

BOSTON SCIENTIFIC CORP

Form 10-K

February 23, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2016

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

Commission File No. 1-11083

BOSTON SCIENTIFIC CORPORATION

(Exact name of registrant as specified in its charter)

DELAWARE

04-2695240

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

300 BOSTON SCIENTIFIC WAY, MARLBOROUGH, MASSACHUSETTS 01752-1234

(Address of principal executive offices) (zip code)

(508) 683-4000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

COMMON STOCK, \$.01 PAR VALUE PER SHARE NEW YORK STOCK EXCHANGE

(Title of each class)

(Name of exchange on which registered)

Securities registered pursuant to Section 12(g) of the Act:

NONE

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

Yes: ☐ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes: ☐ No ☐

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: ☐ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes: ☐ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
		(Do not check if a smaller reporting company)	

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

The aggregate market value of the registrant's common stock held by non-affiliates was approximately \$31.6 billion based on the last reported sale price of \$23.37 of the registrant's common stock on the New York Stock Exchange on

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June 30, 2016, the last business day of the registrant's most recently completed second fiscal quarter. (For this computation, the registrant has excluded the market value of all shares of common stock of the registrant reported as beneficially owned by executive officers, directors and the director emeritus of the registrant; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.)

The number of shares outstanding of the registrant's common stock as of January 31, 2017 was 1,363,488,640.

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Documents Incorporated by Reference

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission in connection with its 2017 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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## PART I

### ITEM 1. BUSINESS

#### The Company

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

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

Our net sales have increased substantially since our formation. Our growth has been fueled in part by strategic acquisitions designed to improve our ability to take advantage of growth opportunities in the medical device industry and to build depth of portfolio within our focus businesses. Our strategic acquisitions have helped us to add promising new technologies to our pipeline and to offer one of the broadest product portfolios in the world for use in less-invasive procedures in our target areas of Cardiovascular, Rhythm Management, and Medical Surgical. We believe that the depth and breadth of our product portfolio has also enabled us to compete more effectively in the current healthcare environment that seeks to improve outcomes and lower costs. Our strategy of category leadership also enables us to compete in a changing contracting landscape and position our products with physicians, managed care, large buying groups, governments, and consolidation among hospitals, while also expanding internationally and managing the complexities of the global healthcare market.

#### Business Strategy

We operate following five strategic imperatives: Strengthen Execution to Grow Share, Expand into High Growth Adjacencies, Drive Global Expansion, Fund the Journey to Fuel Growth, and Develop Key Capabilities. We believe that our execution of these strategic imperatives will drive innovation, accelerate profitable revenue growth and increase stockholder value. Our approach to innovation combines internally-developed products and technologies with those we may obtain externally through strategic acquisitions and alliances. Our research and development efforts are focused largely on the development of next-generation and novel technology offerings across multiple programs and divisions. In addition, we have undertaken several strategic acquisitions to help us to continue to be a leader in the medical device industry. We expect to continue to invest in our core franchises, and also investigate opportunities to further expand our presence in, and diversify into, strategic growth adjacencies and new global markets. During the last several years, we have completed multiple acquisitions to strengthen our core franchises and expand into high growth adjacencies and global markets. To support the achievement of our strategic and organizational objectives, we have an Enterprise Risk Management program that coordinates a consolidated view of the key risks inherent in achieving our business strategies so we can anticipate and adapt to potential challenges to preserve and grow shareholder value. Our Board of Directors oversees risk management and focuses on the most significant risks facing the Company including strategic, operational, financial and legal and compliance risks

#### Products

During 2016, our products were offered for sale by seven core businesses: Interventional Cardiology, Cardiac Rhythm Management, Endoscopy, Peripheral Interventions, Urology and Pelvic Health, Neuromodulation, and Electrophysiology. During 2016, we derived 27 percent of our sales from our Interventional Cardiology business, 22 percent of our sales from our Cardiac Rhythm Management business, 17 percent of our sales from our Endoscopy business, 12 percent of our sales from our Peripheral Interventions business, 12 percent of our sales from our Urology and Pelvic Health business, seven percent of our sales from our Neuromodulation business, and three percent of our sales from our Electrophysiology business.

The following section describes certain of our product offerings. In addition, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report for further information on our core businesses and products.

## Cardiovascular

### Interventional Cardiology

#### Drug-Eluting Coronary Stent Systems

Our broad, innovative product offerings have enabled us to become a leader in the global interventional cardiology market. This leadership is due in large part to our drug-eluting coronary stent product offerings. Coronary stents are tiny, mesh tubes used in the treatment of coronary artery disease, which are implanted in patients to prop open arteries and facilitate blood flow to and from the heart. We believe we have further enhanced the outcomes associated with the use of coronary stents, particularly the processes that lead to restenosis (the growth of neointimal tissue within an artery after angioplasty and stenting), through scientific research and product development of drug-eluting stent systems.

We market the SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System featuring an ultra-thin abluminal (outer) bioabsorbable polymer coating. The SYNERGY Stent is unique in that both its proprietary polymer and everolimus drug coating dissipate by three months. This innovation has the potential to improve post-implant vessel healing and will eliminate long-term polymer exposure, which is a possible cause of late adverse events. In addition, we market the Promus PREMIER™, Promus™ Element™ and Promus™ Element™ Plus Everolimus-Eluting Stents

#### Other Coronary Therapies

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

#### PCI Guidance

We market a family of intravascular catheter-directed ultrasound imaging catheters, fractional flow reserve (FFR) devices, and systems for use in coronary arteries and heart chambers as well as certain peripheral vessels. Our Intravascular Ultrasound Imaging catheter, OptiCross™, has been launched in all major markets worldwide. We initiated the launch of our first FFR product, the COMET™ Pressure Guidewire, in the U.S., Europe, and Japan in 2016. The iLab™ Ultrasound Imaging System with Polaris Software continues as our flagship console and is compatible with our full line of imaging catheters and FFR devices and are designed to enhance the diagnosis and treatment of blocked vessels and heart disorders. These systems have been placed in cardiology labs worldwide and provided an installed base through which we expect to continue to pull through products, including the ongoing launch of our COMET™ FFR Pressure Guidewire.

#### Structural Heart Therapies

Structural heart therapy is one of the fastest growing segments of the medical technology market and is highly synergistic with our Interventional Cardiology and Rhythm Management businesses. Through the acquisition of Sadra Medical, Inc. (Sadra) in January 2011, we have developed a fully repositionable and retrievable device, the Lotus™ Valve System, for transcatheter aortic valve replacement (TAVR) to treat patients with severe aortic stenosis. The Lotus™ Valve System employs a unique Adaptive Seal™ feature designed to minimize the incidence of paravalvular regurgitation, a predictor of mortality. The Lotus™ Valve System is CE-marked in the European Union (EU). In the U.S. it is an investigational device and not available for commercial sale. At the end of 2015, we completed



enrollment in our REPRISE III pivotal clinical trial. We have three valve sizes CE marked: 23, 25 and 27mm, and we are developing 21 and 29mm size valves to complete our size matrix. In September 2016, we commenced a limited launch of our next generation catheter and sheath, the Lotus EDGE™ Valve System, in Europe. In October 2016, we suspended our limited launch and initiated a voluntary removal of field inventory of the Lotus EDGE™ system due to reports that, in some cases, the device could not be fully locked during the procedure due to premature release of a pin connecting the Lotus EDGE™ Valve to the delivery system. In February 2017, we initiated a voluntary removal of all Lotus™ Valve devices, including Lotus with Depth Guard™, from global commercial and clinical sites due to reports of premature release of a pin connecting the Lotus™ Valve to the delivery system. As with the prior announced suspension of our Lotus Edge™ Valve System device, we believe that the issue is caused by excess tension in the pin mechanism introduced during the manufacturing process. We expect to bring the Lotus™ Valve platform back to market in Europe and other regions in the fourth quarter of 2017. We anticipate filing the U.S. PMA submission for the Lotus Edge™ Valve System, the next generation platform, in the fourth quarter of 2017, with a U.S. launch planned for mid-2018.

Through the acquisition of Atritech, Inc. (Atritech) in March 2011, we have developed a novel device, the Watchman™ Left Atrial Appendage Closure (LAAC) Device, designed to close the left atrial appendage to reduce the risk of ischemic stroke in patients with atrial fibrillation (AF). Watchman Device has been commercially available internationally since 2009 and is the leading device in percutaneous LAAC globally. In March of 2015, Watchman Device received FDA approval to treat patients who are at an elevated risk of stroke, deemed suitable for warfarin, and have appropriate rationale to seek a non-pharmacologic alternative to warfarin. We believe that Watchman Device will be the only LAAC technology commercially available in the U.S. for multiple years, and in November 2015, we received CE Mark for our next generation device, Watchman FLX™ LAAC Device. Shortly after approval, we began a European initial market release of Watchman FLX™ Device. The initial market release was suspended near the end of the first quarter of 2016 due to a higher than expected rate of device embolization. Following an extensive data evaluation, we have decided to pursue certain design enhancements prior to returning a next generation device to market.

On December 12, 2016, we completed the acquisition of certain manufacturing assets and capabilities of the Neovasc, Inc. advanced biological tissue business and made a 15 percent equity investment in Neovasc. With this acquisition, we will integrate certain manufacturing assets and biologic tissue capabilities into our structural heart business for use in the manufacturing of the Lotus™ Valve System and future heart valve technologies within our Interventional Cardiology business. We began the process of integrating Neovasc into our Interventional Cardiology business in the fourth quarter of 2016 and expect to be substantially complete by the end of 2018.

#### Peripheral Interventions

We sell various products designed to treat patients with peripheral arterial disease (disease which appears in blood vessels other than in the heart and in the biliary tree), including a broad line of medical devices used in percutaneous transluminal angioplasty (PTA) and peripheral vascular stenting. Our peripheral product offerings include stents, balloon catheters, wires, peripheral embolization devices and vena cava filters. Our peripheral angioplasty balloon technology includes our next-generation Mustang™ PTA Balloon Catheter; our Coyote™ Balloon Catheter, a highly deliverable and ultra-low profile balloon dilatation catheter designed for a wide range of peripheral angioplasty procedures; and our Charger™ PTA Balloon Catheter, a 0.035" percutaneous transluminal angioplasty balloon catheter designed for post-stent dilatation as well as conventional balloon angioplasty to open blocked peripheral arteries. With our Coyote, Mustang and Charger Devices, we offer balloons across all size platforms. Our peripheral stent technology includes our EPIC™ Self-Expanding Nitinol Stent System, our Carotid WALLSTENT™ Stent System, and our Innova™ Self-Expanding Stent System. In addition, we market our 0.035" Rubicon™ Support Catheter in both the U.S. and Europe. We are currently conducting a pivotal study designed to evaluate the safety and performance of the Eluvia™ Drug-Eluting Vascular Stent System, which received CE Mark in February 2016 and is designed to treat patients with narrowing or blockages in the SFA or proximal popliteal artery (PPA). We are also conducting an additional study on the safety and effectiveness of our RANGER™ Drug-Coated Balloon.

In August 2014, we acquired the Interventional Division of Bayer AG (Bayer). The addition of Bayer innovative technologies supports our strategy to provide a comprehensive portfolio of leading solutions to treat peripheral vascular disease, including venous disease. The transaction included the leading AngioJet™ Thrombectomy System which is used in endovascular procedures to remove blood clots from blocked arteries and veins, and the JetStream™ Atherectomy System, used to remove plaque and thrombi from diseased arteries. We have since launched the AngioJet™ ZelanteDVT™ Thrombectomy Catheter to treat deep vein thrombosis (DVT) in large-diameter upper and lower limb peripheral veins, in the U.S. and Europe.

We also sell products designed to treat patients with non-vascular disease (disease that appears outside the blood system), primarily in interventional oncology. Our non-vascular suite of products includes biliary stents, drainage catheters and micro-puncture sets designed to treat, diagnose and ease various forms of benign and malignant tumors. We market our Direxion™ Torqueable Microcatheter in both the U.S. and Europe. In addition, we continue to market

our extensive line of interventional oncology product solutions, including the Renegade™ HI-FLO™ Fathom™ Microcatheter and guidewire system and Interlock™ - 35 Fibered IDC™ and 18 Fibered IDC™ Occlusion System for peripheral embolization.

On December 31, 2015, we completed the acquisition of the interventional radiology business of CeloNova Biosciences (CeloNova). The acquisition includes drug-eluting microspheres designed to be loaded with chemotherapy drugs for delivery to cancerous tumors, and spherical embolic products used to treat uterine fibroids and other conditions. We are in the process of integrating CeloNova into our Peripheral Interventions business and expect to be substantially complete by the second half of 2017.

## Rhythm Management

### Cardiac Rhythm Management

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

Implantable cardioverter defibrillator (ICD) systems used to detect and treat abnormally fast heart rhythms (tachycardia) that could result in sudden cardiac death, including the world's only commercially available subcutaneous implantable cardiac defibrillators (S-ICD), along with implantable transvenous cardiac defibrillators and 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.

In addition, in most geographies, our implantable device systems include our remote LATITUDE™ Patient Management System, which enables physicians to monitor device performance remotely, allowing for more frequent monitoring in order to guide treatment decisions.

We market several lines of ICD's, including our DYNAGEN™ EL, DYNAGEN™ MINI, INOGEN™ EL and INOGEN™ MINI. MINI is the smallest, thinnest ICD and EL (extended longevity) is the longest lasting ICD due to our proprietary EnduraLife™ battery technology. In addition, we offer our EMBLEM™ MRI S-ICD System, which affords physicians the ability to treat patients who are at risk for sudden cardiac arrest without touching the heart or invading the vasculature. Our EMBLEM MRI S-ICD System offers greater longevity, LATITUDE™ Patient Management Remote Monitoring Technology and smaller size as compared to the first generation of S-ICD therapy. We also offer several lines of CRT-D systems, including our X4 line of quadripolar systems, a suite of ACUITY™ X4 Quadripolar LV Leads, and the ACUITY™ PRO Lead Delivery System. We initiated the full U.S. launch of our ACUITY™ X4 Quadripolar LV Leads in March 2016 and began global commercialization of the EMBLEM MRI S-ICD system in the second and third quarters of 2016. Our current generation of transvenous ICD and CRT-D pulse generators, DYNAGEN and INOGEN, when paired with our most current generation of bradycardia, heart failure, and ICD leads have MRI safe labeling in most major countries outside the U.S. In the U.S., we plan to finish enrollment in our High Voltage MRI approval trial, ENABLE MRI, in early 2017.

We market our ACCOLADE™ family of pacemaker systems in nearly all major markets around the world. Approval of our ACCOLADE Pacemaker family in the U.S., Europe and Japan also includes approval for use of these products in patients undergoing magnetic resonance imaging (MRI) scans. We received FDA approval of our ACCOLADE MRI-Compatible Pacemaker and MRI-compatible Ingevity™ Bradycardia Lead in April of 2016. Our cardiac resynchronization therapy pacemaker product offerings include our newest generation VISIONIST™ and VALITUDE™ X4 Quadripolar CRT-P Devices, which are built on the same platform as our high voltage cardiac resynchronization therapy defibrillator, are enabled for remote patient monitoring, and include features that promote ease of use for physician implantation.

### Electrophysiology

Within our Electrophysiology business, we develop less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart. Included in our product offerings are steerable radio frequency (RF) ablation catheters, intracardiac ultrasound catheters, diagnostic catheters, delivery sheaths, and other accessories. Our products include the Blazer® line of temperature ablation catheters, designed to deliver enhanced performance and responsiveness. Our cooled ablation portfolio includes our U.S. and CE Mark approved Blazer™ Open-Irrigated and IntellaNav™ Open-Irrigated Ablation Catheters with a unique Total Tip Cooling™ Design and our closed-loop irrigated catheter, the Chilli II™ Cooled Ablation Catheter. In addition to these open-irrigated catheters, we began global

commercialization of our IntellaNav™ XP and IntellaNav™ MiFi XP Catheters in the second quarter of 2016. Our IntellaTip MiFi™ XP and IntellaNav MiFi XP Catheters include MicroFidelity (MiFi) sensor technology in the catheter tip. All of our IntellaNav™ Catheters are designed to allow magnetic tracking when used with our Rhythmia™ Mapping System.

Our comprehensive diagnostic catheter portfolio includes Blazer™ Dx-20, Dynamic Tip™ and Viking™ Catheters. We have a full offering of capital equipment, including our LabSystem PRO™ Recording System, the Rhythmia Mapping System, Maestro™ RF Generators, and the MetriQ™ pump. In 2015, the Rhythmia Mapping System and IntellaMap Orion™ Mapping Catheter began full global commercialization, bringing to market a next generation system capable of high-density high-resolution mapping to improve procedure efficacy. In December of 2016, we began European commercialization of our next generation Rhythmia™ HDX Mapping System.

MedSurg

Endoscopy

Gastroenterology and Pulmonary

We are dedicated to transforming the lives of patients by advancing the diagnosis and treatment of a broad range of pulmonary and gastrointestinal conditions. We do this through the development of innovative devices for less invasive procedures, tailored services to optimize hospital operations and patient care, and programs in support of education and reimbursement. Common gastrointestinal (GI) disease states include esophageal disorders, GI strictures and bleeding, pancreatobiliary disease and other associated conditions, as well as esophageal, biliary, pancreatic and colon cancer. Some of our product offerings include:

The SpyGlass™ DS System, made available in 2015, brings digital imaging, a wider field of view and a simpler set-up (compared to the legacy SpyGlass System), enabling cholangioscopy to play a greater role in the diagnosis and treatment of pancreatobiliary diseases.

The AXIOS™ Stent and Electrocautery-Enhanced Delivery System for endoscopic ultrasound-guided transmural drainage of pancreatic pseudo cysts, which provides a less invasive alternative to surgical pseudo cyst draining procedures and procedural time savings when compared to a non-electrocautery enhanced system. On April 2, 2015, we acquired Xluma, Inc. (Xluma), a medical device company that developed minimally invasive devices for Endoscopic Ultrasound (EUS) guided transluminal drainage of targeted areas within the gastrointestinal tract. We continue to grow our presence in the field of endoluminal surgery in the U.S. and expand internationally.

The WallFlex™ Biliary RX Fully Covered Stents System RMV is the first and currently only biliary metal stent to receive U.S. FDA clearance for an indication to treat benign biliary strictures due to chronic pancreatitis. This stent can be safely placed and removed for up to 12 months, providing additional treatment options for physicians managing their patients with this condition.

The Resolution 360™ Clip, launched in October 2016, and built on the market-leading technology of our legacy Resolution™ Clip, is a novel hemostatic clipping technology designed to stop and help prevent bleeding during endoscopic procedures. The device is constructed using a multi-wire braided catheter designed to enable healthcare professionals to rotate the device in small, controlled movements in both clockwise and counterclockwise directions. This design enables the clip to be maneuvered to the target area and more accurately placed at the site of a GI bleed or potential GI bleed.

The Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device, initially launched in May 2016 and was in full launch as of January 2017, is designed to obtain larger tissue specimens. FNB devices are used during EUS procedures to collect tissue specimens for histological assessment and are useful when diagnosing diseases such as pancreatic cancer, liver cancer and stomach lesions. This new device is designed to obtain more tissue, providing physicians with confidence that the samples they extract may improve diagnostic yield to help determine the best course of treatment for a patient.

On November 22, 2016, we completed our acquisition of EndoChoice Holdings, Inc. (EndoChoice). EndoChoice is an Alpharetta, Georgia based company focused on the development and commercialization of infection control products, pathology services and single-use devices for specialists treating a wide range of gastrointestinal (GI) conditions. We began the process of integrating EndoChoice into our Endoscopy business in the fourth quarter of 2016 and expect to be substantially complete by the end of 2017.

On November 1, 2016, we acquired the LumenR™ Tissue Retractor System from LumenR LLC (LumenR), a privately held Newark, California based company. The LumenR™ Tissue Retractor System is currently in development for use during endoscopic resection of lesions in the colon, esophagus or stomach.

#### Interventional Bronchoscopy

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

## Urology and Pelvic Health

Our Urology and Pelvic Health business develops, manufactures and sells devices to treat various urological and pelvic conditions. Within our Urology business, we sell a variety of products designed to treat patients with urinary stone disease and benign prostatic hyperplasia (BPH). We offer a full line of stone management products, including ureteral stents, wires, lithotripsy devices, stone retrieval devices, sheaths, balloons and catheters. Within our Pelvic Health business, we market a range of devices for the treatment of conditions such as stress urinary incontinence, pelvic floor reconstruction (rebuilding of the anatomy to its original state), menorrhagia (excessive menstrual bleeding), and uterine fibroids and polyps. We offer a full breadth of mid-urethral sling products, sling materials, graft materials, pelvic floor reconstruction kits, and suturing devices. We market our Genesys Hydro ThermAblator™ (HTA) System, an ablation system designed to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia, Symphion™ System for the removal of intrauterine fibroids and polyps.

On August 3, 2015, we completed the acquisition of the American Medical Systems male urology portfolio (AMS Portfolio Acquisition), which includes the men's health and prostate health businesses, from Endo International plc. The AMS male urology portfolio was integrated with our formerly named Urology and Women's Health business, and the joint businesses became Urology and Pelvic Health. The integration was substantially complete by the end of 2016.

On November 15, 2016, we completed the acquisition of the gynecology and urology portfolio of Distal Access, LLC (Distal), a Salt Lake City based company that designs minimally invasive medical devices. The portfolio includes the Resectr™ Tissue Resection Device, a single-use solution designed to remove uterine polyps. We began the process of integrating the Resectr device into our Urology and Pelvic Health business during the fourth quarter of 2016 and expect to be substantially complete by the end of 2017.

## Neuromodulation

Our Neuromodulation business offers the Precision™ and Precision Spectra™ Spinal Cord Stimulator (SCS) Systems, used for the management of chronic pain. The Precision Spectra™ System is the world's first and only SCS system with 32 contacts and 32 dedicated power sources and is designed to provide improved pain relief to a wide range of patients who suffer from chronic pain. We believe that we continue to have a technological advantage compared to our competitors with proprietary features such as Multiple Independent Current Control and our Illumina 3D Proprietary Programming Software, which together are intended to allow the physician to target specific areas of pain and customize stimulation of nerve fibers more precisely. Additionally, in June 2015, we launched the Precision Novi™ SCS System in Europe. The Precision Novi™ System offers patients and physicians the smallest 16-contact high capacity primary cell (PC), also referred to as non-rechargeable, device for the treatment of chronic pain.

