets, and a $46 million write-down of certain Urology-related intangible assets. We do not believe that the write-down of these assets will have a material impact on future operations or cash flows. Refer to Note E –Goodwill and Other Intangible Assets to our 2008 consolidated financial statements included in Item 8 of this Annual Report for more information.

In 2007, we recorded intangible asset impairment charges of $21 million associated with our acquisition of Advanced Stent Technologies (AST), due to our decision to suspend further significant funding of R&D with respect to the Petal™ bifurcation stent. We do not expect this decision to materially impact our future operations or cash flows.

In 2006, we recorded intangible asset impairment charges of $23 million attributable to the cancellation of the AAA stent-graft program we acquired with TriVascular, Inc. In addition, we recorded intangible asset write-offs of $21 million associated with developed technology obtained as part of our 2005 acquisition of Rubicon Medical Corporation, and $12 million associated with our Real-time Position Management® System (RPM)™ technology, due to our decision to cease investment in these technologies. We do not expect these decisions to materially impact our future operations or cash flows.

Acquisition-related Milestone

In connection with Abbott‘s 2006 acquisition of Guidant’s vascular intervention and endovascular solutions businesses, Abbott agreed to pay us a milestone payment of $250 million upon receipt of FDA approval to sell an everolimus-eluting stent in the U.S. In July 2008, Abbott received FDA approval and launched its

XIENCE V™ everolimus-eluting coronary stent system in the U.S., and paid us $250 million, which we recorded as a gain in the accompanying consolidated statements of operations. Under the terms of the agreement, we are entitled to receive a second milestone payment of $250 million from Abbott upon receipt of an approval from the Japanese Ministry of Health, Labor and Welfare to market the XIENCE V™ stent system in Japan.

Purchased Research and Development

In 2008, we recorded $43 million of purchased research and development charges, including $17 million associated with our acquisition of Labcoat, Ltd., $8 million attributable to our acquisition of CryoCor, Inc., and $18 million associated with entering certain licensing and development arrangements.

The $17 million of in-process research and development associated with our acquisition of Labcoat, Ltd. relates to a novel technology Labcoat is developing for coating drug-eluting stents. We intend to use this technology in future generations of our drug-eluting stent products. The $8 million of in-process research and development associated with CryoCor represents cryogenic technology for use in the treatment of atrial fibrillation, the most common and difficult to treat cardiac arrhythmia (abnormal heartbeat). We intend to use this technology in order to further pursue therapeutic solutions for atrial fibrillation and advance our existing CRM and Electrophysiology product lines.

In 2007, we recorded $85 million of purchased research and development, including $75 million associated with our acquisition of Remon Medical Technologies, Inc., $13 million resulting from the application of equity method accounting for one of our strategic investments, and $12 million associated with payments made for certain early-stage CRM technologies. Additionally, in June 2007, we terminated our product development agreement with Aspect Medical Systems relating to brain monitoring technology that Aspect was developing to aid the diagnosis and treatment of depression, Alzheimer’s disease and other neurological conditions. As a result, we recognized a credit to purchased research and development of approximately $15 million during 2007, representing future payments that we would have been obligated to make prior to the termination of the agreement. We do not expect the termination of the agreement to impact our future operations or cash flows materially.

The $75 million of in-process research and development acquired with Remon consists of a pressure-sensing system development project, which we intend to combine with our existing CRM devices. As of December 31, 2008, we estimate that the total cost to complete the development project is between $75 million and $80 million. We expect to launch devices using pressure-sensing technology in 2012 in our EMEA region and certain Inter-Continental countries, in the U.S. in 2015, and Japan in 2016, subject to regulatory approvals. We expect material net cash inflows from such products to commence in 2015, following the launch of this technology in the U.S.

In 2006, we recorded $4.119 billion of purchased research and development, including a charge of approximately $4.169 billion associated with the in-process research and development obtained in conjunction with the Guidant acquisition; a credit of $67 million resulting primarily from the reversal of accrued contingent payments due to the cancellation of the TriVascular AAA program; and an expense of $17 million resulting primarily from the application of equity method accounting for one of our investments.

The $4.169 billion of purchased research and development associated with the Guidant acquisition consists primarily of approximately $3.26 billion for acquired CRM-related in-process technology and $540 million for drug-eluting stent technology shared with Abbott. The purchased research and development value associated with the Guidant acquisition also includes $369 million representing the estimated fair value of the potential milestone payments of up to $500 million that we may receive from Abbott upon their receipt of regulatory approvals for certain products. We recorded the amounts as purchased research and development at the acquisition date because the receipt of the payments was dependent on future research and development activity and regulatory approvals, and the asset had no alternative future use as of the acquisition date. In 2008, Abbott received FDA approval and launched its XIENCE V™ everolimus-eluting

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coronary stent system in the U.S., and paid us $250 million, which we recognized as a gain in our consolidated financial statements. Under the terms of the agreement, we are entitled to receive a second milestone payment of $250 million from Abbott upon receipt of an approval from the Japanese Ministry of Health, Labor and Welfare to market the XIENCE V™ stent system in Japan. If received, we will record this receipt as a gain in our consolidated financial statements at the time of receipt.