We also have regulatory approval for our Vercise™ Deep Brain Stimulation (DBS) System in various international regions such as Europe, Latin America and Asia Pacific for the treatment of Parkinson's disease, tremor and intractable primary and secondary dystonia, a neurological movement disorder characterized by involuntary muscle contractions. In September 2015, we gained CE-mark approvals for the Vercise™ PC DBS System with its Neural Navigator™ Programming Software. The system allows for programming flexibility, designed to treat a greater range of patients throughout their disease progression. In addition, we received CE Mark approval for the only commercially available Directional Lead powered by current steering. The Cartesia™ Directional Lead uses multi-directional stimulation for greater precision, intended to minimize side effects for patients. We are currently in a U.S. pivotal trial with our Vercise DBS System for the treatment of Parkinson's disease and expect to enter the U.S. market with our Vercise DBS System by the end of 2017.

On July 27, 2016, we acquired Cosman Medical, Inc. (Cosman), a privately held manufacturer of radiofrequency ablation systems, expanding our Neuromodulation portfolio and offering physicians treating patients with chronic pain



a wider choice of non-opioid therapeutic options. We are in the process of integrating Cosman into our Neuromodulation business, and expect the integration to be substantially complete by the end of 2017.

#### Research and Development

Our investment in research and development is critical to driving our future growth. We expended \$920 million on research and development in 2016, \$876 million in 2015, and \$817 million in 2014. Our investment in research and development reflects the following:

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

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

We have directed our development efforts toward innovative technologies designed to expand current markets or enter adjacent markets. We are transforming how we conduct research and development and are scrutinizing our cost structure, which we believe will enable increased development activity and faster concept to market timelines. 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 and manufacture innovative products in a consistent and timely manner. Involvement of the cross-functional teams early in the process is the cornerstone of our product development cycle. We believe this collaboration allows these teams to concentrate resources on the most viable and clinically relevant new products and technologies, and focus on bringing them to market in a timely and cost-effective manner. In addition to internal development, we work with hundreds of leading research institutions, universities and clinicians around the world to develop, evaluate and clinically test our products. We are expanding our collaborations to include research and development teams in emerging markets; these teams will focus on both global and local market requirements at a lower cost of development. We believe that a part of our future success will depend upon the strength of these development efforts.

### Marketing and Sales

During 2016, we marketed our products to approximately 35,000 hospitals, clinics, outpatient facilities and medical offices in the U.S. and to approximately 120 countries worldwide. The majority of our net sales are derived from countries in which we have direct sales organizations. We also have a network of distributors and dealers who offer our products in certain countries and markets. We expect to continue to leverage our infrastructure in markets where commercially appropriate and use third party distributors in those markets where it is not economical or strategic to establish or maintain a direct presence. No single institution accounted for more than ten percent of our net sales in 2016, 2015 or 2014; 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 net sales. We have a dedicated corporate sales organization in the U.S. focused principally on selling to major buying groups and integrated healthcare networks. We consistently strive to understand and exceed the expectations of our customers. Each of our businesses maintains dedicated sales forces and marketing teams focused on physicians who specialize in the diagnosis and treatment of different medical conditions. We believe that this focus on disease state management enables us to develop highly knowledgeable and dedicated sales representatives and to foster collaborative relationships with physicians. We believe that we have positive working relationships with physicians and others in the medical industry which enable us to gain a detailed understanding of new therapeutic and diagnostic alternatives and to respond quickly to the changing needs of physicians and their patients.

### International Operations

International net sales accounted for approximately 43 percent of our net sales in 2016. Maintaining and expanding our international presence is an important component of our long-term growth strategy. 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. In addition, we are investing in infrastructure in emerging markets in order to strengthen our sales capabilities and maximize our opportunities in these countries.

As of December 31, 2016, we had six principal international manufacturing facilities, including three in Ireland, two in Costa Rica and one in Puerto Rico. Approximately 45 percent of our products manufactured in 2016 were produced at these facilities. Additionally, we maintain research and development capabilities in Ireland, Puerto Rico, Costa Rica, Germany, India and China. We operate physician training centers in France, Japan, South Africa, Germany, Italy

and India.

#### 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. We continually strive to improve the efficiency of our Sourcing Operations, and to partner with strategic suppliers to leverage the technical expertise of the broader market. By doing so, we seek to focus our internal resources on the development and commercial launch of new products, and the enhancement of existing products. We continue to implement new systems designed to provide improved quality, reliability, service, greater efficiency and lower supply chain costs, and continue our focus on process controls and validations, supplier controls, distribution controls and providing our operations teams with the training and tools necessary to drive continuous improvement in product quality. In addition, we remain focused on examining our operations and general business activities to identify cost-improvement opportunities in order to enhance our operational effectiveness.

Our products are designed and manufactured in technology centers around the world, either by us or third parties. We consistently monitor our inventory levels, manufacturing and distribution capabilities, and maintain recovery plans to address potential disruptions that we may encounter.

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

#### Quality Assurance

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

#### Environmental Regulation and Management

We are subject to various environmental laws, directives and regulations both in the U.S. and abroad. Our operations involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. We believe that sound environmental, health and safety performance contributes to our competitive strength while benefiting our customers, stockholders and employees. We are focused on continuous improvement in these areas by reducing pollution, the depletion of natural resources, and our overall environmental footprint. Specifically, we are working to optimize energy and resource usage, ultimately reducing greenhouse gas emissions and waste. We are certified to the FTSE4Good Corporate Social Responsibility Index, managed by The Financial Times and the London Stock Exchange, which measures the performance of companies that meet globally recognized standards of corporate responsibility. This certification recognizes our dedication to those standards, and it places us in a select group of companies with a demonstrated commitment to responsible business practices and sound environmental policies.

We have obtained ISO 14001:2004 certifications at our major manufacturing plants and Tier 1 distribution centers around the world, as well as our Corporate Headquarters in Marlborough, Massachusetts. ISO 14001:2004 is a globally recognized standard for Environmental Management Systems, established by the International Standards Organization, which provides a voluntary framework to identify key environmental aspects associated with our business. Using this environmental management system and the specific attributes of our certified locations in the U.S., Ireland, Costa Rica and the Netherlands, we continue to improve our environmental performance and reduce our environmental footprint.

#### Competition

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

We believe that our products and solutions compete primarily on their ability to deliver both clinical and economic outcomes for our customers; while also continuing to perform diagnostic and therapeutic procedures safely and effectively in a less-invasive manner, as well as to provide ease of use, comparative effectiveness, reliability and physician familiarity. In the current environment of managed care, with economically-motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price, value, reliability and efficiency.

We believe the current global economic conditions and healthcare reform measures could continue to put additional competitive pressure on us, including on our average selling prices, overall procedure rates and addressable market sizes. We recognize that our continued competitive success will depend upon our ability to: offer products and solutions that provide differentiated clinical and economic outcomes; create or acquire innovative, scientifically advanced technologies; apply our technology and solutions cost-effectively and with superior quality across product lines and markets; develop or acquire proprietary products and solutions; attract and retain skilled personnel; obtain patent or other protection for our products; obtain required regulatory and reimbursement approvals; continually enhance our quality systems; manufacture and successfully market our products and solutions either directly or through outside parties; and supply sufficient inventory to meet customer demand.

### Medical Device Regulatory Approvals

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

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

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

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

In the European Economic Area (EEA), we are required to comply with applicable Medical Device Directives, specifically the Medical Devices Directive and the Active Implantable Medical Device Directive, and obtain CE Mark Certification in order to market medical devices within the EEA. The CE Mark is applied depending on device classification, either following approval from the appointed independent Notified Body or through self-certification. CE Marking is a symbol of compliance to the applicable Essential Requirements of the Medical Devices Directive and associated Standards. The EU regulatory bodies will finalize a new Medical Device Regulation (MDR) in 2017,

which will replace the existing Directives and will provide three years for transition and compliance. The MDR will change several aspects of the existing regulatory framework, such as clinical data requirements, and introduce new ones, such as Unique Device Identification (UDI). We, and the Notified Bodies who will oversee compliance to the new MDR, face uncertainties as the MDR is rolled out and enforced by the Commission and EEA Competent Authorities, creating risks in several areas including the CE Marking process and data transparency in the upcoming years.

We are also required to comply with the regulations of each other country where we commercialize products before we can launch new products, such as the requirement that we obtain approval from the Japanese Ministry of Health, Labor and Welfare (MHLW) and China Food and Drug Administration. Many countries that previously did not have medical device regulations, or minimal such regulations, are now introducing them. For example, India is in the process of establishing new medical device regulations.

The FDA and other worldwide regulatory agencies and competent authorities actively monitor compliance to local laws and regulations through review and inspection of design and manufacturing practices, record keeping, reporting of adverse events,

labeling and promotional practices. The FDA can ban certain medical devices; detain or seize adulterated or misbranded medical devices; order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the Food, Drug and Cosmetic Act and the Safe Medical Devices Act pertaining to medical devices, or initiate action for criminal prosecution of such violations. Regulatory agencies and authorities in the countries where we do business can halt production in or distribution within their respective country, or otherwise take action in accordance with local laws and regulations.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin first. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and, where needed, 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.

#### Government Affairs

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

#### Healthcare Policies

Political, economic and regulatory influences around the world continue to subject the healthcare industry to potential fundamental changes that could substantially affect our results of operations. Government and private sector initiatives related to limiting the growth of healthcare costs (including price regulation), coverage and payment policies, comparative effectiveness reviews of therapies, technology assessments, and health care delivery structure reforms, are continuing in many countries where we do business. We believe that these changes are causing the marketplace to put increased emphasis on the delivery of treatments that can reduce costs, improve efficiencies, and/or increase patient access. Although we believe our less-invasive products and technologies generate favorable clinical outcomes, value and cost efficiency, the resources necessary to demonstrate value to our customers, patients, payers, and other stakeholders may be significant and new therapies may take a longer period of time to gain widespread adoption.

The impact to our business of the United States' Patient Protection and Affordable Care Act's (ACA) provisions related to coverage expansion, payment reforms, and delivery system has been immaterial. The ACA and Health Care and Education Affordability Reconciliation Act were enacted into law in the U.S. in 2010. The legislation imposed on medical device manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in January 2013. In December 2015, the Promise for Antibiotics and Therapeutics for Health Act, or PATH Act, was passed, which included legislation which temporarily suspended the 2.3 percent excise tax until December 31, 2017. We have substantially reinvested the amounts we would have expended on this tax into jobs, innovation, research and development, collaborations with universities, and other initiatives that will help treat patients and drive revenue



growth.

The Federal government, as part of the ACA, and certain state governments have enacted laws aimed at increasing transparency, or "sunshine," in relationships between medical device, biologics and pharmaceutical companies and healthcare professionals (HCPs). As a result, we are required by law to report many types of payments and items of value provided to HCPs. Certain foreign jurisdictions are currently acting to implement similar laws. Failure to comply with sunshine laws and/or implement and adhere to adequate policies and practices to address changes to legal and regulatory requirements could have a negative impact on our results of operations.

The federal election results in the U.S. may result in changes to insurance coverage, financing of insurance coverage in both the employer-sponsored insurance and individual markets, government programs such as Medicare and Medicaid, and federal sunshine laws. At this point, the impact of any such changes through repeal of, or major changes to, the ACA is unclear because specific changes in laws have not been enacted. Similarly, the status of the medical device tax after December 31, 2017 is not clear. While the specific policies that the new Administration and Congress may enact are not known, as noted below, we expect certain trends to continue placing pressure on pricing in the U.S.

We expect that pricing of medical devices will remain under pressure as alternative payment reform such as prospective payment systems for hospital care, preferential site of service payments, value-based purchasing, and accountable care organizations (ACOs) continue to take shape globally. We also expect marketplace changes to place pressure on medical device pricing globally as hospitals consolidate and large group purchasing organizations, hospital networks and other groups continue to seek to aggregate purchasing power. Similarly, governments are increasing the use of tenders, placing pressure on medical device pricing. Some governments also seek to limit the growth of healthcare costs through price regulation. Implementation of cost containment initiatives and healthcare reforms in significant markets such as the U.S., Japan and Europe and other markets may limit the price of, or the level at which reimbursement is provided for, our products, which in turn may influence a hospital's or physician's selection of products used to treat patients.

#### 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 payers, including government programs (e.g., Medicare and Medicaid in the U.S.) and private insurance payers, for the services provided to their patients.

Third-party payers and governments may approve or deny coverage for certain technologies and associated procedures based on independently determined assessment criteria. Coverage decisions by payers for these technologies and associated procedures are based on a wide range of methodologies that may reflect the assessed resource costs, clinical outcomes and economic value of the technologies and associated procedures.

#### Proprietary Rights and Patent Litigation

We rely on a combination of patents, trademarks, trade secrets and non-disclosure agreements to protect our intellectual property. We generally file patent applications in the U.S. and foreign countries where patent protection for our technology is appropriate and available. As of December 31, 2016, we held more than 19,000 patents, and had approximately 6,000 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. In the aggregate, these intellectual property assets and licenses are of material importance to our business; however, we believe that no single patent, technology, trademark, intellectual property asset or license, except for those relating to our drug-eluting coronary stent systems, is material in relation to our business as a whole.

We rely on non-disclosure and non-competition agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, particularly in the areas in which we compete. We continue to defend ourselves against claims and legal actions alleging infringement of the patent rights of others. 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. Accordingly, we may seek to settle some or all of our pending litigation, particularly to manage risk over time. Settlement may include cross licensing of the patents that are the subject of the litigation as well as our other intellectual property and may involve monetary payments to or from third parties.

We maintain insurance policies providing limited coverage against securities claims, and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The absence of significant third-party insurance coverage increases our potential exposure to unanticipated claims or adverse decisions. See Item 3 and Note K – Commitments and Contingencies to our 2016 consolidated financial statements included in Item 8 of this Annual Report for a discussion of intellectual property, product liability and other litigation and proceedings in which we are involved.

## Employees

As of December 31, 2016, we had approximately 27,000 employees, including approximately 13,000 in operations; 9,000 in selling, marketing and distribution; 4,000 in clinical, regulatory and research and development; and 3,000 in administration. Of these employees, we employed approximately 14,000 outside the U.S., approximately 8,000 of whom are in the manufacturing operations function.

## Community Outreach

We are committed to Advancing Science to transform the lives of others and the communities we all call home. We bring this commitment to life by supporting local, regional and global health and education initiatives, striving to improve patient advocacy, adhering to strong ethical standards that deliver on our commitments, and minimizing our impact on the environment.

We know that the world can be transformed when we apply the forces of compassion and the spirit of possibility to make a difference in communities today and in the future. When people have greater access to healthcare and health information, and when children are given the opportunity to achieve academically, communities become healthy and vibrant. For example, by working with Project HOPE (Health Opportunities for People Everywhere) in 2016, thousands of people in the Ranchi District in India and in rural Johannesburg, South Africa were screened for chronic diseases, such as diabetes and hypertension. Not only were people informed about their health risks and educated about prevention, but new screening protocols were implemented and healthcare workers were trained to provide services well into the future.

Our focus on the next generation of innovators is evident in the over 150 Science, Technology, Engineering and Math (STEM) events and school programs we collaborated on with others to support the ever-curious minds of young learners around the world. Last year, more than 3,000 employee volunteers dedicated their time and talent to make a positive impact at more than 350 global community events in 21 countries.

Through the Boston Scientific Foundation, more than 40 nonprofit organizations across the U.S. received nearly a million dollars in grant awards in 2016. These community grants are targeted to benefit disadvantaged populations by investing in programs that increase access to quality healthcare and improve educational opportunities, particularly related to STEM education. In addition, the Foundation also provides scholarships to college-bound students of U.S. based Boston Scientific employees.

## Seasonality

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

## Available Information

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), are available free of charge on our website ([www.bostonscientific.com](http://www.bostonscientific.com)) as soon as reasonably practicable after we electronically file the material with or furnish it to the U.S. SEC. Printed copies of these posted materials are also available free of charge to stockholders who request them in writing from Investor Relations, 300 Boston Scientific Way, Marlborough, MA 01752-1234. Information on our website or linked to our website is not incorporated by reference into this Annual Report.

## Safe Harbor for Forward-Looking Statements

Certain statements that we may make from time to time, including statements contained in this Annual Report and information incorporated by reference into this Annual Report, constitute “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Forward-looking statements may be identified by words like “anticipate,” “expect,” “project,” “believe,” “plan,” “may,” “estimate,” “intend” and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements. Except as required by law, we do not intend to update any forward-looking statements even if new information becomes available or other events occur in the future.

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

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

#### Our Businesses

Our ability to increase net sales, expand the market and capture market share;

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

The on-going impact on our business, of physician alignment to hospitals, governmental investigations and audits of hospitals, and other market and economic conditions on the overall number of procedures performed;

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

The performance of, and physician and patient confidence in, our products and technologies, or those of our competitors;

The impact and outcome of ongoing and future clinical trials, and market studies undertaken by us, our competitors or other third parties, or perceived product performance of our or our competitors' products;

Variations in clinical results, reliability or product performance of our and our competitor's products;

Our ability to acquire or develop, launch and supply new or next-generation products and technologies worldwide and across our businesses in line with our commercialization strategies in a timely and successful manner, including our S-ICD® system and the acquisition and integration of Neovasc, Inc., EndoChoice Holdings, Inc., the Resectr™ Tissue Resection Device from Distal Access, LLC, the LumenR™ Tissue Retractor System from LumenR LLC, Cosman Medical, Inc., the interventional radiology portfolio of CeloNova Biosciences, the American Medical Systems male urology portfolio and Xlumena, Inc.;

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

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

Our ability to retain and attract key personnel;

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

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

## Regulatory Compliance and Litigation

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

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

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

The impact of increased scrutiny of and heightened global regulatory enforcement facing the medical device industry arising from political and regulatory changes, economic pressures or otherwise, including under U.S. Anti-Kickback Statute, U.S. False Claims Act and similar laws in other jurisdictions; U.S. Foreign Corrupt Practices Act (FCPA) and/or similar laws in other jurisdictions, and U.S. and foreign export control, trade embargo and custom laws;

Costs and risks associated with litigation;

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

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

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

## Innovation and Certain Growth Initiatives

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

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

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

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

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



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

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

## International Markets

Our dependency on international net sales to achieve growth, including in emerging markets;

The impact of changes in our international structure and leadership;

Risks associated with international operations and investments, including the timing and collectability of customer payments, political and economic conditions, protection of our intellectual property, compliance with established and developing U.S. and foreign legal and regulatory requirements, including FCPA and similar laws in other jurisdictions and U.S. and foreign export control, trade embargo and custom laws, as well as changes in reimbursement practices and policies;

Our ability to maintain or expand our worldwide market positions in the various markets in which we compete or seek to compete, including through investments in product diversification and emerging markets such as Brazil, Russia, India and China;

Our ability to execute and realize anticipated benefits from our investments in emerging markets; and

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

## Liquidity

- Our ability to generate sufficient cash flow to fund operations, capital expenditures, global expansion initiatives, any litigation settlements and judgments, share repurchases and strategic investments and acquisitions as well as maintaining our investment grade ratings and managing our debt levels and covenant compliance;

Our ability to access the public and private capital markets when desired and to issue debt or equity securities on terms reasonably acceptable to us;

The unfavorable resolution of open tax matters, exposure to additional tax liabilities and the impact of changes in U.S. and international tax laws;

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

Our ability to collect outstanding and future receivables and/or sell receivables under our factoring programs.

## Cost Reduction and Optimization Initiatives

Risks associated with significant changes made or expected to be made to our organizational and operational structure, pursuant to our 2016 Restructuring plan as well as any further restructuring or optimization plans we may undertake in the future, and our ability to recognize benefits and cost reductions from such programs; and

Business disruption and employee distraction as we execute our global compliance program, restructuring and optimization plans and divestitures of assets or businesses and implement our other strategic and cost reduction initiatives.



## ITEM 1A. RISK FACTORS

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

We face intense competition and may not be able to keep pace with the rapid technological changes in the medical devices industry, which could have an adverse effect on our business, financial condition or results of operations. The medical device markets in which we primarily participate are highly competitive. We encounter significant competition across our product lines and in each market in which our products are sold from various medical device companies, some of which may have greater financial and marketing resources than we do, including as a result of consolidation among our competitors in the healthcare industry. Our primary competitors include Abbott Laboratories; Medtronic plc; and Cook Medical, as well as a wide range of medical device companies that sell a single or limited number of competitive products or which participate in only a specific market segment. We also face competition from non-medical device companies, including pharmaceutical companies, which may offer alternative therapies for disease states intended to be treated using our products.

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

We may experience declines in market size, average selling prices for our products, medical procedure volumes, and our share of the markets in which we compete, which may materially adversely affect our results of operations and financial condition.

We continue to experience pressures across many of our businesses due to competitive activity, increased market power of our customers as the healthcare industry consolidates, economic pressures experienced by our customers, and the impact of managed care organizations and other third-party payers. These and other factors may adversely impact market sizes, as well as our share of the markets in which we compete, the average selling prices for our products or medical procedure volumes. There can be no assurance that the size of the markets in which we compete will increase above existing levels, that we will be able to regain or gain market share or compete effectively on the basis of price or that the number of procedures in which our products are used will increase above existing levels. Decreases in market sizes or our market share and declines in average selling prices or procedural volumes could materially adversely affect our results of operations or financial condition.

Continued consolidation in the healthcare industry or additional governmental controls exerted over pricing in key markets

could lead to increased demands for price concessions or limit or eliminate our ability to sell to certain of our significant market segments, which could have an adverse effect on our business, financial condition or results of operations.

Numerous initiatives and reforms by legislators, regulators and third-party payers to curb the rising cost of healthcare have catalyzed a consolidation of aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services is expected to intensify, resulting in pricing pressures, decreased average

selling prices, and the exclusion of certain suppliers from important market segments. We expect that market demand, government regulation, third-party coverage and 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, which may increase competition, exert further downward pressure on the prices of our products and services and may adversely impact our business, financial condition or results of operations.

Healthcare cost containment pressures, government payment and delivery system reforms, changes in private payer policies, and marketplace consolidations 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 payers, including governmental programs (e.g., Medicare and Medicaid in the United States) and private health plans, for the healthcare services provided to their patients. Governments and payers may also institute changes in health care delivery systems that may reduce funding for services or encourage greater scrutiny of health care costs. The ability of customers to obtain appropriate reimbursement for their products and services from private and governmental third-party payers is critical to the success of medical technology companies because it affects which products customers purchase and the prices they are willing to pay. Reimbursement varies by country and can significantly impact the acceptance of new products and technologies. Even if we develop a promising new product, we may find limited demand for the product unless reimbursement approval is obtained from private and governmental third-party payers. Further legislative or administrative reforms to the reimbursement systems in the United States, Japan, or other countries in a manner that significantly reduces reimbursement for procedures using our medical devices or denies coverage for those procedures, including price regulation, competitive bidding and tendering, coverage and payment policies, comparative effectiveness of therapies, heightened clinical data requirements, technology assessments and managed-care arrangements, could have a material adverse effect on our business, financial condition or results of operations.

We are subject to a number of market, business, financial, legal and regulatory risks and uncertainties with respect to our international operations that could have a material impact on our business, financial condition or results of operations.

International net sales accounted for approximately 43 percent of our global net sales in 2016, with sales from emerging markets accounting for approximately 10 percent. An important part of our growth strategy is to continue pursuing growth opportunities in net sales and market share outside of the U.S. by expanding global presence, including in emerging markets. Our international operations are subject to a number of market, business and financial risks and uncertainties, including those related to political and economic instability; foreign currency exchange and interest rate fluctuations; competitive product offerings; local changes in health care financing and payment systems and health care delivery systems; local product preferences and requirements, including preferences for local manufacturers; workforce instability; less intellectual property protection in certain countries than exists in the United States; and, in certain foreign countries, longer accounts receivable cycles. Such risks and uncertainties may adversely impact our ability to implement our growth strategy in these markets and, as a result, our sales growth, market share and operating profits from our international operations may be adversely affected.

Our international operations are subject to established and developing legal and regulatory requirements for medical devices in each country in which our products are marketed and sold. Most foreign countries have medical device regulations. Further, most countries outside of the U.S. require product approvals be renewed or recertified on a regular basis in order to continue to be marketed and sold there. In addition, several countries that previously did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded, or plan to expand, on existing regulations, including requiring local clinical data in addition to global clinical data. These factors have caused or may cause us to experience more uncertainty, risk, expense and delay in commercializing products in certain foreign jurisdictions, which could affect our ability to obtain approvals for our products in those jurisdictions and adversely impact our net sales, market share and operating profits from our international operations.

Further, international markets are affected by economic pressure to contain healthcare costs, which can lead to more rigorous evidence requirements and lower reimbursement rates for either our products directly or procedures in which our products are used. Governments and payers may also institute changes in health care delivery systems that may reduce funding for services or encourage greater scrutiny of health care costs. In addition, certain international markets may also be affected by foreign government efforts to reference reimbursement rates in other countries. All of these types of changes may ultimately reduce selling prices of our products or reduce the number of procedures in

which our products are used, which may adversely impact our net sales, market share and operating profits from our international operations.

In addition, our international operations are subject to other established and developing U.S. and foreign legal and regulatory requirements, including the U.S. Foreign Corrupt Practices Act (FCPA) and/or similar laws in other countries; and U.S. and foreign import and export controls and licensing requirements, trade protection and embargo measures and customs laws. Global businesses, including those in the medical device industry, are facing increasing scrutiny of, and heightened enforcement efforts with respect to, their international operations. Any alleged or actual failure to comply with legal and regulatory requirements may subject us to government scrutiny, civil and/or criminal proceedings, sanctions and other liabilities, which may have a material adverse effect on our international operations, financial condition, results of operations and/or liquidity.

Following a referendum in June 2016 in which voters in the United Kingdom (UK) approved an exit from the EU, the UK government is expected to initiate a process to withdraw from the EU (often referred to as “Brexit”) and begin negotiating the terms of the UK’s future relationship with the EU. A withdrawal could, among other outcomes, result in the deterioration of economic conditions, volatility in currency exchange rates, and increased regulatory complexities. These outcomes may adversely affect our business, financial condition or results of operations.

Any significant changes in the political and economic, financial, competitive, legal and regulatory or reimbursement conditions where we conduct, or plan to expand, our international operations may have a material impact on our business, financial condition or results of operations.

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

As part of our strategy to maximize stockholder value, we use financial leverage to reduce our cost of capital. Our outstanding debt balance was \$5.484 billion as of December 31, 2016 and \$5.677 billion as of December 31, 2015. Although we currently have investment grade ratings at Moody's Investor Service, Standard & Poor's Rating Service and Fitch Ratings, our inability to maintain investment grade credit ratings could increase our cost of borrowing funds in the future. Delays in our product development and new product launches disruption in our cash flow or our ability to continue to effectively manage our debt levels could have an adverse effect on our cost of borrowing, financial condition or results of operations. In addition, our credit and security facilities contain covenants that require us to maintain specified financial ratios and place other limits on our business. If we are unable to satisfy these covenants, we may be required to obtain waivers from our lenders and no assurance can be made that our lenders would grant such waivers on favorable terms or at all, and we could be required to repay any borrowings on demand.

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

We test our goodwill balances during the second quarter of each year for impairment, or more frequently if indicators are present or changes in circumstances suggest that impairment may exist. We assess goodwill for impairment at the reporting unit level and, in evaluating the potential for impairment of goodwill, we make assumptions regarding estimated revenue projections, growth rates, cash flows and discount rates. In the second quarter of 2016, we performed our annual goodwill impairment test for all of our reporting units. In conjunction with our annual test, the fair value of each reporting unit exceeded its carrying value. Therefore, it was deemed not necessary to proceed to the second step of the impairment test. Refer to Critical Accounting Policies and Estimates within our Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Item 7 of this Annual Report on Form 10-K for a discussion of key assumptions used in our testing.

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

Failure to integrate acquired businesses into our operations successfully could adversely affect our business, financial condition and operating results.

As part of our strategy to realign our business portfolio, we completed several acquisitions in 2016, 2015 and 2014 and may pursue additional acquisitions in the future. Our integration of acquired businesses requires significant efforts, including corporate restructuring, the coordination of information technologies, research and development, sales and marketing, operations, regulatory, supply chain, manufacturing, quality systems and finance. These efforts result in additional expenses and involve significant management time. Some of the factors that could affect the success of our acquisitions include, among others, the effectiveness of our due diligence process, our ability to execute our business plan for the acquired companies, the strength of the acquired technology, results of clinical trials, regulatory approvals and reimbursement levels of the acquired products and related procedures, the continued



performance of critical transition services, our ability to adequately fund acquired in-process research and development projects and retain key employees, and our ability to achieve synergies with our acquired companies, such as increasing sales of our products, achieving cost savings and effectively combining technologies to develop new products. In addition, foreign acquisitions involve unique risks, including those related to integration of operations across different geographies, cultures, and languages; currency risks; and risks associated with the economic, political, legal and regulatory environment in specific countries. Our failure to manage successfully and coordinate the growth of the acquired companies could have an adverse impact on our business and our future growth. In addition, we cannot be certain that the businesses we acquire will become profitable or remain

so, and if our acquisitions are not successful, we may record related asset impairment charges in the future or experience other negative consequences on our results.

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

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

- our ability to identify suitable opportunities for acquisition, investment or alliance, if at all;
- the ability of our due diligence process to uncover potential issues with target companies;
- our ability to finance any future acquisition, investment or alliance on terms acceptable to us, if at all;
- whether we are able to complete acquisitions, investments or alliances in a timely manner on terms that are satisfactory to us, if at all;
- our ability to successfully integrate and operate acquired businesses;
- our ability to successfully identify and retain key target employees;
- our ability to comply with applicable laws and regulations, including foreign laws and regulations; and
- intellectual property and litigation related to newly acquired technologies.

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

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

We monitor the dynamics of the economy, the healthcare industry and the markets in which we compete and assess opportunities for improved operational effectiveness and efficiency and to better align expenses with revenues, while preserving our ability to make investments in research and development projects, capital and our people that we believe are important to our long-term success. As a result of these assessments, we have undertaken restructuring and optimization initiatives in order to enhance our growth potential and position us for long-term success. For example, in June 2016, we announced a restructuring initiative (the “2016 Restructuring Plan”) intended to develop global commercialization, technology and manufacturing capabilities in key growth markets, build on our Plant Network Optimization (PNO) strategy which is intended to simplify our manufacturing plant structure by transferring certain production lines among facilities, and expand operational efficiencies in support of our operating income margin goals. Key activities under the 2016 Restructuring Plan include strengthening global infrastructure through evolving global real estate and workplaces, developing global commercial and technical competencies, enhancing manufacturing and distribution expertise in certain regions, and continuing implementation of our PNO strategy. Activities under the plan were initiated in the second quarter of 2016 and are expected to be substantially completed by the end of 2018. The 2016 Restructuring Plan is expected to result in total pre-tax charges of approximately \$175

million to \$225 million and reduce gross annual expenses by approximately \$115 million to \$150 million by the end of 2020 as program benefits are realized. We expect a substantial portion of the savings to be reinvested in strategic growth initiatives. Expense reduction initiatives under the plan include various cost and efficiency improvement measures, which may include movement of business activities, facility consolidations and closures, and the transfer of product lines between manufacturing facilities, which, due to the highly regulated nature of our industry, requires a significant investment in time and cost to create duplicate manufacturing lines, run product validations, and seek regulatory approvals. These measures could yield unintended consequences, such as distraction of our management and employees, business disruption, inability to attract or retain key personnel, and reduced employee productivity, which could negatively affect our business, sales, financial condition and results of operations. Moreover, our restructuring and optimization initiatives result in charges and expenses that impact our operating results. We cannot guarantee that the activities under the 2016 Restructuring Plan or other optimization initiatives will result in the desired efficiencies and estimated cost savings.

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

Uncertainty about global economic conditions, including as a result of credit and sovereign debt issues, has caused and may continue to cause disruption in the financial markets, including diminished liquidity and credit availability. These conditions may adversely affect our suppliers, leading them to experience financial difficulties or to be unable to borrow money to fund their operations, which could cause disruptions in our ability to produce our products. Our customers may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability or decision to purchase our products, particularly capital equipment, or to pay for our products they do purchase on a timely basis, if at all. In addition, we have accounts receivable factoring programs in certain European countries. Continued deterioration of the global economy or increase in sovereign debt issues may impact our ability to transfer receivables to third parties in certain of those countries in the future. Third parties such as banks offering factoring programs in these countries are looking to reduce their exposure levels to government owned or supported debt. This could result in terminations of, or changes to the costs or credit limits of our existing factoring programs. Such terminations or changes could have a negative impact on our cash flow and days sales outstanding.

The strength and timing of economic recovery remains uncertain and there can be no assurance that there will not be further deterioration in the global economy. Accordingly, we cannot predict to what extent global economic conditions, including sovereign debt issues and increased focus on healthcare systems and costs in the U.S. and abroad, may continue to negatively impact our average selling prices, net sales and profit margins, procedural volumes and reimbursement rates from third party payers. In addition, conditions in the financial markets and other factors beyond our control may adversely affect our ability to borrow money in the credit markets, access the capital markets and to obtain financing for acquisitions or other general corporate and commercial purposes.

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

Political, economic and policy influences are leading the healthcare industry to make substantial structural and financial changes that will continue affecting our results of operations. Government and private sector initiatives limiting the growth of healthcare costs (including price regulation), coverage and payment policies, comparative effectiveness of therapies, technology assessments and healthcare delivery structure reforms, are continuing in many countries where we do business. We believe that these changes are causing the marketplace to put increased emphasis on the delivery of more treatments that can reduce costs, improve efficiencies, and/or increase patient access. Although we believe our less-invasive products and technologies generate favorable clinical outcomes, value and cost efficiency, the resources necessary and evidence necessary to demonstrate value to our customers, patients, payers, and other stakeholders may be significant and it may take a longer period of time to gain widespread adoption. Moreover, there can be no assurance that our strategies will succeed for every product.

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act of 2010 were enacted into law in the U.S. in March 2010. As a U.S. headquartered company with significant sales in the United States, the medical device tax included in this law has materially affected us. The law imposed on medical device manufacturers a 2.3 percent excise tax on U.S. sales of Class I, II and III medical devices beginning in January 2013. Under the current administration, there may be a permanent repeal or an alteration of some or all elements of the ACA, but at this time it is not definite that a change will be enacted or what new healthcare provisions may be implemented. While the implementation of the medical device tax has been suspended until December 31, 2017, the status of the tax for sales after December 31, 2017 is not clear. The tax may continue to be suspended, or may be reinstated at the same or at a different level. Other provisions of this law, including comparative effectiveness research, pilot programs to evaluate alternative payment methodologies and other changes to the payment systems, could meaningfully change the way healthcare is developed and delivered, and may adversely affect our business and

results of operations.

We cannot predict the specific healthcare programs and regulations that will be ultimately implemented by regional and national governments globally. However, any changes that lower reimbursements for either our products and/or procedures using our products, reduce medical procedure volumes or increase cost containment pressures on us or others in the healthcare sector could adversely affect our business and results of operations.

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

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

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

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

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

The European Union regulatory bodies will finalize a new Medical Device Regulation (MDR) in 2017, which will replace the existing Directives and will provide three years for transition and compliance. The MDR will change several aspects of the existing regulatory framework, such as clinical data requirements, and introduce new ones, such as Unique Device Identification (UDI). We, and the Notified Bodies who will oversee compliance to the new MDR,

face uncertainties as the MDR is rolled out and enforced by the Commission and EEA Competent Authorities, creating risks in several areas including the CE Marking process and data transparency in the upcoming years. The FDA and other worldwide regulatory agencies actively monitor compliance with local laws and regulations through review and inspection of design and manufacturing practices, recordkeeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices; detain or seize adulterated or misbranded medical devices; order repair, replacement or refund of these devices; and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA can take action against a company that promotes "off-label" uses. The FDA may also enjoin and restrain a company for certain violations of the FDC Act and other amending Acts pertaining to medical devices, or initiate action for criminal prosecution of such violations. Any adverse regulatory action, depending

on its magnitude, may restrict a company from effectively marketing and selling its products, may limit a company's ability to obtain future premarket clearances or approvals, and could result in a substantial modification to the company's business practices and operations. International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements.

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

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

As a part of the regulatory process of obtaining marketing clearance for new products and new indications for existing 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 FDA's or the market's perception of this clinical data, may adversely impact our ability to obtain product approvals, our position in, and share of, the markets in which we participate and our business, financial condition, results of operations or future prospects.

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

In order to develop new products and enhance existing products, we focus our research and development programs largely on the development of next-generation and novel technology offerings across multiple programs and businesses. The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials and regulatory approvals. The results of our product development efforts may be affected by a number of factors, including our ability to anticipate customer needs, innovate, and develop new products, complete clinical trials, obtain regulatory approvals and reimbursement in the United States and abroad, manufacture products in a cost-effective manner, obtain appropriate intellectual property protection for our products, and gain and maintain market approval of our products. There can be no assurance that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to develop and launch new products and enhanced products, our ability to maintain or expand our market position in the markets in which we participate may be materially adversely impacted. Further, we are continuing to investigate, and have completed several acquisitions that involve opportunities to further expand our presence in, and diversify into priority growth areas by accessing new products and technologies. There can be no assurance that our investments will be successful or we will be able to access new products and technologies on terms favorable to us, or that these products and technologies will achieve commercial feasibility, obtain regulatory approval or gain market acceptance. A delay in the development or approval of new products and technologies or our decision to reduce our investments may adversely impact the contribution of these technologies to our future growth.

Additionally, certain products or groups of products, in particular new products or enhancements of existing products, may have a disproportionate impact on our business, financial condition, and results of operations. Failure to meet growth projections, poor clinical outcomes, increasing regulatory requirements, launch delays, and inability to effectively scale manufacturing and achieve targeted margins with respect to any of these products or groups of



products in particular may materially adversely impact on our business, financial condition, and results of operations.

The medical device industry and its customers continue to face scrutiny and regulation by governmental authorities and are often the subject of numerous investigations, often involving marketing and other business practices or product quality issues including device recalls or advisories. These investigations could result in the commencement of civil and criminal proceedings; imposition of substantial fines, penalties and administrative remedies, including corporate integrity agreements, stipulated judgments or exclusion; diversion of our employees and management's attention; imposition of administrative costs and have an adverse effect on our financial condition, results of operations and liquidity; and may lead to greater governmental regulation in the future.

The medical devices we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. These authorities continue to highly scrutinize our industry. We have received, and in the future may receive, subpoenas and other requests for information from Congress and other state and federal governmental agencies, including, among others, the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services (HHS), and the Department of Defense, as well as from foreign governments and agencies. The requests and/or subpoenas we have received relate primarily to financial arrangements with healthcare providers, regulatory compliance and sale and/or product promotional practices. We have cooperated with these subpoenas and other requests for information, and expect to continue to do so in the future. We cannot predict when a matter will be resolved, the outcome of the matter or its impact on us, and cooperation may involve significant costs, including document production costs. An adverse outcome in any matter could include the commencement of an investigation, civil and criminal proceedings; substantial fines, penalties and administrative remedies, including exclusion from government reimbursement programs, entry into Corporate Integrity Agreements (CIAs) with governmental agencies and amendments to any existing CIAs. In addition, resolution of any matter could involve the imposition of additional and costly compliance obligations. For example, in 2009, we entered into a civil settlement with the DOJ regarding the DOJ's investigation relating to certain post-market surveys conducted by Guidant Corporation before we acquired Guidant in 2006. As part of the settlement, we entered into a 5-year CIA with the Office of Inspector General for HHS, which required various provisions, including enhancements to certain compliance procedures related to financial arrangements with healthcare providers. Cooperation with requests and investigations from external agencies result in employee resource costs and diversion of employee focus. If any requests or investigations continue over a long period of time, they could divert the attention of management from the day-to-day operations of our business and impose significant additional administrative burdens on us. These potential consequences, as well as any adverse outcome from these requests or investigations, could have a material adverse effect on our financial condition, results of operations and liquidity.

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

We anticipate that governmental authorities will continue to scrutinize our industry closely, and that additional regulation may increase compliance and legal cost and exposure to litigation, and have additional adverse effects on our operations.

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

We are subject to income taxes as well as non-income based taxes, in both the U.S. and various foreign jurisdictions. We are subject to on-going tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision and have established contingency reserves for material, known tax exposures.

However, the calculation of such tax exposures involves the application of complex tax laws and regulations in many jurisdictions, as well as interpretations as to the legality under European Union state aid rules of tax advantages granted in certain jurisdictions. Therefore, there can be no assurance that we will accurately predict the outcomes of these disputes or other tax audits or that issues raised by tax authorities will be resolved at a financial cost that does not exceed our related reserves, and the actual outcomes of these disputes and other tax audits could have a material impact on our results of operations or financial condition.

On July 19, 2016, we entered into a Stipulation of Settled Issues with the Internal Revenue Service (IRS) intended to resolve certain transfer pricing issues, as well as certain issues related to our transaction with Abbott, for the 2001 through 2007 tax years. The Stipulation of Settled Issues is contingent upon IRS Office of Appeals (IRS Appeals) applying the same basis of settlement to all transfer pricing issues for the Company's 2008, 2009, and 2010 tax years, and if applicable, review by the U.S. Congress Joint Committee on Taxation. In October 2016, we reached an agreement in principle with IRS Appeals as to the resolution of the

transfer pricing issues in 2008, 2009, and 2010 tax years, subject to additional calculations of tax as well as documentation to memorialize our agreement. The final resolution of these issues is contingent and if the Stipulation of Settled Issues is not finalized, it could have a material impact on our financial condition, results of operations, or cash flows.

Additionally, changes in tax laws could materially impact our effective tax rate. For example, proposals for fundamental U.S. corporate tax reform, if enacted, could have a significant adverse impact on our future results of operations. Additionally, the U.S. Congress, government agencies in non-U.S. jurisdictions where we and our affiliates do business, and the Organization for Economic Co-operation and Development have recently focused on issues related to the taxation of multinational corporations. One example is in the area of “base erosion and profit shifting,” where profits are claimed to be earned for tax purposes in low-tax jurisdictions, or payments are made between affiliates from a jurisdiction with high tax rates to a jurisdiction with lower tax rates. The Organization for Economic Co-operation and Development has released several components of its comprehensive plan to create an agreed set of international rules for fighting base erosion and profit shifting. As a result, the tax laws in the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could materially adversely affect our business.

Our operations in Puerto Rico and Costa Rica presently benefit from various tax incentives and grants. Unless these incentives and grants are extended, they will expire between 2023 and 2028. If we are unable to renew, extend, or obtain new incentive and grants, the expiration of the existing incentives and grants could have a material impact on our financial results in future periods.

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

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

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

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

Patents and other proprietary rights are and will continue to be essential to our business, and our ability to compete effectively with other companies will be dependent upon the proprietary nature of our technologies. We rely upon

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

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

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

We rely on the proper function, availability and security of information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business, financial condition or results of operations.

We rely on information technology systems to process, transmit, and store electronic information in our day-to-day operations. Similar to other large multi-national companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect patient and customer information, and changing customer patterns. In addition, third parties may attempt to hack into our products to obtain data relating to patients or disrupt performance of our products or to access our proprietary information. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. In the U.S., Federal and State privacy and security laws require certain of our operations to protect the confidentiality of personal information including patient medical records and other health information. In Europe, the Data Protection Directive requires us to manage individually identifiable information in the EU and, the new General Data Protection Regulation may impose fines of up to four percent of our global revenue in the event of violations. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. We believe that we meet the expectations of applicable regulations and that the ongoing costs and impacts of ensuring compliance with such rules are not material to our business. However, there is no guarantee that we will avoid enforcement actions by governmental bodies. Enforcement actions can be costly and interrupt regular operations of our business. Any of these events, in turn, may cause us to lose existing customers, have difficulty preventing, detecting, and controlling fraud, have disputes with customers, physicians, and other health care professionals, be subject to legal claims and liability, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues as a result of a data privacy breach or theft of intellectual property, or suffer other adverse consequences, any of which could have a material adverse effect on our business, financial condition or results of operations.