The most significant in-process purchased research and development projects acquired from Guidant included the next-generation CRM pulse generator platform and rights to the everolimus-eluting stent technology that we share with Abbott. The next-generation pulse generator platform incorporates new components and software while leveraging certain existing intellectual property, technology, manufacturing know-how and institutional knowledge of Guidant. We expect to leverage this platform across all CRM product families, including ICD systems, cardiac resynchronization therapy (CRT) devices and pacemaker systems to treat electrical dysfunction in the heart. During 2008, we substantially completed the in-process CRM pulse generator project with the regulatory approval and launch of the COGNIS® CRT-D and TELIGEN® ICD devices in the U.S., EMEA, and certain Inter-Continental countries. We expect to launch the INGENIO™ pacemaker system, utilizing this platform in both EMEA and the U.S. in the first half of 2011. As of December 31, 2008, we estimate that the total cost to complete the INGENIO™ technology is between $30 million and $35 million and expect material net cash inflows from the INGENIO™ device to commence in the second half of 2011.

The $540 million attributable to everolimus-eluting stent technology represents the estimated fair value of the rights to Guidant's everolimus-based drug-eluting stent technology we share with Abbott. In December 2006, we launched the PROMUS® everolimus-eluting coronary stent system, supplied to us by Abbott, in certain EMEA countries. In 2007, we expanded our launch in EMEA, as well as certain Inter-Continental countries and, in July 2008, launched in the U.S. We expect to launch an internally developed and manufactured next-generation everolimus-based stent, our PROMUS® Element™ stent system, in Europe in late 2009 and in the U.S. and Japan in mid-2012. We expect that net cash inflows from our internally developed and manufactured everolimus-based drug-eluting stent will commence in 2010. As of December 31, 2008, we estimate that the cost to complete our internally manufactured next-generation everolimus-eluting stent technology project is between $150 million and $175 million.

Gain on Divestitures

During 2008, we recorded a $250 million gain in connection with the sale of our Fluid Management and Venous Access businesses and our TriVascular EVAR program. Refer to the Strategic Initiatives section and Note F – Divestitures and Assets Held for Sale to our 2008 consolidated financial statements included in Item 8 of this Annual Report for more information on these transactions.

Loss on Assets Held for Sale

During 2007, we recorded a $560 million loss attributable primarily to the write-down of goodwill in connection with the sale of certain of our non-strategic businesses. Refer to the Strategic Initiatives section and Note F – Divestitures and Assets Held for Sale to our 2008 consolidated financial statements included in Item 8 of this Annual Report for more information on these transactions.

Restructuring

In October 2007, our Board of Directors approved, and we committed to, an expense and head count reduction plan, which resulted in the elimination of approximately 2,300 positions worldwide. We are

providing affected employees with severance packages, outplacement services and other appropriate assistance and support. The plan is intended to bring expenses in line with revenues as part of our initiatives to enhance short- and long-term shareholder value. Key activities under the plan include the restructuring of several businesses, corporate functions and product franchises in order to better utilize resources, strengthen competitive positions, and create a more simplified and efficient business model; the elimination, suspension or reduction of spending on certain R&D projects; and the transfer of certain production lines from one facility to another. We initiated these activities in the fourth quarter of 2007 and expect to be substantially complete worldwide in 2010.

We expect that the execution of this plan will result in total pre-tax expenses of approximately $425 million to $450 million. We are recording a portion of these expenses as restructuring charges and the remaining portion through other lines within our consolidated statements of operations. We expect the plan to result in cash payments of approximately $395 million to $415 million. The following provides a summary of our expected total costs associated with the plan by major type of cost:

Type of cost	Total estimated amount expected to be incurred
Restructuring charges:	
Termination benefits	$225 million to $230 million
Fixed asset write-offs	$20 million
Other (1)	$65 million to $70 million
Restructuring-related expenses:	
Retention incentives	$75 million to $80 million
Accelerated depreciation	$10 million to $15 million
Transfer costs (2)	$30 million to $35 million
	$425 million to $450 million

(1) Consists primarily of consulting fees and contractual cancellations.

(2) Consists primarily of costs to transfer product lines from one facility to another, including costs of transfer teams, freight and product line validations.

During 2008, we recorded $78 million of restructuring charges. In addition, we recorded $55 million of expenses within other lines of our consolidated statements of operations related to our restructuring initiatives. The following presents these costs by major type and line item within our consolidated statements of operations:

(in millions)	Termination Benefits	Retention Incentives	Asset Write-offs	Accelerated Depreciation	Transfer Costs	Other	Total
Restructuring charges	$ 34		$ 10			$ 34	$ 78
Restructuring-related expenses:							
Cost of products sold		$ 9		$ 4	$ 4		17
Selling, general and administrative expenses		27		4			31
Research and development expenses		7					7
		43		8	4		55
	$ 34	$ 43	$ 10	$ 8	$ 4	$ 34	$ 133

During 2007, we recorded $176 million of restructuring charges, and $8 million of restructuring-related expenses within other lines of our consolidated statements of operations. The following presents these costs by major type and line item within our consolidated statements of operations:

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(in millions)	Termination Benefits	Retention Incentives	Asset Write-offs