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

We operate in an industry that is susceptible to significant intellectual property litigation and, in recent years, it has been common for companies in the medical device field to aggressively challenge the patent rights of other companies. We are currently the subject of various patent litigation proceedings and other proceedings described in more detail under Note K – Commitments and Contingencies to our 2016 consolidated financial statements included in Item 8 of this Annual Report. Intellectual property litigation is expensive, complex and lengthy, and its outcome is difficult to predict. Adverse outcomes in one or more of these matters could have a material adverse effect on our

ability to sell certain products and on our operating margins, financial condition, results of operation or liquidity. Pending or future patent litigation may result in significant royalty or other payments or injunctions that can prevent the sale of products and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, we may be required to obtain a license on terms which may not be favorable to us, if at all. If we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected.

Pending and future product liability claims and other litigation, including private securities litigation, stockholder derivative suits and contract litigation, may adversely affect our financial condition and results of operations or liquidity.

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

We are currently the subject of product liability litigation proceedings and other proceedings described in more detail under Note K – Commitments and Contingencies to our 2016 consolidated financial statements included in Item 8 of this Annual Report. The outcome of litigation, particularly class action lawsuits, is difficult to assess or quantify. Plaintiffs in these types of lawsuits often seek recovery of very large or indeterminate amounts, including not only actual damages, but also punitive damages. The magnitude of the potential losses relating to these lawsuits may remain unknown for substantial periods of time. In addition, the cost to defend against any future litigation may be significant. Product liability claims, securities and commercial litigation and other litigation in the future, regardless of the outcome, could have a material adverse effect on our financial condition, results of operations or liquidity. Additionally, we maintain an insurance policy providing limited coverage against securities claims, and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. The fact that we do not maintain third-party insurance coverage for all categories of losses increases our exposure to unanticipated claims and adverse decisions, and these losses could have a material adverse effect on our financial condition, results of operations or liquidity.

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

As a medical device manufacturer, we are required to register our establishments and list our devices with the FDA and are subject to periodic inspection by the FDA for compliance with its Quality System Regulation requirements, which require manufacturers of medical devices to adhere to certain regulations, including testing, quality control and documentation procedures. In addition, the Federal Medical Device Reporting regulations require us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or, if a malfunction were to occur, could cause or contribute to a death or serious injury. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA which may result in observations on Form 483, and in some cases warning letters, that require corrective action. In the European Community, we are required to maintain certain International Standards Organization (ISO) certifications in order to sell our products and must undergo periodic inspections by notified bodies to obtain and maintain these certifications. Many other countries in which we do business have requirements similar to those of the US or the EU, and other foreign governments or agencies may subject us to periodic inspections as well. If we, or our manufacturers, fail to adhere to quality system regulations or ISO requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

Interruption of our manufacturing operations could adversely affect our results of operations and financial condition. Our products are designed and manufactured in technology centers around the world, either by us or third parties. In most cases, the manufacturing of our products is concentrated in one or a few locations. Factors such as a failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to one or more of our facilities could adversely affect our ability to manufacture our products. In the event of an interruption in manufacturing, we may be unable to quickly move to alternate means of producing affected products or to meet



customer demand. In the event of a significant interruption, for example, as a result of a failure to follow regulatory protocols and procedures, we may experience lengthy delays in resuming production of affected products due primarily to needs for regulatory approvals. As a result, we may experience loss of market share, which we may be unable to recapture, and harm to our reputation, which could adversely affect our results of operations and financial condition.

Disruptions in the supply of the materials and components used in manufacturing our products or the sterilization of our products by third-party vendors could adversely affect our results of operations and financial condition.

We purchase many of the materials and components used in manufacturing our products from third-party vendors. Certain of these materials and components are purchased from single sources due to quality considerations, expertise, costs or constraints resulting from regulatory requirements. In certain cases we may not be able to establish additional or replacement vendors for such materials or components in a timely or cost effective manner, largely as a result of FDA regulations that require validation of materials and components prior to their use in our products and the complex nature of our and many of our vendors' manufacturing processes. A reduction or interruption in the supply of materials and components used in manufacturing our products; an inability to timely develop and validate alternative sources if required; or a significant increase in the price of such materials or components could adversely affect our results of operations and financial condition.

In addition, many of our products require sterilization prior to sale, and we utilize a mix of internal resources and contract sterilizers to perform this service. To the extent we or our contract sterilizers are unable to sterilize our products, whether due to capacity, availability of materials for sterilization, regulatory or other constraints, we may be unable to transition to other contract sterilizer, sterilizer locations or sterilization methods in a timely or cost effective manner or at all, which could have an adverse impact on our results of operations and financial condition.

Our share price has been volatile and may fluctuate, and accordingly, the value of an investment in our common stock may also fluctuate.

Stock markets in general, and our common stock in particular, have experienced significant price and volume volatility over recent years. The market price and trading volume of our common stock may continue to be subject to significant fluctuations due to factors described under this Item 1A entitled "Risk Factors," as well as economic and geopolitical conditions in general, and also to variability in the prevailing sentiment regarding our operations or business prospects, as well as, among other things, changing investment priorities of our stockholders. Because the market price of our common stock fluctuates significantly, stockholders may not be able sell their shares at attractive prices.

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

In our industry, there is substantial competition for key personnel in the regions in which we operate, and we may face increased competition for such employees, particularly in emerging markets as the trend toward globalization continues. Our business depends to a significant extent on the continued service of senior management and other key personnel, the development of additional management personnel and the hiring of new qualified employees. There can be no assurance that we will be successful in retaining and developing existing personnel or recruiting new personnel. The loss of one or more key employees, our ability to attract or develop additional qualified employees or any delay in hiring key personnel could have material adverse effects on our business, financial condition or results of operations.

## ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

## ITEM 2. PROPERTIES

Our world headquarters is located in Marlborough, Massachusetts, with regional headquarters located in Singapore and Voisins-le-Bretonneux, France. As of December 31, 2016, our principal manufacturing and technology centers were located in Minnesota, California, and Indiana within the U.S.; as well as internationally in Ireland, Costa Rica and Puerto Rico. Our products are distributed worldwide from customer fulfillment centers in Massachusetts and the Netherlands. As of December 31, 2016, we maintained 13 principal manufacturing facilities, including seven in the U.S., three in Ireland, two in Costa Rica, and one in Puerto Rico, as well as various distribution and technology centers around the world. Many of these facilities produce and manufacture products for more than one of our divisions and include research facilities. The following is a summary of our facilities as of December 31, 2016 (in approximate square feet):

	Owned *	Leased **	Total
U.S.	4,256,000	1,824,000	6,080,000
International	1,522,000	1,483,000	3,005,000
	5,778,000	3,307,000	9,085,000

\* Includes our principal manufacturing facilities in Minnesota, Ireland, Puerto Rico and one facility in Costa Rica; our customer fulfillment centers in Massachusetts, the Netherlands and Japan; and our global headquarters location in Marlborough, Massachusetts.

\*\* Includes our principal manufacturing facilities in California, Indiana, and one facility in Costa Rica; and our regional headquarters located in Singapore and Voisins-le-Bretonneux, France.

We regularly evaluate the condition and capacity of our facilities to ensure they are suitable for the development, manufacturing, and marketing of our products, and provide adequate capacity for current and expected future needs. Further, our 2016 restructuring plan continues the implementation of our Plant Network Optimization (PNO) strategy, which is intended to simplify our manufacturing plant structure by transferring certain production lines among facilities. Refer to Restructuring Initiatives within Results of Operations included in Item 7 of this Annual Report and Note H – Restructuring-related Activities to our 2016 consolidated financial statements included in Item 8 of this Annual Report.

## ITEM 3. LEGAL PROCEEDINGS

See Note K – Commitments and Contingencies to our 2016 consolidated financial statements included in Item 8 of this Annual Report and incorporated herein by reference.

## ITEM 4. MINE SAFETY DISCLOSURES

None.

## PART II

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

## Market Information

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

2016	High	Low
First Quarter	\$18.82	\$16.07
Second Quarter	23.37	18.94
Third Quarter	24.48	23.11
Fourth Quarter	23.77	20.09

## 2015

First Quarter	\$18.07	\$13.22
Second Quarter	18.51	17.18
Third Quarter	18.02	15.78
Fourth Quarter	18.94	16.42

## Holders

The closing price of our common stock on January 31, 2017 was \$24.06. As of January 31, 2017, there were 9,573 holders of record of our common stock.

## Dividends

We did not pay a cash dividend in 2016 or 2015, and currently we do not intend to pay cash dividends. We may consider declaring and paying a cash dividend in the future; however, there can be no assurance that we will do so.

## Securities Authorized for Issuance under Equity Compensation Plans

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

## Purchases of Equity Securities by the Issuer and Affiliated Purchases

On January 25, 2013, our Board of Directors approved and on January 29, 2013, we announced a program authorizing the repurchase of up to \$1.0 billion of our common stock. During 2014 we used \$125 million of cash generated from operations to repurchase approximately 10 million shares of our common stock pursuant to our share repurchase authorizations discussed in Note L - Stockholders' Equity to our consolidated financial statements contained in Item 8 of this Annual Report. We made no share repurchases in 2016 or 2015. As of December 31, 2016, we had approximately \$535 million remaining available under the 2013 share repurchase program.

#### Stock Performance Graph

The graph below compares the five-year total return to stockholders on our common stock with the return of the Standard & Poor's (S&P) 500 Stock Index and the S&P Health Care Equipment Index. The graph assumes \$100 was invested in our common stock and in each of the named indices on December 31, 2011, and that all dividends were reinvested.

Note: The stock price performance shown on the graph above is not indicative of future price performance. This graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, regardless of any general incorporation language in such filing.

ITEM 6. SELECTED FINANCIAL DATA  
FIVE-YEAR SELECTED FINANCIAL DATA

(in millions, except per share data)

Operating Data

Year Ended December 31,	2016	2015	2014	2013	2012
Net sales	\$8,386	\$7,477	\$7,380	\$7,143	\$7,249
Gross profit	5,962	5,304	5,170	4,969	4,900
Total operating expenses	5,515	5,631	5,471	4,849	8,768
Operating income (loss)	447	(327 )	(301 )	120	(3,868 )
Income (loss) before income taxes	177	(650 )	(509 )	(223 )	(4,107 )
Net income (loss)	347	(239 )	(119 )	(121 )	(4,068 )
Net income (loss) per common share:					
Basic	\$0.26	\$(0.18 )	\$(0.09 )	\$(0.09 )	\$(2.89 )
Assuming dilution	\$0.25	\$(0.18 )	\$(0.09 )	\$(0.09 )	\$(2.89 )

Balance Sheet Data

As of December 31,	2016	2015	2014	2013	2012
Cash, cash equivalents and marketable securities	\$196	\$319	\$587	\$217	\$207
Working capital	(348 )	1,041	760	1,187	1,250
Total assets	18,096	18,133	17,024	16,549	17,136
Borrowings (short-term)	64	3	403	3	4
Borrowings (long-term)	5,420	5,674	3,841	4,215	4,234
Stockholders' equity	6,733	6,320	6,457	6,539	6,870
Book value per common share*	\$4.94	\$4.69	\$4.86	\$4.95	\$5.07

\*Book value per common share is calculated using shares outstanding as of December 31, for each year, respectively shown.

The data above include certain charges (credits) recorded in conjunction with goodwill and other intangible asset impairments, acquisitions, divestitures, restructuring and restructuring-related activities, debt extinguishment charges, amortization, pension termination charges, discrete tax items and/or litigation. The data above should be read in conjunction with our consolidated financial statements, including the notes thereto, included in Item 8 of this Annual Report, as well as prior year Form 10-K filings.

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

The following discussion and analysis provides information management believes to be relevant to understanding the financial condition and results of operations of Boston Scientific Corporation and its subsidiaries. For full understanding of financial condition and results of operations, you should read this discussion along with our consolidated financial statements and accompanying notes included in Item 8 of this Annual Report.

### Executive Summary

#### Financial Highlights and Trends

In 2016, we generated net sales of \$8.386 billion, as compared to \$7.477 billion in 2015, an increase of \$909 million, or 12 percent. Our net sales were unfavorably impacted by \$99 million from foreign currency fluctuations in 2016, as compared to 2015. Excluding the impact of foreign currency exchange rates, our net sales increased \$1.008 billion, or 12 percent, as compared to the prior year.<sup>1</sup> This increase included net sales of approximately \$236 million in 2016, with no prior year period related net sales, due to the AMS Portfolio Acquisition and the EndoChoice Holdings, Inc. (EndoChoice) acquisition. Refer to the Business and Market Overview section for further discussion of our net sales by global business.

Our reported net income in 2016 was \$347 million, or \$0.25 per diluted share. Our reported results for 2016 included intangible asset impairment charges, acquisition-related net charges, restructuring and restructuring-related net charges, litigation-related charges, and amortization expense totaling \$1.187 billion (after-tax), or \$0.86 per share. Excluding these items, net income for 2016 was \$1.534 billion, or \$1.11 per share.<sup>1</sup> Our reported net loss in 2015 was \$239 million, or \$0.18 per share. Our reported results for 2015 included intangible asset impairment charges, acquisition-related net charges, restructuring and restructuring-related net charges, litigation-related charges, pension termination charges, debt extinguishment charges, discrete tax items, and amortization expense totaling \$1.506 billion (after-tax), or \$1.11 per share. Excluding these items, net income for 2015 was \$1.267 billion, or \$0.93 per share<sup>1</sup>.

<sup>1</sup> Adjusted net sales growth rates, which exclude the impact of changes in foreign currency exchange rates, and adjusted net income and adjusted net income per share, which exclude certain items required by generally accepted accounting principles in the United States (U.S. GAAP) are not prepared in accordance with U.S. GAAP. Refer to Additional Information for a discussion of management's use of these non-GAAP financial measures.

The following is a reconciliation of our results of operations prepared in accordance with U.S. GAAP to those adjusted results considered by management. Refer to Results of Operations for a discussion of each reconciling item:

	Year Ended December 31, 2016			
	Tax			Impact per
in millions, except per share data	Pre-Tax	Impact	After-Tax	share
GAAP net income (loss)	\$177	\$170	\$ 347	\$0.25
Non-GAAP adjustments:				
Intangible asset impairment charges	11	(1 )	10	0.01
Acquisition-related net charges	136	(10 )	126	0.09
Restructuring and restructuring-related net charges	78	(17 )	61	0.04
Litigation-related net charges	804	(292 )	512	0.37
Amortization expense	545	(67 )	478	0.35
Adjusted net income	\$1,751	\$(217)	\$ 1,534	\$ 1.11
	Year Ended December 31, 2015			
	Tax			Impact per
in millions, except per share data	Pre-Tax	Impact	After-Tax	share
GAAP net income (loss)	\$(650 )	\$411	\$( 239 )	\$(0.18)
Non-GAAP adjustments:				
Intangible asset impairment charges	19	(3 )	16	0.01
Acquisition-related net charges	255	(33 )	222	0.17
Restructuring and restructuring-related net charges	83	(14 )	69	0.05
Litigation-related net charges	1,105	(400 )	705	0.52
Pension termination charges	44	(16 )	28	0.02
Debt extinguishment charges	45	(16 )	29	0.02
Discrete tax items	—	(9 )	(9 )	(0.01 )
Amortization expense	495	(49 )	446	0.33
Adjusted net income	\$1,396	\$(129)	\$ 1,267	\$0.93

\*Assumes dilution of 21.5 million shares for 2015 for all or a portion of these non-GAAP adjustments.

Cash provided by operating activities was \$972 million in 2016, as compared to cash provided by operating activities of \$600 million in 2015. This increase in cash provided by operating activities was primarily driven by the increase in net income for 2016 compared to 2015. Our cash generated from operations continues to be a significant source of funds for investing in our growth, including acquisitions and strategic alliances, managing our contingencies and reducing our debt levels.

As of December 31, 2016, we had total debt of \$5.484 billion, cash and cash equivalents of \$196 million and a working capital deficit of \$348 million. We hold investment-grade ratings with all three major credit-rating agencies. We believe our investment grade credit profile reflects the size and diversity of our product portfolio, our leading share position in several of our served markets, our strong cash flow, our solid financial fundamentals and our financial strategy.

Refer to Liquidity and Capital Resources for further discussion.



## Business and Market Overview

### Cardiovascular

#### Interventional Cardiology

Our Interventional Cardiology division develops and manufactures technologies for diagnosing and treating coronary artery disease and other cardiovascular disorders including structural heart conditions. Product offerings include coronary stents, including drug-eluting and bare metal stent systems, balloon catheters, rotational atherectomy systems, guide wires, guide catheters, embolic protection devices, crossing and re-entry devices for the treatment of chronically occluded coronary vessels, diagnostic catheters, and intravascular ultrasound (IVUS) imaging systems. Our structural heart product offerings include a device for transcatheter aortic valve replacement and a device designed to close the left atrial appendage in patients with atrial fibrillation that are at risk for ischemic stroke. Our worldwide net sales of Interventional Cardiology products were \$2.281 billion for 2016, or approximately 27 percent of our consolidated net sales for the year. Our worldwide net sales of Interventional Cardiology products increased \$248 million, or 12 percent, in 2016, as compared to 2015. Excluding the impact of changes in foreign currency exchange rates, which had a \$34 million negative impact on our Interventional Cardiology net sales in 2016, as compared to 2015, net sales of these products increased \$282 million, or 13 percent. This year-over-year increase was primarily related to sales of our drug-eluting stents, led by our ongoing global launch of the SYNERGY™ Stent, our WATCHMAN™ Device following the U.S. commercial launch during the first quarter of 2015 and our Lotus™ Valve System in the EU, along with operational growth in our PCI Guidance System product offerings.

Worldwide sales from our drug-eluting coronary stents were \$1.199 billion during 2016, as compared to \$1.074 billion during 2015, representing a significant portion of our Interventional Cardiology net sales. Our drug-eluting stent systems include our next generation SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System and our Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System, both of which are designed to provide physicians with improved drug-eluting stent performance in treating patients with coronary artery disease. SYNERGY features an ultra-thin abluminal (outer) bioabsorbable polymer coating, while Promus PREMIER™ features a unique customized platinum chromium alloy stent architecture and an enhanced stent delivery system. We received FDA approval of the SYNERGY™ Stent technology and Japanese regulatory approval in the fourth quarter of 2015.

Our structural heart product offerings include our Lotus™ Valve System, a device for transcatheter aortic valve replacement, and our WATCHMAN™ device designed to close the left atrial appendage in patients with non-valvular atrial fibrillation who are at risk for ischemic stroke. The Lotus Valve System consists of a stent-mounted tissue valve prosthesis and catheter delivery system for guidance and placement of the valve.

The original Lotus Valve System as well as our next generation Lotus EDGE™ System are CE-marked in the European Union (EU), and in the U.S. they are investigational devices and not commercially available. In October 2016, we suspended our limited launch and initiated a voluntary removal of field inventory of the Lotus EDGE™ system due to reports that, in some cases, the device could not be fully locked during the procedure due to premature release of a pin connecting the Lotus EDGE™ Valve to the delivery system. In February 2017, we initiated a voluntary removal of all Lotus™ Valve devices, including Lotus with Depth Guard™, from global commercial and clinical sites due to reports of premature release of a pin connecting the Lotus™ Valve to the delivery system. As with the prior announced suspension of our Lotus Edge™ Valve System device, we believe that the issue is caused by excess tension in the pin mechanism introduced during the manufacturing process. We expect to bring the Lotus™ Valve platform back to market in Europe and other regions in the fourth quarter of 2017. We anticipate filing the U.S. PMA submission for the Lotus Edge™ Valve System, the next generation platform, in the fourth quarter of 2017, with a U.S. launch planned for mid-2018.

The WATCHMAN Left Atrial Appendage Closure Technology (WATCHMAN) is the first device studied in a randomized clinical trial to offer an alternative to warfarin, and is marketed in CE-mark countries and other international countries, as well as the U.S. following FDA approval in March 2015. We believe that Watchman will be the only LAAC technology commercially available in the U.S. for multiple years. In November 2015, we received CE

Mark for our next generation device, Watchman FLX™. Shortly after approval, we began a European initial market release of Watchman FLX. The initial market release was suspended near the end of the first quarter of 2016 due to a higher than expected rate of device embolization. Following an extensive data evaluation, we have decided to pursue potential design enhancements prior to returning a next generation device to market.

On December 12, 2016, we completed the acquisition of certain manufacturing assets and capabilities of the Neovasc, Inc. (Neovasc) advanced biological tissue business and made a 15 percent equity investment in Neovasc for a total upfront cash payment of \$75

million. With this acquisition, we will integrate certain manufacturing assets and biologic tissue capabilities into our structural heart business for use in the manufacturing of the Lotus Valve System and future heart valve technologies within our Interventional Cardiology business. We expect this integration to be substantially completed by the end of 2018.

#### Peripheral Interventions

Our Peripheral Interventions (PI) product offerings include stents, balloon catheters, wires, peripheral embolization devices and other devices used to diagnose and treat peripheral vascular disease, along with products to treat, diagnose and ease various forms of cancer.

Our worldwide net sales of PI products were \$1.011 billion for 2016, or approximately 12 percent of our consolidated net sales for the year. Our worldwide net sales of PI products increased \$107 million, or 12 percent, in 2016, as compared to 2015. Excluding the impact from changes in foreign currency exchange rates, which had an \$11 million negative impact on our worldwide PI net sales in 2016, as compared to 2015, net sales of these products increased \$118 million, or 12 percent. This year-over-year increase was primarily driven by revenues from our Atherectomy and Thrombectomy systems, as well as growth in our core PI franchises, particularly our stent franchise following FDA approval and launch of our Innova™ Vascular self-expanding stent system in the U.S. and Japan, our interventional oncology franchise and our drug-eluting product franchise.

On December 31, 2015, we completed the acquisition of the interventional radiology business of CeloNova Biosciences (CeloNova). The acquisition includes drug-eluting microspheres designed to be loaded with chemotherapy drugs for delivery to cancerous tumors, and spherical embolic products used to treat uterine fibroids and other conditions. We are in the process of integrating CeloNova into our Peripheral Interventions business and expect to be substantially complete by the second half of 2017.

#### Rhythm Management

##### Cardiac Rhythm Management

Our Cardiac Rhythm Management (CRM) business develops, manufactures and markets a variety of implantable devices including implantable cardioverter defibrillator (ICD) systems and implantable cardiac resynchronization therapy defibrillators, including the world's first and only commercially available subcutaneous implantable cardioverter defibrillator, the S-ICD System, and pacemaker systems that monitor the heart and deliver electricity to treat cardiac abnormalities. In addition, in most geographies, we monitor device performance remotely, allowing for more frequent monitoring in order to guide treatment decisions.

Our worldwide net sales of CRM products were \$1.850 billion for 2016, or approximately 22 percent of our consolidated net sales for the year. Our worldwide net sales of CRM products increased \$43 million, or two percent, in 2016, as compared to 2015. Excluding the impact of changes in foreign currency exchange rates, which had a \$17 million negative impact on our CRM net sales in 2016, as compared to 2015, net sales of these products increased \$60 million, or three percent. This year-over-year increase was primarily driven by strong global pacemaker growth including the U.S. launch of the ACCOLADE™ family of magnetic resonance imaging (MRI) safe pacemakers and the Ingevity™ MRI pacing lead in the U.S., global growth from our quadripolar cardiac resynchronization therapy pacemakers (CRT-P), global S-ICD sales growth and benefits from our sales collaboration agreement with Preventice Solutions, Inc., (Preventice). In the U.S., the fourth quarter of 2016 represented our second full quarter of U.S. MRI pacemaker commercialization, the third quarter of commercialization for our Acuity™ X4 Quadripolar LV Pacing Lead in both the cardiac resynchronization therapy defibrillator (CRT-D) and CRT-P franchises, and global commercialization of our EMBLEM™ MRI S-ICD system. These combined launches more than offset lower volumes of replacement procedures for our defibrillators due to their extended longevity and pressure from competitor high voltage MRI technologies primarily in the U.S. On April 30, 2015, we acquired a 27 percent ownership interest in Preventice, which includes 18.5 percent of Preventice's common stock. Preventice is a privately-held company

headquartered in Minneapolis, MN, and a leading developer of mobile health solutions and services. In addition to the equity agreement, we entered into a commercial agreement with Preventice, under which we became Preventice's exclusive, worldwide sales and marketing representative. In October 2016, we notified Preventice of our intent to terminate the commercial agreement and will transition the sales force back to Preventice in 2017 under the terms of the agreement.

The following are the components of our CRM net sales:

	Year Ended	
(in millions)	December 31, 2016	December 31, 2015
Defibrillator systems	\$1,274	\$ 1,313
Pacemaker systems	576	494
CRM products	\$1,850	\$ 1,807
Electrophysiology		

Our Electrophysiology business develops less-invasive medical technologies used in the diagnosis and treatment of rate and rhythm disorders of the heart. Our leading products include the Blazer™ line of ablation catheters, designed to deliver enhanced performance and responsiveness, and the Rhythmia™ Mapping System, a next-generation, catheter-based, 3-D cardiac mapping and navigation solution designed to help diagnose and treat a variety of arrhythmias.

Our worldwide net sales of Electrophysiology products were \$243 million for 2016, or approximately three percent of our consolidated net sales for the year. Our worldwide net sales of Electrophysiology products increased \$10 million, or four percent, in 2016, as compared to 2015. Excluding the impact from changes in foreign currency exchange rates, which had a \$3 million negative impact on our Electrophysiology net sales in 2016, as compared to 2015, net sales of these products increased \$13 million, or five percent. This year-over-year increase was primarily driven by increased sales of our Rhythmia Mapping System and related products. In the first quarter of 2016, we initiated a full European launch of our Blazer IntellaNav™ OI Catheter which is used with our Rhythmia Mapping System and, in July of 2016, we received FDA approval for this same catheter. In the second quarter of 2016, we received FDA approval for IntellaNav™ XP and the IntellaNav MiFi™ XP Navigation-Enabled Ablation Catheters that are used with the Rhythmia Mapping System. We also received FDA approval for our Blazer™ Open Irrigated System with Atrial Flutter indication and began full U.S. commercialization in the second quarter of 2016. Our global roll-out of our Rhythmia Mapping System, including early Europe commercialization of our next generation Rhythmia™ HDx System late in the fourth quarter, along with continued global expansion of our new navigation enabled therapeutic catheter portfolio, will continue as we expand our global Rhythmia installed base.

#### MedSurg Endoscopy

Our Endoscopy division develops and manufactures devices to treat a variety of medical conditions including diseases of the digestive and pulmonary systems. Our worldwide net sales of Endoscopy products were \$1.440 billion for 2016, or approximately 17 percent of our consolidated net sales for the year. Our worldwide net sales of Endoscopy products increased \$134 million, or 10 percent, in 2016, as compared to 2015. Excluding the impact from changes in foreign currency exchange rates, which had a negative \$9 million impact on our Endoscopy net sales in 2016 as compared to 2015, net sales of these products increased \$143 million, or 10 percent. This year-over-year increase was primarily driven by growth across several of our key product franchises, including our biliary device franchise with our SpyGlass™ DS Direct Visualization System and our AXIOS Stent and Electrocautery-Enhanced Delivery System for endoscopic ultrasound-guided transmural drainage of pancreatic pseudocysts; our metal stent franchise driven by our Biliary WallFlex® product family; and our hemostasis franchise, featuring our Resolution™ and Resolution 360™ Clips. This increase also includes revenue of approximately \$10 million with no prior year period related net sales, due to the EndoChoice acquisition in November 2016, as described below.

On November 22, 2016, we completed our acquisition of EndoChoice. EndoChoice is an Alpharetta, Georgia based company focused on the development and commercialization of infection control products, pathology services and single-use devices for specialists treating a wide range of gastrointestinal (GI) conditions. We began the process of integrating EndoChoice into our Endoscopy business in the fourth quarter of 2016 and expect to be substantially complete by the end of 2017.

On November 1, 2016, we acquired the LumenR™ Tissue Retractor System from LumenR LLC (LumenR), a privately held Newark, California based company. The LumenR™ Tissue Retractor System is currently in development for use during endoscopic resection of lesions in the colon, esophagus or stomach.

On April 2, 2015, we acquired Xlumen, Inc. (Xlumen), a medical device company that developed minimally invasive devices for Endoscopic Ultrasound (EUS) guided transluminal drainage of targeted areas within the gastrointestinal tract. In 2016, we completed the integration of Xlumen into our Endoscopy business.

## Urology and Pelvic Health

Our Urology and Pelvic Health division develops and manufactures devices to treat various urological and pelvic conditions, such as kidney stones, benign prostatic hyperplasia (BPH), erectile dysfunction, male incontinence, pelvic floor disorders, abnormal uterine bleeding, and uterine fibroids and polyps. Our worldwide net sales of Urology and Pelvic Health products were \$1.005 billion for 2016, or approximately 12 percent of our consolidated net sales for the year. Our worldwide net sales of Urology and Pelvic Health products increased \$312 million, or 45 percent, in 2016, as compared to 2015. Excluding the impact from changes in foreign currency exchange rates, which had a negative \$18 million impact on our Urology and Pelvic Health net sales in 2016, as compared to 2015, net sales of these products increased \$330 million, or 45 percent. This year-over-year increase was primarily attributable to revenue of approximately \$226 million with no prior year period related net sales, due to the AMS Portfolio Acquisition in August 2015, along with growth across all of our other global franchises, including our Pelvic Floor franchise as a result of market share gains primarily driven by a competitor exiting the market during the first quarter of 2016. On November 15, 2016, we completed the acquisition of the gynecology and urology portfolio of Distal Access, LLC (Distal), a Salt Lake City based company that designs minimally invasive medical devices. The portfolio includes the Resectr™ Tissue Resection Device, a single-use solution designed to remove uterine polyps. We began the process of integrating the Resectr device into our Urology and Pelvic Health business during the fourth quarter of 2016 and expect to be substantially complete by the end of 2017.

On August 3, 2015, we completed the acquisition of the American Medical Systems male urology portfolio (AMS Portfolio Acquisition), which includes the men's health and prostate health businesses, from Endo International plc. The AMS male urology portfolio was integrated with our formerly named Urology and Women's Health business, and the joint businesses became Urology and Pelvic Health. The integration was substantially complete by the end of 2016.

## Neuromodulation

Our Neuromodulation business offers the Precision™, Precision Spectra™, Precision Montage™ and Precision Novi™ Spinal Cord Stimulator (SCS) Systems, used for the management of chronic pain, and our Vercise™ Deep Brain Stimulation (DBS) System in various international regions such as Europe, Latin America and Asia Pacific for the treatment of Parkinson's disease, tremor and intractable primary and secondary dystonia, a neurological movement disorder characterized by involuntary muscle contractions. Our worldwide net sales of Neuromodulation products were \$556 million for the year ended December 31, 2016, or approximately seven percent of our consolidated net sales for the year ended December 31, 2016. Our worldwide net sales of Neuromodulation products increased \$55 million, or 11 percent, in 2016, as compared to 2015. Excluding the impact from changes in foreign currency exchange rates, which had a negative \$7 million impact on our Neuromodulation net sales in 2016, as compared to 2015, net sales of these products increased \$62 million, or 12 percent. The year-over-year increase was primarily driven by share gains from our Montage™ System, continued adoption of the Precision Spectra™ SCS System in the U.S. and increased net sales in Europe, driven by our Vercise™ DBS Systems and non-rechargeable Precision Novi™ SCS System.

On July 27, 2016, we acquired Cosman Medical, Inc. (Cosman), a privately held manufacturer of radiofrequency ablation systems, expanding our Neuromodulation portfolio and offering physicians treating patients with chronic pain a wider choice of non-opioid therapeutic options. We are in the process of integrating Cosman into our Neuromodulation business, and expect the integration to be substantially complete by the end of 2017.

## Emerging Markets

As part of our strategic imperatives to drive global expansion, described in Item 1 of this Annual Report, we are seeking to grow net sales and market share by expanding our global presence, including in Emerging Markets. We define Emerging Markets as including 20 countries that we believe have strong growth potential based on their economic conditions, healthcare sectors, and our global capabilities. We are seeking to expand our presence and strengthen relationships in order to grow net sales and market share within our Emerging Markets, and we have

increased our investment in infrastructure in these countries in order to maximize opportunities. Our Emerging Markets revenue grew nine percent, as compared to the prior year, and was approximately 10 percent of our consolidated net sales in 2016. Excluding the impact from changes in foreign currency exchange rates, which had a negative impact of 11 percent, net sales in these markets grew 20 percent.



## Results of Operations

## Net Sales

We manage our global businesses on a constant currency basis, and we manage market risk from currency exchange rate changes at the corporate level. Management excludes the impact of changes in foreign currency exchange rates for purposes of reviewing revenue growth rates to facilitate an evaluation of current operating performance and comparison to past operating performance. To calculate revenue growth rates that exclude the impact of changes in foreign currency exchange rates, we convert current period and prior period net sales from local currency to U.S. dollars using standard internal currency exchange rates held constant for each year.

The following table provides our net sales by global business and the relative change on an as reported and constant currency basis. The constant currency growth rates in the tables below can be recalculated from our net sales presented in Note O - Segment Reporting to our consolidated financial statements contained in Item 8 of this Annual Report. Net sales that exclude the impact of changes in foreign currency exchange rates and net sales from divested businesses are not financial measures prepared in accordance with U.S. GAAP and should not be considered in isolation from, or as a replacement for, the most directly comparable GAAP financial measure. Refer to Additional Information of this Item 7 for a further discussion of management's use of this non-GAAP financial measure.

(in millions)	Year Ended December 31,			2016 versus 2015			2015 versus 2014		
				As Reported Currency Basis	Constant Currency Basis	%	As Reported Currency Basis	Constant Currency Basis	%
Interventional Cardiology	\$2,281	\$2,033	\$2,057	12	% 13	%	(1 )	% 7	%
Peripheral Interventions	1,011	904	850	12	% 12	%	6	% 13	%
Cardiovascular	3,292	2,937	2,907	12	% 12	%	1	% 9	%
Cardiac Rhythm Management	1,850	1,807	1,912	2	% 3	%	(5 )	% 1	%
Electrophysiology	243	233	227	4	% 5	%	2	% 9	%
Rhythm Management	2,093	2,040	2,139	3	% 3	%	(5 )	% 1	%
Endoscopy	1,440	1,306	1,323	10	% 10	%	(1 )	% 6	%
Urology and Pelvic Health	1,005	693	535	45	% 45	%	30	% 36	%
Neuromodulation	556	501	472	11	% 12	%	6	% 8	%
MedSurg	3,001	2,500	2,330	20	% 20	%	7	% 13	%
Subtotal Core Businesses	8,386	7,477	7,376	12	% 12	%	1	% 8	%
Divested Businesses	—	—	4	N/A	N/A		N/A	N/A	
Net Sales	\$8,386	\$7,477	\$7,380	12	% 12	%	1	% 8	%

Refer to Executive Summary for further discussion of our net sales and a comparison of our 2016 and 2015 net sales.

In 2015, we generated net sales of \$7.477 billion, as compared to \$7.380 billion in 2014, an increase of \$97 million, or one percent. Our net sales were unfavorably impacted by \$505 million from foreign currency fluctuations in 2015 as compared to 2014. Excluding the impact of foreign currency and sales from divested businesses, our net sales increased \$606 million, or eight percent, as compared to the prior year. This increase was due primarily to constant currency increases in net sales from our Urology and Pelvic Health business of \$193 million, primarily due to the AMS Portfolio Acquisition; from our Interventional Cardiology business of \$150 million; from our Peripheral Interventions business of \$114 million; and from our Endoscopy business of \$79 million.



### Gross Profit

Our gross profit was \$5.962 billion in 2016, \$5.304 billion in 2015, and \$5.170 billion in 2014. As a percentage of net sales, our gross profit increased to 71.1 percent in 2016, as compared to 70.9 percent in 2015 and 70.1 percent in 2014. The following is a reconciliation of our gross profit margins and a description of the drivers of the change from period to period:

	Year Ended December 31,	
	2016	2015
Gross profit - prior year	70.9 %	70.1 %
Manufacturing cost reductions	2.0 %	1.8 %
Sales pricing and mix	(0.1 )%	(0.6 )%
Inventory step-up due to acquisition accounting	(0.2 )%	(0.4 )%
Net impact of foreign currency	(0.9 )%	0.5 %
All other, including other inventory charges and other period expense	(0.6 )%	(0.5 )%
Gross profit - current year	71.1 %	70.9 %

The primary factor contributing to the increase in our gross profit margin for 2016, as compared to 2015, was the positive impact of cost reductions as a result of our restructuring and other process improvement programs. Partially offsetting these factors was the net negative impact of foreign currency fluctuations and other inventory charges and period expenses. The increase in our gross profit margin for 2015, as compared to 2014, primarily resulted from manufacturing cost reductions as a result of our restructuring and other process improvement programs. Partially offsetting these factors was the net negative impact of pricing declines related primarily to sales of our drug-eluting stent and CRM products. In addition, in connection with the accounting for the AMS Portfolio Acquisition, we adjusted acquired inventory from manufacturing cost to fair value. The step-up in value is amortized through gross profit over an average estimated inventory turnover period. We recorded increased cost of \$22 million in 2016 and \$36 million in 2015 associated with the step-up.

### Operating Expenses

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

	Year Ended December 31,					
	2016		2015		2014	
	% of		% of		% of	
	Net		Net		Net	
(in millions)	\$	Sales	\$	Sales	\$	Sales
Selling, general and administrative expenses	3,099	37.0 %	2,873	38.4 %	2,902	39.3 %
Research and development expenses	920	11.0 %	876	11.7 %	817	11.1 %
Royalty expense	79	0.9 %	70	0.9 %	111	1.5 %

#### Selling, General and Administrative (SG&A) Expenses

In 2016, our SG&A expenses increased \$226 million, or eight percent, as compared to 2015, and were 140 basis points lower as a percentage of net sales. This decrease in SG&A as a percentage of sales was primarily driven by the benefit of our targeted initiatives focused on reducing SG&A, as well as the reduction in expenses resulting from the suspension of the Medical Device Excise Tax, which was substantially reinvested into our strategic growth initiatives. The Medical Device Excise Tax was temporarily suspended in December 2015 through December 31, 2017.

In 2015, our SG&A expenses decreased \$29 million, or one percent, as compared to 2014, and were 90 basis points lower as a percentage of net sales. This decrease was driven by the impacts of our foreign currency fluctuations and declines in spending as a result of our restructuring and other cost reduction initiatives. We recorded \$78 million in 2015 and \$72 million in 2014 related to the Medical Device Excise Tax.

## Research and Development (R&D) Expenses

We remain committed to advancing medical technologies and investing in meaningful research and development projects across our businesses. In 2016, our R&D expenses increased \$44 million, or five percent, as compared to 2015, and were 70 basis points lower as a percentage of net sales. In 2015, our R&D expenses increased \$59 million, or seven percent, as compared to 2014, and were 60 basis points higher as a percentage of net sales. The year-over-year increase in expenses was due primarily to investments across all of our businesses in order to maintain a healthy pipeline of new products that we believe will contribute to profitable sales growth and increased cost related to recent acquisitions and alliances, partially offset by the favorable impact of foreign currency fluctuations.

## Royalty Expense

In 2016, our royalty expense increased \$9 million, or 13 percent, as compared to 2015 and remained flat at approximately one percent of net sales for both periods. The increase in royalty expense was primarily due to increases in net sales of our drug-eluting coronary stent systems in 2016.

In 2015, our royalty expense decreased \$41 million, or 37 percent, as compared to 2014, and was 60 basis points lower as a percentage of net sales. The decrease relates primarily to the renegotiation of a royalty agreement in the second quarter of 2014 that resulted in a lower royalty rate structure.

## Amortization Expense

Our amortization expense was \$545 million in 2016, as compared to \$495 million in 2015, an increase of \$50 million or 10 percent. Amortization expense was \$495 million in 2015, as compared to \$438 million in 2014, an increase of \$57 million or 13 percent. The increases in each period were primarily due to amortizable intangible assets acquired in the AMS Portfolio Acquisition on August 3, 2015.

Amortization expense is excluded by management for purposes of evaluating operating performance.

## Intangible Asset Impairment Charges

We have recorded intangible asset impairment charges, including impairments of in-process research and development, of \$11 million in 2016, \$19 million in 2015 and \$195 million in 2014.

See Note D - Goodwill and Other Intangible Assets to our consolidated financial statements contained in Item 8 of this Annual Report on Form 10-K, for additional details related to our intangible asset impairment charges.

Refer to Critical Accounting Estimates for a discussion of key assumptions used in our goodwill and intangible asset impairment testing and future events that could have a negative impact on the recoverability of our goodwill and amortizable intangible assets. Intangible asset impairment charges are excluded by management for purposes of evaluating operating performance and assessing liquidity.

## Contingent Consideration Expense

We recorded a net expense related to the change in fair value of our contingent consideration liabilities of \$29 million in 2016, a net expense of \$123 million in 2015 and a net benefit of \$85 million in 2014. Refer to Note B – Acquisitions and Strategic Investments to our consolidated financial statements contained in Item 8 of this Annual Report for additional details related to our contingent consideration expenses.

Contingent consideration expense is excluded by management for purposes of evaluating operating performance.

## Restructuring-related Activities and Charges

We recorded restructuring charges pursuant to our restructuring plans of \$28 million during 2016, \$26 million during 2015, and \$69 million during 2014. In addition, we recorded expenses within other lines of our accompanying consolidated statements of operations related to our restructuring initiatives of \$50 million during 2016, \$57 million during 2015, and \$48 million during 2014. Restructuring and restructuring-related costs are excluded by management for purposes of evaluating operating performance.

The 2016 Restructuring Plan is expected to result in total pre-tax charges of approximately \$175 million to \$225 million and reduce gross annual expenses by approximately \$115 million to \$150 million by the end of 2020 as program benefits are realized. The

2014 Restructuring Plan resulted in total pre-tax charges of \$261 million and will reduce annual expenses by approximately \$200 million. We expect a substantial portion of the savings to be reinvested in strategic growth initiatives.

We made cash payments of \$82 million in 2016, \$95 million in 2015, and \$112 million in 2014 associated with our restructuring initiatives.

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

#### Litigation-related Charges and Credits

We recorded net litigation-related charges in the amount of \$804 million in 2016, \$1.105 billion in 2015, and \$1.036 billion in 2014. The net charges recorded in 2016 include primarily amounts related to transvaginal surgical mesh product liability cases and claims. The net charges recorded in 2015 include amounts primarily related to transvaginal surgical mesh product liability cases and claims and the charge related to the Mirowski Family Venture LLC (Mirowski) lawsuit following a jury verdict that Guidant Corporation (Guidant) breached their license agreement with Mirowski. The net charges recorded in 2014 include a \$600 million charge related to the agreement between our subsidiary, Guidant and Johnson & Johnson signed on February 13, 2015, to settle the breach of merger agreement lawsuit brought by Johnson & Johnson, stemming from our acquisition of Guidant. In exchange, we made aggregate payments totaling \$600 million to Johnson & Johnson during 2015. The 2014 net charges also include amounts related to transvaginal surgical mesh product liability cases and claims and certain other items.

Litigation related charges and credits are excluded by management for purposes of evaluating operating performance.

We continue to assess certain litigation and claims to determine the amounts, if any, that management believes will be paid as a result of such claims and litigation and, therefore, additional losses may be accrued and paid in the future, which could materially adversely impact our operating results, cash flows and/or our ability to comply with our debt covenants. Refer to Note K – Commitments and Contingencies to our consolidated financial statements contained in Item 8 of this Annual Report for additional discussion of our material legal proceedings.

#### Pension Termination Charges

We recorded pension termination charges of \$44 million during 2015 associated with the termination of the Guidant Retirement Plan, a frozen defined benefit plan. We do not expect to incur any additional charges in the future related to the termination of the Guidant Retirement Plan.

The pension termination charges are excluded by management for purposes of evaluating operating performance.

#### Gain on Divestiture

In January 2011, we closed the sale of our Neurovascular business to Stryker Corporation. We recorded a pre-tax gain of \$12 million during 2014 associated with the transaction. These divestiture-related gains are excluded by management for purposes of evaluating operating performance.

#### Interest Expense

Our interest expense was \$233 million in 2016 with an average borrowing rate of 4.0 percent, as compared to \$284 million in 2015, with an average borrowing rate of 5.2 percent. Interest expense in 2015 included a pre-tax charge of approximately \$45 million associated with debt extinguishment charges, representing premiums, accelerated amortization of debt issuance costs and investor discount costs net of interest rate hedge gains related to the early extinguishment of \$1.000 billion of debt during the second quarter of 2015.

Our interest expense was \$284 million in 2015, with an average borrowing rate of 5.2 percent, as compared to \$216 million in 2014, with an average borrowing rates of 4.8 percent. The increase was primarily due to the pre-tax charge of approximately \$45 million associated with debt extinguishment charges, along with incremental debt to finance the

AMS Portfolio Acquisition offset by savings from refinancing our senior notes.

Debt extinguishment charges are excluded by management for purposes of evaluating operating performance. Refer to Liquidity and Capital Resources, Note E – Fair Value Measurements and Note F – Borrowings and Credit Arrangements to our consolidated financial statements contained in Item 8 of this Annual Report for information regarding our debt obligations.

## Other, net

Our other, net reflected expense of \$37 million in 2016, expense of \$39 million in 2015, and income of \$8 million in 2014. The following are the components of other, net:

	Year Ended December 31,		
(in millions)	2016	2015	2014
Interest income	\$5	\$5	\$5
Foreign currency losses	(13)	(21)	(18)
Net gains (losses) on investments	(21)	(9)	27
Other expense, net	(8)	(14)	(6)
	\$(37)	\$(39)	\$8

During 2016, we recognized net losses of \$21 million due to equity method adjustments on investments and investment impairments which were partially offset by a gain on our Neovasc investment. During 2015, we recognized net losses of \$9 million due to equity method adjustments on investments and investment impairments. During 2014, we recognized gains of \$19 million associated with the acquisition of IoGyn, Inc. related to previously held investments and other net gains related to our investment portfolio of \$8 million. The acquisition-related gains from previously held investments are excluded by management for purposes of evaluating operating performance. Refer to Note B – Acquisitions and Strategic Investments to our consolidated financial statements contained in Item 8 of this Annual Report for information regarding our strategic investments.

## Tax Rate

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

	Year Ended December 31,		
	2016	2015	2014
Reported tax rate	(95.9)%	63.2%	76.7%
Impact of certain receipts/charges*	108.3%	(53.5)%	(64.5)%
	12.4%	9.7%	12.2%

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

The change in our reported tax rate for 2016, as compared to 2015 and 2014, relates primarily to the impact of certain receipts and charges that are taxed at different rates than our effective tax rate, including intangible asset impairment charges, acquisition-related net charges, contingent consideration, litigation-related net charges, restructuring-related net charges, pension termination charges and debt extinguishment charges, as well as the impact of certain discrete tax items.

In 2016, these receipts and charges included intangible asset impairment charges, acquisition-related net charges, litigation-related net charges and restructuring-related net charges. Our reported tax rate for 2016 was also affected by discrete items primarily related to the resolution of various uncertain tax positions through settlement or expiration of statute, offset by a charge related to changes in state apportionment.

In 2015, these receipts and charges included intangible asset impairment charges, acquisition-related net charges, litigation-related net charges, restructuring-related net charges, pension termination charges, and debt extinguishment charges. Our reported tax rate for 2015 was also affected by discrete items primarily related to benefits due to settlement of various uncertain tax positions and reinstatement of certain tax legislation that has been retroactively applied.

In 2014, these receipts and charges included intangible asset impairment charges, acquisition- and divestiture-related net charges, litigation-related net charges and restructuring-related net charges. Our reported tax rate for 2014 was also affected by discrete tax items primarily related to resolution of various uncertain tax positions resulting from the expiration of the statute of limitations for assessing tax in certain jurisdictions and benefit due to change in uncertain tax positions due to a favorable court ruling, offset by a charge due to translation gain on previously taxed income.

We are contesting in U.S. Tax Court significant proposed adjustments from the Internal Revenue Service (IRS) related to its audit of our transfer pricing methodologies for the 2001 through 2007 tax years. The IRS also proposed similar transfer pricing adjustments for the 2008 through 2010 tax years. We disagree with the transfer pricing methodologies being applied by the IRS



and we were scheduled to go to trial in the U.S. Tax Court in late July 2016. On July 19, 2016, we entered a Stipulation of Settled Issues with the IRS intended to resolve all of the aforementioned transfer pricing issues, as well as issues related to our transaction with Abbott, for the 2001 through 2007 tax years. The Stipulation of Settled Issues is contingent upon the IRS Office of Appeals (IRS Appeals) applying the same basis of settlement to all transfer pricing issues for the Company's 2008, 2009, and 2010 tax years, and if applicable, review by the United States Congress Joint Committee on Taxation. In October 2016, we reached an agreement in principle with IRS Appeals as to the resolution of the transfer pricing issues in 2008, 2009, and 2010 tax years, subject to additional calculations of tax as well as documentation to memorialize our agreement. In the event that the conditions in the Stipulation of Settled Items are satisfied, we expect to make net tax payments of approximately \$275 million, plus interest through the date of payment. If finalized, payments related to the resolution are expected in the next nine to 18 months. We believe that our income tax reserves associated with these matters are adequate as of December 31, 2016 and we do not expect to recognize any additional charges related to resolution of this controversy. However, the final resolution of these issues is contingent and if the Stipulation of Settled Issues is not finalized, it could have a material impact on our financial condition, results of operations, or cash flows.

See Note J - Income Taxes to our consolidated financial statements included in Item 8 of this Annual Report for additional details on our tax rate and our tax litigation.

### Liquidity and Capital Resources

Based on our current business plan, we believe our existing balance of cash and cash equivalents, future cash generated from operations and access to capital markets and credit facilities will be sufficient to fund our operations, invest in our infrastructure, pay our legal-related liabilities, pay taxes due, fund possible mergers and/or acquisitions and service and repay our existing debt. Please refer to our Contractual Obligations and Commitments table for additional details on our future payment obligations and commitments.

As of December 31, 2016, we had \$196 million of cash and cash equivalents on hand, comprised of \$42 million invested in money market and government funds and \$154 million in short-term time deposits and interest bearing and non-interest bearing bank accounts. We invest excess cash on hand in short-term financial instruments that earn market interest rates while mitigating principal risk through instrument and counterparty diversification, as well as what we believe to be prudent instrument selection. We limit our direct exposure to securities in any one industry or issuer. We also have full access to our \$2.000 billion revolving credit facility and \$240 million of available borrowings under our credit and security facility secured by our U.S. trade receivables as of December 31, 2016, both described below.

The following provides a summary and description of our net cash inflows (outflows) for the years ended December 31, 2016, 2015 and 2014:

	Year Ended December 31,		
(in millions)	2016	2015	2014
Cash provided by operating activities	\$972	\$600	\$1,269
Cash used for investing activities	(887)	(2,186)	(745)
Cash provided by (used for) financing activities	(206)	1,322	(150)

#### Operating Activities

During 2016, cash provided by operating activities was \$972 million, as compared to \$600 million in 2015, an increase of \$372 million or 62 percent. This increase was primarily driven by the increase in net income for 2016 compared to 2015, partially offset by approximately \$100 million increase in litigation-related payments. During 2016, we made litigation-related payments primarily associated with the transvaginal surgical mesh product liability cases and to Mirowski.

Refer to Note K – Commitments and Contingencies for additional information on litigation-related matters.

During 2015, we generated \$600 million of cash from operating activities, as compared to \$1.269 billion in 2014, a decrease of \$669 million, or 53 percent. This decrease was primarily due to the \$600 million of payments to Johnson

& Johnson.

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### Investing Activities

During 2016, cash used for investing activities was \$887 million. Our investing activities primarily included \$408 million of payments, net of cash acquired, for acquisitions including Cosman, EndoChoice, LumenR, Distal and Neovasc; along with \$376 million in purchases of property, plant and equipment and \$132 million of payments related to strategic investments, partially offset by proceeds from the sale of one of two buildings located in Quincy, Massachusetts for \$29 million. We intend to invest approximately \$300 million in purchases of property, plant and equipment during 2017.

During 2015, cash used for investing activities was \$2.186 billion. Our investing activities included \$1.734 billion of payments net of cash acquired, for acquisitions, including the AMS Portfolio Acquisition, CeloNova and Xlumena; along with \$266 million of payments related to strategic investments, including equity investments in Preventice, Inc. and Frankenman Medical Equipment Company. Cash used for investing activities also included purchases of property, plant and equipment of \$247 million.

During 2014, cash used for investing activities was \$745 million. Our investing activities included \$486 million of payments, net of cash acquired, for acquisitions including IoGyn and the Interventional Division of Bayer AG; along with purchases of property, plant and equipment of \$259 million.

### Financing Activities

Our cash flows from financing activities reflect issuances and repayments of debt, payments of acquisition-related contingent consideration, and cash used to new share settle and stock issuances related to our equity incentive programs, as discussed in Note L - Stockholders' Equity to our consolidated financial statements included in Item 8 of this Annual Report. Additionally, our financing activities included \$65 million of contingent payments in 2016, \$156 million of payments in 2015 and \$34 million of payments in 2014 associated with our previous acquisitions.

Our liquidity plans are subject to a number of risks and uncertainties, including those described in Item 1A. Risk Factors of this Annual Report, some of which are outside our control. Macroeconomic conditions, adverse litigation outcomes and other risk and uncertainties could limit our ability to successfully execute our business plans and adversely affect our liquidity plans.

### Debt

We had total debt of \$5.484 billion as of December 31, 2016 and \$5.677 billion as of December 31, 2015 which consisted of the following:

#### Revolving Credit Facility

In April 2015, we entered into a new \$2.000 billion revolving credit facility (the 2015 Facility) with a global syndicate of commercial banks and terminated our previous \$2.000 billion revolving credit facility. The 2015 Facility matures in April 2020. There were no amounts borrowed under our current or prior revolving credit facility as of December 31, 2016 or December 31, 2015.

#### Term Loans

As of December 31, 2016, we had an aggregate \$750 million outstanding under our unsecured term loan facilities and \$1.000 billion outstanding under these facilities as of December 31, 2015. These facilities include an unsecured term loan facility entered into in August 2013 (2013 Term Loan) which had \$150 million outstanding as of December 31, 2016 and \$250 million outstanding as of December 31, 2015, along with an unsecured term loan credit facility entered into in April 2015 (2015 Term Loan) which had \$600 million outstanding as of December 31, 2016 and \$750 million outstanding as of December 31, 2015.

Our revolving credit facility and our term loan facilities require that we maintain certain financial covenants as outlined in Note F – Borrowings and Credit Arrangements to our consolidated financial statements contained in Item 8 of this Annual Report. As of and through December 31, 2016, we were in compliance with the required covenants. Any inability to maintain compliance with these covenants could require us to seek to renegotiate the terms of our credit facility or seek waivers from compliance with these covenants, both of which could result in additional borrowing costs. Further, there can be no assurance that our lenders would agree to such new terms or grant such waivers.

### Senior Notes

We had senior notes outstanding of \$4.650 billion as of December 31, 2016 and as of December 31, 2015. Our senior notes were issued in public offerings, are redeemable prior to maturity and are not subject to any sinking fund requirements. Our senior notes are unsecured, unsubordinated obligations and rank on parity with each other. These notes are effectively junior to borrowings under our credit and security facility, to the extent if borrowed by our subsidiaries, and to liabilities of our subsidiaries.

On January 12, 2017, we used our existing credit facilities to repay the \$250 million plus interest of our senior notes due in January 2017.

The debt maturity schedule for the significant components of our debt obligations as of December 31, 2016 is as follows:

(in millions)	2017	2018	2019	2020	2021	Thereafter	Total
Senior Notes	\$250	\$600	\$—	\$1,450	\$—	\$2,350	\$4,650
Term Loans	—	225	150	375	—	—	750
	\$250	\$825	\$150	\$1,825	\$—	\$2,350	\$5,400

Note: The table above does not include unamortized discounts associated with our senior notes, or amounts related to interest rate contracts used to hedge the fair value of certain of our senior notes or debt issuance costs.

#### Other Arrangements

We maintained a \$300 million credit and security facility secured by our U.S. trade receivables maturing on June 9, 2017. We had borrowings of \$60 million outstanding under this facility as of December 31, 2016 and no borrowings outstanding as of December 31, 2015. On February 7, 2017, we amended the terms of this credit and security facility, including increasing the facility size to \$400 million. This amendment retained a similar maximum leverage ratio requirement and extended the facility maturity to February 2019.

We also have accounts receivable factoring programs in certain European countries that we account for as sales under Financial Accounting Standards Board (FASB) Accounting Standards Codification® (ASC) Topic 860, Transfers and Servicing. These agreements provide for the sale of accounts receivable to third parties, without recourse, of up to approximately \$391 million as of December 31, 2016. We de-recognized \$152 million of receivables as of December 31, 2016 at an average interest rate of 1.8 percent, and \$151 million as of December 31, 2015 at an average interest rate of 2.4 percent.

In addition, we have uncommitted credit facilities with a commercial Japanese bank that provide for borrowings, promissory notes discounting and receivables factoring of up to 21,000 billion Japanese yen (approximately \$180 million as of December 31, 2016). We de-recognized \$149 million of notes receivable as of December 31, 2016 at an average interest rate of 1.6 percent and \$132 million of notes receivable as of December 31, 2015 at an average interest rate of 1.6 percent. De-recognized accounts and notes are excluded from trade accounts receivable, net in the accompanying audited consolidated balance sheets.

We had outstanding letters of credit of \$44 million as of December 31, 2016 and as of December 31, 2015. As of December 31, 2016 and 2015, none of the beneficiaries had drawn upon the letters of credit or guarantees. We believe we will generate sufficient cash from operations to fund these arrangements and intend to fund these arrangements without drawing on the letters of credit.

For additional details related to our debt, including our revolving credit facility, term loans, senior notes and other arrangements, see Note F – Borrowings and Credit Arrangements to our consolidated financial statements included in Item 8 of this Annual Report.

#### Equity

During 2016 we received \$111 million in proceeds from stock issuances related to our stock option and employee stock purchase plans, as compared to \$114 million in 2015 and \$60 million 2014. Proceeds from the exercise of employee stock options and employee stock purchases vary from period to period based upon, among other factors, fluctuations in the trading price of our common stock and in the exercise and stock purchase patterns of employees. We repurchased 10 million shares for \$125 million during 2014. No share repurchases were made in 2016 or 2015. As of December 31, 2016, we had remaining approximately \$535 million authorized under our 2013 share repurchase program. There were approximately 248 million shares in treasury as of December 31, 2016 and December 31, 2015. Stock-based compensation expense related to our stock ownership plans was \$116 million in 2016, \$107 million in 2015, and \$103 million in 2014. Stock-based compensation expense varies from period to period based upon, among other factors: the timing, number and fair value of awards granted during the period; forfeiture levels related to unvested awards; and employee contributions to our employee stock purchase plan.



## Contractual Obligations and Commitments

The following table provides a summary of certain information concerning our obligations and commitments to make future payments, and is based on conditions in existence as of December 31, 2016.

(in millions)	2017	2018	2019	2020	2021	Thereafter	Total
Long-term debt obligations	\$250	\$825	\$150	\$1,825	\$—	\$ 2,350	\$5,400
Interest payments (1)	224	216	194	151	111	899	1,795
Lease obligations (1)	66	60	42	34	25	64	291
Purchase obligations (1)	321	52	39	19	12	15	458
Minimum royalty obligations (1)	1	2	1	2	1	1	8
Legal reserves	1,062	—	—	—	—	—	1,062
Unrecognized tax benefits (2)	577	—	—	—	—	—	577
	\$2,501	\$1,155	\$426	\$2,031	\$149	\$ 3,329	\$9,591

(1) In accordance with U.S. GAAP, these obligations relate to expenses associated with future periods and are not reflected in our consolidated balance sheets.

(2) Includes accrued interest and penalties and other related items.

The amounts in the table above with respect to lease obligations represent amounts pursuant to contractual arrangements for the lease of property, plant and equipment used in the normal course of business. Purchase obligations relate primarily to non-cancellable inventory commitments and capital expenditures entered in the normal course of business. Royalty obligations reported above represent minimum contractual obligations under our current royalty agreements. The table above does not include \$584 million of unrecognized tax benefits and \$197 million of accrued interest and penalties, and other related items because the timing of their future cash settlement is uncertain. Refer to Note J - Income Taxes to our consolidated financial statements included in Item 8 of this Annual Report for more information on these unrecognized tax benefits. In addition, the table above does not reflect our accrual for legal matters that are probable and estimable of \$961 million due to the timing of payment being uncertain. Refer to Note K – Commitments and Contingencies to our consolidated financial statements included in Item 8 of this Annual Report for more information on our legal accrual.

With certain of our acquisitions, we acquired in-process research and development projects that require future funding to complete the projects. The primary basis for determining the technological feasibility or completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. We estimate that the total remaining cost to complete the in-process research and development projects we acquired is between \$25 million and \$50 million. Net cash inflows from the projects currently in development are expected to commence in 2017 through 2030, following the respective launches of these technologies in the U.S., Europe and Japan. Certain of our acquisitions also involve the potential payment of contingent consideration. The table above does not reflect any such obligations, as the timing and amounts are uncertain. See Note B – Acquisitions and Strategic Investments to our consolidated financial statements included in Item 8 of this Annual Report for the estimated maximum potential amount of future contingent consideration we could be required to pay associated with prior acquisitions and the fair value of our contingent consideration liabilities as of December 31, 2016.

## Legal Matters

For a discussion of our material legal proceedings see Note K – Commitments and Contingencies to our consolidated financial statements included in Item 8 of this Annual Report.

## Critical Accounting Policies and Estimates

Our financial results are affected by the selection and application of accounting policies and methods. We have adopted accounting policies to prepare our consolidated financial statements in conformity with U.S. GAAP. To prepare our consolidated financial statements in accordance with U.S. GAAP, management makes estimates and assumptions that may affect the reported amounts of our assets and liabilities, the disclosure of contingent liabilities as of the date of our financial statements and the reported amounts of our revenues and expenses during the reporting period. Our actual results may differ from these estimates. We consider estimates to be critical if (i) we are required to make assumptions about material matters that are uncertain at the time of estimation or if (ii) materially different

estimates could have been made or it is reasonably likely that the accounting estimate will change from period to period. The following are areas considered to be critical and require management's



judgment: Revenue Recognition, Bad Debt Reserves, Inventory Provisions, Valuation of Contingent Consideration Liabilities and Intangible Assets, Goodwill Valuation, Legal and Product Liability Accruals and Income Taxes. See Note A – Significant Accounting Policies to our consolidated financial statements included in Item 8 of this Annual Report for additional information related to our accounting policies and our consideration of these critical accounting areas. In addition, see Note B – Acquisitions and Strategic Investments and Note D - Goodwill and Other Intangible Assets for further discussion on the valuation of goodwill and intangible assets and contingent consideration; Note J - Income Taxes for further discussion on income tax related matters and Note K – Commitments and Contingencies for further discussion on legal and product liability matters.

#### Revenue Recognition

We generally allow our customers to return defective, damaged and, in certain cases, expired products for credit. We base our estimate for sales returns upon historical trends and record these amounts as a reduction of revenue when we sell the initial product. In addition, we may allow customers to return previously purchased products for next-generation product offerings. For these transactions, we defer recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount to be returned when the next-generation products are shipped to the customer. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls and variation in product utilization all affect our estimates related to sales returns and could cause actual returns to differ from these estimates.

Many of our CRM product offerings combine the sale of a device with our LATITUDE™ Patient Management System, which represents a future service obligation. For revenue arrangements with multiple deliverables, where the sale of a device is combined with a future service obligation, we defer revenue on the undelivered element and recognize this revenue over the related service period. Generally, we do not have vendor specific objective evidence of selling price available related to our future service obligations; therefore, we determine our estimates of selling price using third party evidence when available; otherwise, we use our best estimate of selling price. We allocate arrangement consideration using the relative selling price method. The use of alternative estimates of fair value could result in a different amount of revenue deferral.

#### Inventory Provisions

We base our provisions for excess, expired and obsolete inventory primarily on our estimates of forecasted net sales. A significant change in the timing or level of demand for our products as compared to forecasted amounts may result in recording additional provisions for excess, expired and obsolete inventory in the future. Further, the industry in which we participate is characterized by rapid product development and frequent new product introductions. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls and variation in product utilization all affect our estimates related to excess, expired and obsolete inventory.

#### Valuation of Intangible Assets and Contingent Consideration Liabilities

We base the fair value of identifiable intangible assets acquired in a business combination, including in-process research and development, on detailed valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. Further, for those arrangements that involve potential future contingent consideration, we record on the date of acquisition a liability equal to the fair value of the estimated additional consideration we may be obligated to make in the future. We re-measure this liability each reporting period and record changes in the fair value through a separate line item within our consolidated statements of operations. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, as well as changes in the timing and amount of revenue estimates or in the timing or likelihood of achieving regulatory, revenue or commercialization-based milestones. The use of alternative valuation assumptions, including estimated revenue projections; growth rates; cash flows and discount rates and alternative estimated useful life assumptions, or probabilities surrounding the achievement of clinical, regulatory or revenue-based milestones could result in different purchase price allocations, amortization expense, and contingent consideration expense in current and future periods. We review intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. If an impairment indicator exists, we test the intangible asset for recoverability. If the carrying value of the intangible asset

is not recoverable, we will write the carrying value down to fair value in the period identified. We calculate fair value of our intangible assets as the present value of estimated future cash flows we expect to generate from the asset using a risk-adjusted discount rate. The use of alternative assumptions, including estimated cash flows, discount rates, and alternative estimated remaining useful lives could result in different calculations of impairment. In addition, we test our indefinite-lived intangible assets at least annually for impairment and reassess their classification as indefinite-lived assets, or more frequently if change in circumstance or indicators exist. We

assess qualitative factors to determine whether the existence of events and circumstances indicate that it is more likely than not that our indefinite-lived intangible assets are impaired. If we conclude that it is more likely than not that the asset is impaired, we then determine the fair value of the intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying value in accordance with FASB ASC Topic 350, Intangibles - Goodwill and Other (Topic 350). If the carrying value exceeds the fair value of the indefinite-lived intangible asset, we write the carrying value down to the fair value.

#### Goodwill Valuation

We allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination to goodwill. We test our goodwill balances during the second quarter of each year for impairment, or more frequently if indicators are present or changes in circumstances suggest that impairment may exist. We assess goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a component. In 2016, we identified six operating segments including Interventional Cardiology, Peripheral Interventions, Rhythm Management, Endoscopy, Urology and Pelvic Health, and Neuromodulation for purposes of identifying our reporting units. We then assessed whether any components of these segments constitute a business for which discrete financial information is available and where segment management regularly reviews the operating results of that component. We identified Rhythm Management as having two components: Cardiac Rhythm Management and Electrophysiology.

For our 2016, 2015 and 2014 annual impairment assessment we identified seven reporting units, which align to our seven core businesses: Interventional Cardiology, Peripheral Interventions, Cardiac Rhythm Management, Electrophysiology, Endoscopy, Urology and Pelvic Health and Neuromodulation. For our 2016 annual impairment assessment we aggregated the Cardiac Rhythm Management and Electrophysiology reporting units, components of the Rhythm Management operating segment, based on the criteria prescribed in FASB ASC Topic 350. These reporting units were aggregated due to a reorganization that commenced in 2015 that resulted in integrated leadership, shared resources and consolidation of certain sites in 2016.

In performing the goodwill impairment assessment, we utilize both the optional qualitative assessment and the two-step approach prescribed under FASB ASC Topic 350. Beginning in 2016, the qualitative assessment was used for testing certain reporting units where fair value has historically exceeded carrying value by greater than 100%. All other reporting units were tested using the two-step approach described below. The qualitative assessment requires an evaluation of whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount based on an assessment of relevant events including macroeconomic factors, industry and market conditions, cost factors, overall financial performance and other entity-specific factors. After assessing the totality of events, if it is determined that it is not more likely than not that the fair value of the reporting unit is less than its carrying value, the first and second steps of the goodwill impairment test are unnecessary. If it is determined that impairment is more likely than not, then we perform the first step of the two-step impairment test. In 2016, for all reporting units tested using the optional qualitative assessment, we concluded that it was not necessary to perform the first step of the two-step goodwill impairment test. The first step requires a comparison of the carrying value of the reporting units to the fair value of these units.

For our 2016, 2015 and 2014 annual impairment assessment, for those reporting units for which a quantitative test was performed, we used only the income approach, specifically the discounted cash flow (DCF) method, to derive the fair value of each of our reporting units in preparing our goodwill impairment assessments. This approach calculates fair value by estimating the after-tax cash flows attributable to a reporting unit and then discounting these after-tax cash flows to a present value using a risk-adjusted discount rate. We selected this method as being the most meaningful in preparing our goodwill assessments because we believe the income approach most appropriately measures our income producing assets. We have considered using the market approach and cost approach but concluded they are not appropriate in valuing our reporting units given the lack of relevant market comparisons available for application of the market approach and the inability to replicate the value of the specific technology-based assets within our reporting units for application of the cost approach. Therefore, we believe that the income approach represents the

most appropriate valuation technique for which sufficient data are available to determine the fair value of our reporting units.

In applying the income approach to our accounting for goodwill, we make assumptions about the amount and timing of future expected cash flows, terminal value growth rates and appropriate discount rates. The amount and timing of future cash flows within our DCF analysis is based on our most recent operational budgets, long range strategic plans and other estimates. The terminal value growth rate is used to calculate the value of cash flows beyond the last projected period in our DCF analysis and reflects our best estimates for stable, perpetual growth of our reporting units. We use estimates of market-participant risk-adjusted weighted-average cost of capital (WACC) as a basis for determining the discount rates to apply to our reporting units' future expected cash flows.

If the carrying value of a reporting unit exceeds its fair value, we then perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any. If the carrying value of a reporting unit is zero or negative, we evaluate whether

it is more likely than not that a goodwill impairment exists. If we determine adverse qualitative factors exist that would indicate it is more likely than not an impairment exists, we then perform the second step of the goodwill test. The second step of the goodwill impairment test compares the estimated fair value of a reporting unit's goodwill to its carrying value.

Although we use consistent methodologies in developing the assumptions and estimates underlying the fair value calculations used in our impairment tests, these estimates are uncertain by nature and can vary from actual results. The use of alternative valuation assumptions, including estimated revenue projections, growth rates, cash flows and discount rates could result in different fair value estimates.

In the second quarter of 2016, we performed our annual goodwill impairment test for all of our reporting units and concluded the fair value of each reporting unit exceeded its carrying value. Because our global Electrophysiology reporting unit was identified as being at higher risk of potential goodwill impairment during our 2015 annual test, it was tested for impairment on a stand-alone basis in the second quarter of 2016, immediately prior to aggregating it with our global Cardiac Rhythm Management reporting unit. The fair value of the stand-alone global Electrophysiology reporting unit exceeded the carrying value by approximately 36 percent. In comparison, the global Electrophysiology reporting unit had excess fair value of approximately 28 percent as of our 2015 annual test. As of the date of our 2016 annual goodwill impairment test, the aggregated global Electrophysiology and Cardiac Rhythm Management operating segment (Rhythm Management) had excess fair value over carrying value of approximately 70 percent and held \$292 million of allocated goodwill. As such, it was not deemed at higher risk of future impairment. Changes in our reporting units or in the structure of our business as a result of future reorganizations, acquisitions or divestitures of assets or businesses could result in future impairments of goodwill within our reporting units.

Refer to Note D - Goodwill and Other Intangible Assets to our consolidated financial statements contained in Item 7 of this Annual Report on Form 10-K for additional details related to our annual goodwill impairment tests.

#### Legal and Product Liability Accruals

In the normal course of business, we are involved in various legal and regulatory proceedings, including intellectual property, breach of contract, securities litigation and product liability suits. In some cases, the claimants seek damages, as well as other relief, which, if granted, could require significant expenditures or impact our ability to sell our products. We accrue anticipated costs of settlement, damages, losses for product liability claims and, under certain conditions, costs of defense, based on historical experience or to the extent specific losses are probable and estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range. Litigation and product liability matters are inherently uncertain and the outcomes of individual matters are difficult to predict and quantify. As such, significant judgment is required in determining our legal and product liability accruals. Our estimates related to our legal and product liability accruals may change as additional information becomes available to us, including information related to the nature or existence of claims against us; trial court or appellate proceedings; and mediation, arbitration or settlement proceedings.

#### Income Taxes

We provide for potential amounts due in various tax jurisdictions. In the ordinary course of conducting business in multiple countries and tax jurisdictions, there are many transactions and calculations where the ultimate tax outcome is uncertain. Therefore, judgment is required based on individual facts, circumstances and information available in determining whether or not based on technical merits, the position will be sustained upon examination. In our opinion, we have made adequate provisions for income taxes in determining our worldwide income tax position for all years subject to audit.

#### New Accounting Pronouncements

See Note Q - New Accounting Pronouncements to our consolidated financial statements included in Item 8 of this Annual Report for additional information on Standards Implemented since December 31, 2015 and Standards to be Implemented.

#### Additional Information

Use of Non-GAAP Financial Measures by Boston Scientific

To supplement our consolidated financial statements presented on a GAAP basis, we disclose certain non-GAAP financial measures, including adjusted net income and adjusted net income per share that exclude certain amounts, and adjusted net sales that exclude the impact of sales from divested businesses and/or changes in foreign currency exchange rates. These non-GAAP financial measures are not in accordance with generally accepted accounting principles in the United States.

The GAAP financial measure most directly comparable to adjusted net income is GAAP net income (loss) and the GAAP financial measure most directly comparable to adjusted net income per share is GAAP net income (loss) per share. To calculate adjusted net sales that exclude sales from divested businesses and/or changes in foreign currency exchange rates, we convert actual net sales from local currency to U.S. dollars using constant foreign currency exchange rates in the current and prior period and/or eliminate the net sales from businesses that were divested during the period. The GAAP financial measure most directly comparable to constant currency growth rate and/or growth rates excluding sales from divested business is growth rate percentages using net sales on a GAAP basis.

Reconciliations of each of these non-GAAP financial measures to the corresponding GAAP financial measure are included in the relevant sections of this Annual Report.

Management uses these supplemental non-GAAP financial measures to evaluate performance period over period, to analyze the underlying trends in our business, to assess our performance relative to our competitors, and to establish operational goals and forecasts that are used in allocating resources. In addition, management uses these non-GAAP financial measures to further its understanding of the performance of our operating segments. The adjustments excluded from our non-GAAP financial measures are consistent with those excluded from our operating segments' measures of net sales and profit or loss. These adjustments are excluded from the segment measures that are reported to our chief operating decision maker that are used to make operating decisions and assess performance.

We believe that presenting adjusted net income, adjusted net income per share, and adjusted net sales that exclude certain amounts, such as sales from divested businesses and/or the impact of changes in foreign currency exchange rates, in addition to the corresponding GAAP financial measures, provides investors greater transparency to the information used by management for its operational decision-making and allows investors to see our results "through the eyes" of management. We further believe that providing this information assists our investors in understanding our operating performance and the methodology used by management to evaluate and measure such performance.

The following is an explanation of each of the adjustments that management excluded as part of these non-GAAP financial measures as well as reasons for excluding each of these individual items:

#### Adjusted Net Income and Adjusted Net Income per Share

- Intangible asset impairment charges - This amount represents write-downs of certain intangible asset balances during 2016, 2015 and 2014. We review intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment and test our indefinite-lived intangible assets at least annually for impairment. If we determine the carrying value of the amortizable intangible asset is not recoverable or we conclude that it is more likely than not that the indefinite-lived asset is impaired, we will write the carrying value down to fair value in the period identified. We exclude the impact of impairment charges from management's assessment of operating performance and from our operating segments' measures of profit and loss used for making operating decisions and assessing performance. Accordingly, management has excluded intangible asset impairment charges for purposes of calculating these non-GAAP financial measures to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Acquisition- and divestiture related net charges (credits) - These adjustments may consist of (a) contingent consideration fair value adjustments; (b) gains on previously held investments; (c) purchased and/or funded in-process research and development expenses incurred outside of a business combination; (d) due diligence, other fees, inventory step-up amortization, and integration and exit costs; and (e) separation costs and gains primarily associated with the sale of our Neurovascular business in January 2011. The contingent consideration adjustments represent accounting adjustments to state contingent consideration liabilities at their estimated fair value. These adjustments can be highly variable depending on the assessed likelihood and amount of future contingent consideration payments. Due diligence, other fees, inventory step-up amortization, and integration and exit costs include legal, tax, severance and

other expenses associated with prior and potential future acquisitions and divestitures that can be highly variable and not representative of ongoing operations. Separation costs and gains on the sale of a business unit primarily represent those associated with the Neurovascular divestiture and are not representative of ongoing operations. Accordingly, management excluded these amounts for purposes of calculating these non-GAAP financial measures to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Restructuring and restructuring-related net charges (credits) - These adjustments represent severance and other direct costs associated with our restructuring plans. These restructuring plans each consist of distinct initiatives that are fundamentally different from our ongoing, core cost reduction initiatives in terms of, among other things, the frequency with which each action is performed and the required planning, resourcing, cost and timing. Examples of such initiatives include the movement of business activities, facility consolidations and closures, and the transfer of product lines



between manufacturing facilities, which, due to the highly regulated nature of our industry, requires a significant investment in time and cost to create duplicate manufacturing lines, run product validations, and seek regulatory approvals. Restructuring initiatives generally take approximately two years to complete and have a distinct project timeline that begins subsequent to approval by our Board of Directors. In contrast to our ongoing cost reduction initiatives, restructuring initiatives typically result in duplicative cost and exit costs over this period of time, are one-time shut downs or transfers, and are not considered part of our core, ongoing operations. Because these restructuring plans are incremental to the core activities that arise in the ordinary course of our business, management excluded these costs for purposes of calculating these non-GAAP financial measures to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Litigation-related net charges (credits) - These adjustments include certain significant product liability and other litigation-related charges and credits. We record these charges and credits, which we consider to be unusual or infrequent and significant, within the litigation-related charges line in our consolidated statement of operations; all other legal and product liability charges, credits and costs are recorded within selling general and administrative expenses. These amounts are excluded by management in assessing our operating performance, as well as from our operating segments' measures of profit and loss used for making operating decisions and assessing performance. Accordingly, management excluded these amounts for purposes of calculating these non-GAAP financial measures to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Debt extinguishment charges - This item represents premiums, accelerated amortization of debt issuance costs and investor discount costs net of interest rate hedge gains related to the early extinguishment of \$1.0 billion of senior notes during the second quarter of 2015. These adjustments are not expected to recur and do not reflect expected ongoing operating results. Accordingly, management excluded these amounts for purposes of calculating these non-GAAP financial measures to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Pension termination charges - This item represents charges associated with the termination of the Guidant Retirement Plan, a frozen defined benefit plan. These charges are not expected to recur after 2015 and do not reflect expected ongoing operating results. Accordingly, management has excluded these amounts for purposes of calculating these non-GAAP financial measures to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Amortization expense - We record intangible assets at historical cost and amortize them over their estimated useful lives. Amortization expense is excluded from management's assessment of operating performance and is also excluded from our operating segments' measures of profit and loss used for making operating decisions and assessing performance. Accordingly, management has excluded amortization expense for purposes of calculating these non-GAAP financial measures to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Discrete tax items - These items represent adjustments of certain tax positions, which were initially established in prior periods in conjunction with the purchase accounting for an acquisition or as a result of intangible asset impairment charges; acquisition-, divestiture-, restructuring- or litigation-related charges or credits. These adjustments do not reflect expected on-going operating results. Accordingly, management excluded these amounts for purposes of calculating these non-GAAP financial measures to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Adjusted Net Sales Excluding the Impact of Sales from Divested Businesses and/or Changes in Foreign Currency Exchange Rates

•

Sales from divested businesses are primarily associated with the Neurovascular divestiture and are not representative of ongoing operations. The impact of changes in foreign currency exchange rates is highly variable and difficult to predict. Accordingly, management excludes the impact of sales from divested businesses and/or changes in foreign currency exchange rates for purposes of reviewing adjusted net sales to facilitate an evaluation of our current operating performance and a comparison to our past operating performance.

Adjusted net income, adjusted net income per share and adjusted net sales that exclude certain amounts, such as the sales from divested businesses and/or the impact of changes in foreign currency exchange rates, are not in accordance with U.S. GAAP and should not be considered in isolation from or as a replacement for the most directly comparable GAAP financial measures. Further, other companies may calculate these non-GAAP financial measures differently than we do, which may limit the usefulness of those measures for comparative purposes.

#### Rule 10b5-1 Trading Plans by Executive Officers

Periodically, certain of our executive officers adopt written stock trading plans in accordance with Rule 10b5-1 under the Exchange Act and our own Stock Trading Policy. A Rule 10b5-1 Trading Plan is a written document that pre-establishes the amount, prices and dates (or formulas for determining the amounts, prices and dates) of future purchases or sales of our stock, including shares issued upon exercise of stock options or vesting of deferred stock units. These plans are entered into at a time when the person is not in possession of material non-public information about our company. We disclose details regarding individual Rule 10b5-1 Trading Plans on the Investor Relations section of our website.

Management's Annual Report on Internal Control over Financial Reporting

As the management of Boston Scientific Corporation, we are responsible for establishing and maintaining adequate internal control over financial reporting. We designed our internal control process to provide reasonable assurance to management and the Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

We assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control–Integrated Framework (2013 framework). Based on our assessment, we believe that, as of December 31, 2016, our internal control over financial reporting is effective at a reasonable assurance level based on these criteria.

Ernst & Young LLP, an independent registered public accounting firm, has issued an audit report on the effectiveness of our internal control over financial reporting. This report in which they expressed an unqualified opinion is included below.

/s/ Michael F. Mahoney

/s/ Daniel J. Brennan

Michael F. Mahoney

President and Chief Executive Officer

Daniel J. Brennan

Executive Vice President and Chief  
Financial Officer

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Boston Scientific Corporation

We have audited Boston Scientific Corporation's internal control over financial reporting as of December 31, 2016 based on criteria established in Internal Control---Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission 2013 framework (the COSO criteria). Boston Scientific Corporation's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Boston Scientific Corporation maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Boston Scientific Corporation as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016 of Boston Scientific Corporation and our report dated February 23, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
February 23, 2017



**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We develop, manufacture and sell medical devices globally and our earnings and cash flows are exposed to market risk from changes in currency exchange rates and interest rates. We address these risks through a risk management program that includes the use of derivative financial instruments. We operate the program pursuant to documented corporate risk management policies. We do not enter derivative transactions for speculative purposes. Gains and losses on derivative financial instruments substantially offset losses and gains on underlying hedged exposures. Furthermore, we manage our exposure to counterparty risk on derivative instruments by entering into contracts with a diversified group of major financial institutions and by actively monitoring outstanding positions.

Our currency risk consists primarily of foreign currency denominated firm commitments, forecasted foreign currency denominated intercompany and third-party transactions and net investments in certain subsidiaries. We use both nonderivative (primarily European manufacturing operations) and derivative instruments to manage our earnings and cash flow exposure to changes in currency exchange rates. We had currency derivative instruments outstanding in the contract amount of \$4.100 billion as of December 31, 2016 and \$3.547 billion as of December 31, 2015. We recorded \$199 million of other assets and \$26 million of other liabilities to recognize the fair value of these derivative instruments as of December 31, 2016, as compared to \$237 million of other assets and \$23 million of other liabilities as of December 31, 2015. A ten percent appreciation in the U.S. dollar's value relative to the hedged currencies would increase the derivative instruments' fair value by \$257 million as of December 31, 2016 and \$155 million as of December 31, 2015. A ten percent depreciation in the U.S. dollar's value relative to the hedged currencies would decrease the derivative instruments' fair value by \$223 million as of December 31, 2016 and by \$189 million as of December 31, 2015. Any increase or decrease in the fair value of our currency exchange rate sensitive derivative instruments would be substantially offset by a corresponding decrease or increase in the fair value of the hedged underlying asset, liability or forecasted transaction, resulting in minimal impact on our consolidated statements of operations.

Our interest rate risk relates primarily to U.S. dollar borrowings partially offset by U.S. dollar cash investments. We have historically used interest rate derivative instruments to manage our earnings and cash flow exposure to changes in interest rates. We have no interest rate derivative instruments outstanding as of December 31, 2016. As of December 31, 2016, \$4.670 billion of our outstanding debt obligations was at fixed interest rates, representing approximately 85 percent of our total debt.

See Note E – Fair Value Measurements to our 2016 consolidated financial statements contained in Item 8 of this Annual Report for further information regarding our derivative financial instruments.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Boston Scientific Corporation

We have audited the accompanying consolidated balance sheets of Boston Scientific Corporation as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2016. Our audits also included the financial statement schedule listed in the Index at Item 15(a)2. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Boston Scientific Corporation at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Boston Scientific Corporation's internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 23, 2017 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts  
February 23, 2017



## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS

in millions, except per share data	Year Ended December 31,		
	2016	2015	2014
Net sales	\$8,386	\$7,477	\$7,380
Cost of products sold	2,424	2,173	2,210
Gross profit	5,962	5,304	5,170
Operating expenses:			
Selling, general and administrative expenses	3,099	2,873	2,902
Research and development expenses	920	876	817
Royalty expense	79	70	111
Amortization expense	545	495	438
Intangible asset impairment charges	11	19	195
Contingent consideration expense (benefit)	29	123	(85 )
Restructuring charges	28	26	69
Litigation-related charges	804	1,105	1,036
Pension termination charges	—	44	—
Gain on divestiture	—	—	(12 )
	5,515	5,631	5,471
Operating income (loss)	447	(327 )	(301 )
Other income (expense):			
Interest expense	(233 )	(284 )	(216 )
Other, net	(37 )	(39 )	8
Income (loss) before income taxes	177	(650 )	(509 )
Income tax (benefit) expense	(170 )	(411 )	(390 )
Net income (loss)	\$347	\$(239 )	\$(119 )
Net income (loss) per common share — basic	\$0.26	\$(0.18 )	\$(0.09 )
Net income (loss) per common share — assuming dilution	\$0.25	\$(0.18 )	\$(0.09 )
Weighted-average shares outstanding			
Basic	1,357.6	1,341.2	1,324.3
Assuming dilution	1,377.2	1,341.2	1,324.3

See notes to the consolidated financial statements.

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Year Ended December		
(in millions)	31,	2016	2015
	2016	2015	2014
Net income (loss)	\$347	\$(239)	\$(119)
Other comprehensive income (loss), net of tax:			
Foreign currency translation adjustment	(25 )	(16 )	(22 )
Net change in unrealized gains and losses on derivative financial instruments, net of tax	(45 )	(67 )	78
Net change in available-for-sale securities	(6 )	—	—
Net change in unrealized costs associated with certain retirement plans	(11 )	27	(18 )
Total other comprehensive income (loss)	(87 )	(56 )	38
Total comprehensive income (loss)	\$260	\$(295)	\$(81 )

See notes to the consolidated financial statements.

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS

	As of December 31,	
in millions, except share and per share data	2016	2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$196	\$319
Trade accounts receivable, net	1,472	1,275
Inventories	955	1,016
Deferred and prepaid income taxes	75	496
Other current assets	541	365
Total current assets	3,239	3,471
Property, plant and equipment, net	1,630	1,490
Goodwill	6,678	6,473
Other intangible assets, net	5,883	6,194
Other long-term assets	666	505
<b>TOTAL ASSETS</b>	<b>\$18,096</b>	<b>\$18,133</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Current debt obligations	\$64	\$3
Accounts payable	447	209
Accrued expenses	2,312	1,970
Other current liabilities	764	248
Total current liabilities	3,587	2,430
Long-term debt	5,420	5,674
Deferred income taxes	18	735
Other long-term liabilities	2,338	2,974
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value - authorized 50,000,000 shares, none issued and outstanding		
Common stock, \$0.01 par value - authorized 2,000,000,000 shares; issued 1,609,670,817 shares as of December 31, 2016 and 1,594,213,786 shares as of December 31, 2015	16	16
Treasury stock, at cost - 247,566,270 shares as of December 31, 2016 and December 31, 2015	(1,717 )	(1,717 )
Additional paid-in capital	17,014	16,860
Accumulated deficit	(8,581 )	(8,927 )
Accumulated other comprehensive income (loss), net of tax:		
Foreign currency translation adjustment	(79 )	(54 )
Unrealized gain on derivative financial instruments	107	152
Unrealized loss on available-for-sale securities	(6 )	—
Unrealized costs associated with certain retirement plans	(21 )	(10 )
Total stockholders' equity	6,733	6,320
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$18,096</b>	<b>\$18,133</b>

See notes to the consolidated financial statements.

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock	Par Value	Treasury Stock	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)
in millions, except share data	Shares Issued					
Balance as of December 31, 2013	1,560,302,634	\$ 16	\$(1,592)	\$ 16,579	\$ (8,570)	\$ 106
Net loss					(119)	
Changes in other comprehensive income (loss), net of tax						
Foreign currency translation adjustment						(22)
Net change in derivative financial instruments						78
Net change in certain retirement plans						(18)
Impact of stock-based compensation plans, net of tax	14,715,602	—		124		
Acquisition of treasury stock			(125)			
Balance as of December 31, 2014	1,575,018,236	\$ 16	\$(1,717)	\$ 16,703	\$ (8,689)	\$ 144
Net loss					(239)	
Changes in other comprehensive income (loss), net of tax						
Foreign currency translation adjustment						(16)
Net change in derivative financial instruments						(67)
Net change in certain retirement plans						27
Impact of stock-based compensation plans, net of tax	19,195,550	—		157		
Rounding					1	
Balance as of December 31, 2015	1,594,213,786	\$ 16	\$(1,717)	\$ 16,860	\$ (8,927)	\$ 88
Net income					347	
Changes in other comprehensive income (loss), net of tax						
Foreign currency translation adjustment						(25)
Net change in derivative financial instruments						(45)
Net change in available-for-sale securities						(6)
Net change in certain retirement plans						(11)
Impact of stock-based compensation plans, net of tax	15,457,031			153		
Rounding		—		1	(1)	
Balance as of December 31, 2016	1,609,670,817	\$ 16	\$(1,717)	\$ 17,014	\$ (8,581)	\$ 1

See notes to the consolidated financial statements.

BOSTON SCIENTIFIC CORPORATION AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,		
in millions	2016	2015	2014
<b>Operating Activities</b>			
Net income (loss)	\$347	\$(239)	\$(119)
Adjustments to reconcile net income (loss) to cash provided by operating activities			
Gain on sale of businesses	—	—	(12 )
Gain on sale of property, plant and equipment	(11 )	—	—
Depreciation and amortization	815	769	725
Deferred and prepaid income taxes	(305 )	(532 )	(397 )
Stock-based compensation expense	116	107	103
Intangible asset impairment charges	11	19	195
Net losses (gains) on investments and notes receivable	21	9	(27 )
Contingent consideration expense (benefit)	29	123	(85 )
Payment of contingent consideration in excess of amounts established in purchase accounting	(57 )	(57 )	(103 )
Pension termination charges	—	44	—
Inventory step-up amortization	22	36	9
Other, net	(12 )	41	18
Increase (decrease) in operating assets and liabilities, net of acquisitions:			
Trade accounts receivable	(216 )	(17 )	53
Inventories	40	3	(81 )
Other assets	(253 )	(23 )	(33 )
Accounts payable and accrued expenses	553	(20 )	620
Other liabilities	(128 )	337	403
Cash provided by operating activities	972	600	1,269
<b>Investing Activities</b>			
Purchases of property, plant and equipment	(376 )	(247 )	(259 )
Proceeds on disposals of property, plant and equipment	29	—	—
Payments for acquisitions of businesses, net of cash acquired	(408 )	(1,734)	(486 )
Proceeds from business divestitures, net of costs	—	—	12
Payments for investments and acquisitions of certain technologies	(132 )	(266 )	(26 )
Proceeds from investments and collections of notes receivable	—	61	14
Cash used for investing activities	(887 )	(2,186)	(745 )
<b>Financing Activities</b>			
Payments of contingent consideration amounts previously established in purchase accounting	(65 )	(156 )	(34 )
Proceeds from long-term borrowings, net of debt issuance costs	—	2,580	—
Payments on long-term borrowings	(250 )	(1,150)	—
Proceeds from borrowings on credit facilities	630	565	810
Payments on borrowings from credit facilities	(570 )	(565 )	(810 )
Payments for acquisitions of treasury stock	—	—	(125 )
Cash used to net share settle employee equity awards	(62 )	(66 )	(51 )
Proceeds from issuances of shares of common stock	111	114	60
Cash provided by (used for) financing activities	(206 )	1,322	(150 )
Effect of foreign exchange rates on cash	(2 )	(4 )	(4 )

Net increase (decrease) in cash and cash equivalents	(123 )	(268 )	370
Cash and cash equivalents at beginning of period	319	587	217
Cash and cash equivalents at end of period	\$196	\$319	\$587

Supplemental Information

Cash paid for income taxes, net	\$94	\$80	\$74
Cash paid for interest	233	283	221
Fair value of contingent consideration recorded in purchase accounting	50	63	3
See notes to the consolidated financial statements.			

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

### NOTE A – SIGNIFICANT ACCOUNTING POLICIES

#### Principles of Consolidation

Our consolidated financial statements include the accounts of Boston Scientific Corporation and our wholly-owned subsidiaries, after the elimination of intercompany transactions. We assess the terms of our investment interests to determine if any of our investees meet the definition of a variable interest entity (VIE). For any VIEs, we perform an analysis to determine whether our variable interests give us a controlling financial interest in a VIE. The analysis identifies the primary beneficiary of a VIE as the enterprise that has both 1) the power to direct activities of a VIE that most significantly impact the entity's economic performance and 2) the obligation to absorb losses of the entity or the right to receive benefits from the entity. Based on our assessments under the applicable guidance, we did not have controlling financial or operating interests in any VIEs and therefore did not consolidate any VIEs for 2016, 2015, and 2014.

On January 3, 2011, we closed the sale of our Neurovascular business to Stryker Corporation (Stryker). Due to our continuing involvement in the operations of the Neurovascular business following the divestiture, the divestiture did not meet the criteria for presentation as a discontinued operation and, therefore, the results of the Neurovascular business were included in our results of operations for 2014. Refer to Note C – Divestitures for a description of this business divestiture.

#### Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and with the instructions to Form 10-K and Regulation S-X.

Additionally, certain prior year balances related to debt issuance costs have been restated to reflect our adoption of Accounting Standards Codification Update No. 2015-03, Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs. Amounts reclassified from other long-term assets to long-term debt were not material. Refer to Note Q - New Accounting Pronouncements for additional information on our adoption of the accounting pronouncement.

#### Subsequent Events

We evaluate events occurring after the date of our accompanying consolidated balance sheets for potential recognition or disclosure in our financial statements. We did not identify any material subsequent events requiring adjustment to our accompanying consolidated financial statements (recognized subsequent events). Those items requiring disclosure (unrecognized subsequent events) in the financial statements have been disclosed accordingly. Refer to Note F – Borrowings and Credit Arrangements and Note K – Commitments and Contingencies for further details. In addition, in February 2017, we initiated a voluntary removal of all Lotus™ Valve devices, including Lotus with Depth Guard™, from global commercial and clinical sites due to reports of premature release of a pin connecting the Lotus Valve to the delivery system.

#### Accounting Estimates

To prepare our consolidated financial statements in accordance with U.S. GAAP, management makes estimates and assumptions that may affect the reported amounts of our assets and liabilities, the disclosure of contingent liabilities as of the date of our financial statements and the reported amounts of our revenues and expenses during the reporting



period. Our actual results may differ from these estimates. Refer to Critical Accounting Estimates included in Item 7 of this Annual Report for further discussion.

#### Cash and Cash Equivalents

We record cash and cash equivalents in our consolidated balance sheets at cost, which approximates fair value. Our policy is to invest excess cash in short-term marketable securities earning a market rate of interest without assuming undue risk to principal, and we limit our direct exposure to securities in any one industry or issuer. We consider all highly liquid investments purchased with a remaining maturity of three months or less at the time of acquisition to be cash equivalents.

We record available-for-sale investments at fair value and exclude unrealized gains and temporary losses on available-for-sale securities from earnings, reporting such gains and losses, net of tax, as a separate component of stockholders' equity, until realized. We compute realized gains and losses on sales of available-for-sale securities based on the average cost method, adjusted for any other-than-temporary declines in fair value. Refer to Investments in Publicly Traded and Privately Held Entities below for additional details.

## Concentrations of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents, derivative financial instrument contracts and accounts and notes receivable. Our investment policy limits exposure to concentrations of credit risk and changes in market conditions. Counterparties to financial instruments expose us to credit-related losses in the event of nonperformance. We transact our financial instruments with a diversified group of major financial institutions with investment grade credit ratings and actively monitor their credit ratings and our outstanding positions to limit our credit exposure. We provide credit, in the normal course of business, to hospitals, healthcare agencies, clinics, doctors' offices and other private and governmental institutions and generally do not require collateral. We record our accounts receivable in our consolidated balance sheets at net realizable value. We perform on-going credit evaluations of our customers and maintain allowances for potential credit losses, based on historical information and management's best estimates. Amounts determined to be uncollectible are written off against this reserve. We recorded write-offs of uncollectible accounts receivable of \$11 million in 2016, \$16 million in 2015, and \$15 million in 2014. We are not dependent on any single institution and no single customer accounted for more than ten percent of our net sales in 2016, 2015, and 2014 or accounts receivable at December 31, 2016 or 2015; however, large group purchasing organizations, hospital networks and other buying groups have become increasingly important to our business and represent a substantial portion of our U.S. net sales.

We closely monitor outstanding receivables for potential collection risks, including those that may arise from economic conditions, in both the U.S. and international economies. Our European sales to government-owned or supported customers in Southern Europe, specifically Greece, Italy, Spain and Portugal are subject to an increased number of days outstanding relative to other countries prior to payment. Historically, receivable balances with certain publicly-owned hospitals in these countries accumulate over a period of time and are then subsequently settled as large lump sum payments. While we believe our allowance for doubtful accounts in these countries is adequate as of December 31, 2016, if significant changes were to occur in the payment practices of these European governments or if government funding becomes unavailable, we may not be able to collect on receivables due to us from these customers and our write-offs of uncollectible amounts may increase.

## Revenue Recognition

We generate revenue primarily from the sale of single-use medical devices, and present revenue net of sales taxes in our consolidated statements of operations. We sell our products primarily through a direct sales force. In certain international markets, we sell our products through independent distributors. We consider revenue to be realized or realizable and earned when all of the following criteria are met: persuasive evidence of a sales arrangement exists; delivery has occurred or services have been rendered; the price is fixed or determinable; and collectability is reasonably assured. Revenue is recognized upon passage of title and risk of loss to customers, unless we are required to provide additional services, and provided we can form an estimate for sales returns. We recognize revenue from consignment arrangements based on product usage, or implant, which indicates that the sale is complete. For revenue arrangements with multiple deliverables, where the sale of a device is combined with a future service obligation, we defer revenue on the undelivered element and recognize this revenue over the related service period. Many of our Cardiac Rhythm Management (CRM) product offerings combine the sale of a device with our LATITUDE™ Patient Management System, which represents a future service obligation. Generally, we do not have vendor specific objective evidence of selling price available related to our future service obligations; therefore, we determine our estimates of selling price using third party evidence when available; otherwise, we use our best estimate of selling price. We allocate arrangement consideration using the relative selling price method.

We generally allow our customers to return defective, damaged and, in certain cases, expired products for credit. We base our estimate for sales returns upon historical trends and record the amount as a reduction to revenue when we sell the initial product. In addition, we may allow customers to return previously purchased products for next-generation

product offerings. For these transactions, we defer recognition of revenue on the sale of the earlier generation product based upon an estimate of the amount of product to be returned when the next-generation products are shipped to the customer.

We also offer sales rebates and discounts to certain customers. We treat sales rebates and discounts as a reduction of revenue and classify the corresponding liability as current. We estimate rebates for products where there is sufficient historical information available to predict the volume of expected future rebates. If we are unable to estimate the expected rebates reasonably, we record a liability for the maximum rebate percentage offered. We have entered certain agreements with group purchasing organizations to sell our products to participating hospitals at negotiated prices. We recognize revenue from these agreements following the same revenue recognition criteria discussed above.

## Warranty Obligations

We offer warranties on certain of our product offerings. The majority of our warranty liability relates to implantable devices offered by our CRM business, which include defibrillator and pacemaker systems. Our CRM products come with a standard limited warranty covering the replacement of these devices. We offer a full warranty for a portion of the period post-implant, and a partial warranty for a period of time thereafter. We estimate the costs that we may incur under our warranty programs based on the number of units sold, historical and anticipated rates of warranty claims and cost per claim, and record a liability equal to these estimated costs as cost of products sold at the time the product sale occurs. We assess the adequacy of our recorded warranty liabilities on a quarterly basis and adjust these amounts as necessary.

Changes in our product warranty accrual during 2016, 2015, and 2014 consisted of the following (in millions):

	Year Ended December 31,		
	2016	2015	2014
Beginning balance	\$23	\$25	\$28
Provision	25	15	9
Settlements/ reversals	(26 )	(17 )	(12 )
Ending balance	\$22	\$23	\$25

## Inventories

We state inventories at the lower of first-in, first-out cost or market. We base our provisions for excess, expired and obsolete inventory primarily on our estimates of forecasted net sales. A significant change in the timing or level of demand for our products as compared to forecasted amounts may result in recording additional provisions for excess, expired and obsolete inventory in the future. Further, the industry in which we participate is characterized by rapid product development and frequent new product introductions. Uncertain timing of next-generation product approvals, variability in product launch strategies, product recalls and variation in product utilization all affect our estimates related to excess, expired and obsolete inventory. Approximately 40 percent of our finished goods inventory as of December 31, 2016 and December 31, 2015 was at customer locations pursuant to consignment arrangements or held by sales representatives.

## Property, Plant and Equipment

We state property, plant, equipment, and leasehold improvements at historical cost. We charge expenditures for maintenance and repairs to expense and capitalize additions and improvements that extend the life of the underlying asset. We provide for depreciation using the straight-line method at rates that approximate the estimated useful lives of the assets. We depreciate buildings over a 20 to 40 year life; building improvements over the remaining useful life of the building structure; equipment, furniture and fixtures over a three to ten year life; and leasehold improvements over the shorter of the useful life of the improvement or the term of the related lease. Depreciation expense was \$270 million in 2016, \$274 million in 2015 and \$287 million in 2014.

## Valuation of Business Combinations

We allocate the amounts we pay for each acquisition to the assets we acquire and liabilities we assume based on their fair values at the dates of acquisition, including identifiable intangible assets and in-process research and development which either arise from a contractual or legal right or are separable from goodwill. We base the fair value of identifiable intangible assets acquired in a business combination, including in-process research and development, on

detailed valuations that use information and assumptions provided by management, which consider management's best estimates of inputs and assumptions that a market participant would use. We allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired to goodwill. Transaction costs associated with these acquisitions are expensed as incurred through selling, general and administrative costs.

In those circumstances where an acquisition involves a contingent consideration arrangement, we recognize a liability equal to the fair value of the contingent payments we expect to make as of the acquisition date. We re-measure this liability each reporting period and record changes in the fair value through a separate line item within our consolidated statements of operations. Increases or decreases in the fair value of the contingent consideration liability can result from changes in discount periods and rates, as well as changes in the timing and amount of revenue estimates or in the timing or likelihood of achieving regulatory, revenue or commercialization-based milestones.

## Indefinite-lived Intangibles, including In-Process Research and Development

Our indefinite-lived intangible assets that are not subject to amortization include acquired balloon and other technology, which is foundational to our continuing operations within the Cardiovascular market and other markets within interventional medicine, and in-process research and development intangible assets acquired in a business combination. Our in-process research and development represents intangible assets acquired in a business combination that are used in research and development activities but have not yet reached technological feasibility, regardless of whether they have alternative future use. The primary basis for determining the technological feasibility or completion of these projects is obtaining regulatory approval to market the underlying products in an applicable geographic region. We classify in-process research and development acquired in a business combination as an indefinite-lived intangible asset until the completion or abandonment of the associated research and development efforts. Upon completion of the associated research and development efforts, we will determine the useful life of the technology and begin amortizing the assets to reflect their use over their remaining lives. Upon permanent abandonment, we would write-off the remaining carrying amount of the associated in-process research and development intangible asset.

We test our indefinite-lived intangible assets at least annually during the third quarter for impairment and reassess their classification as indefinite-lived assets; in addition, we review our indefinite-lived assets for classification and impairment more frequently if changes in circumstances or indicators exist. We assess qualitative factors to determine whether the existence of events and circumstances indicate that it is more likely than not that our indefinite-lived intangible assets are impaired. If we conclude that it is more likely than not that the asset is impaired, we then determine the fair value of the intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying value in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification® (ASC) Topic 350, Intangibles - Goodwill and Other (Topic 350). If the carrying value exceeds the fair value of the indefinite-lived intangible asset, we write the carrying value down to the fair value.

We use the income approach to determine the fair values of our in-process research and development. This approach calculates fair value by estimating the after-tax cash flows attributable to an in-process project over its useful life and then discounting these after-tax cash flows back to a present value. We base our revenue assumptions on estimates of relevant market sizes, expected market growth rates, expected trends in technology and expected levels of market share. In arriving at the value of the in-process projects, we consider, among other factors: the in-process projects' stage of completion; the complexity of the work completed as of the acquisition date; the costs already incurred; the projected costs to complete; the contribution of other acquired assets; the expected regulatory path and introduction dates by region; and the estimated useful life of the technology. We apply a market-participant risk-adjusted discount rate to arrive at a present value as of the date of acquisition. See Note D - Goodwill and Other Intangible Assets for more information related to indefinite-lived intangibles, including in-process research and development during 2016, 2015, and 2014.

For asset purchases outside of business combinations, we expense any purchased research and development assets as of the acquisition date.

## Amortization and Impairment of Intangible Assets

We record intangible assets at historical cost and amortize them over their estimated useful lives. We use a straight-line method of amortization, unless a method that better reflects the pattern in which the economic benefits of the intangible asset are consumed or otherwise used up can be reliably determined. The approximate useful lives for amortization of our intangible assets are as follows: patents and licenses, two to 20 years; definite-lived technology-related, five to 25 years; customer relationships, five to 25 years; other intangible assets, various.

We review intangible assets subject to amortization quarterly to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. Conditions that may indicate impairment include, but are not limited to, a significant adverse change in legal factors or business climate that could affect the value of an asset, a product recall, or an adverse action or assessment by a regulator. If an impairment indicator exists, we test the intangible asset for recoverability. For purposes of the recoverability test, we group our amortizable intangible assets with other assets and liabilities at the lowest level of identifiable cash flows if the intangible asset does not generate cash flows independent of other assets and liabilities. If the carrying value of the intangible asset (asset group) exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the intangible asset (asset group), we will write the carrying value down to the fair value in the period identified.

We calculate fair value of our intangible assets as the present value of estimated future cash flows we expect to generate from the asset using a risk-adjusted discount rate. In determining our estimated future cash flows associated with our intangible assets, we use estimates and assumptions about future revenue contributions, cost structures and remaining useful lives of the asset (asset

group). See Note D - Goodwill and Other Intangible Assets for more information related to impairments of intangible assets during 2016, 2015, and 2014.

For patents developed internally, we capitalize costs incurred to obtain patents, including attorney fees, registration fees, consulting fees, and other expenditures directly related to securing the patent.

#### Goodwill Valuation

Based on information regularly reviewed by our chief operating decision maker, we have three global reportable segments comprised of Cardiovascular, Rhythm Management, and MedSurg. We determined our global reporting units by identifying our operating segments and assessing whether any components of these segments constituted a business for which discrete financial information is available and whether segment management regularly reviews the operating results of any components. Through this process, we identified the following global reporting units: Interventional Cardiology, Peripheral Interventions, Cardiac Rhythm Management, Electrophysiology, Endoscopy, Urology and Pelvic Health, and Neuromodulation.

We allocate any excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination to goodwill. We test our goodwill balances during the second quarter of each year for impairment, or more frequently if indicators are present or changes in circumstances suggest that impairment may exist. We assess goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment, referred to as a component. In 2016, we identified six operating segments including Interventional Cardiology, Peripheral Interventions, Rhythm Management, Endoscopy, Urology and Pelvic Health, and Neuromodulation. For purposes of identifying our reporting units, we then assessed whether any components of these segments constitute a business for which discrete financial information is available and where segment management regularly reviews the operating results of that component. We identified Rhythm Management as having two components: Cardiac Rhythm Management and Electrophysiology.

For our 2016, 2015 and 2014 annual impairment assessment we identified seven reporting units, which align to our seven core businesses: Interventional Cardiology, Peripheral Interventions, Cardiac Rhythm Management, Electrophysiology, Endoscopy, Urology and Pelvic Health and Neuromodulation. As noted above, for our 2016 annual impairment assessment we aggregated the Cardiac Rhythm Management and Electrophysiology reporting units, components of the Rhythm Management operating segment, based on the criteria prescribed in FASB ASC Topic 350. These reporting units were aggregated due to a reorganization that commenced in 2015 that resulted in integrated leadership, shared resources and consolidation of certain sites in 2016.

In performing the goodwill impairment assessment for 2016, we utilized both the optional qualitative assessment and the two-step approach prescribed under FASB ASC Topic 350. Beginning in 2016, the qualitative assessment was used for testing certain reporting units where fair value has historically exceeded carrying value by greater than 100%. All other reporting units were tested using the two-step approach. The qualitative assessment requires an evaluation of whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount based on an assessment of relevant events including macroeconomic factors, industry and market conditions, cost factors, overall financial performance and other entity-specific factors. After assessing the totality of events, if it is determined that it is not more likely than not that the fair value of the reporting unit is less than its carrying value, the first and second steps of the goodwill impairment test are unnecessary. If it is determined that impairment is more likely than not, then we perform the first step of the two-step impairment test. In 2016, for all reporting units tested using the optional qualitative assessment, we concluded that it was not necessary to perform the first step of the two-step goodwill impairment test. The first step requires a comparison of the carrying value of the reporting units to the fair value of these units.



When allocating goodwill from business combinations to our reporting units, we assign goodwill to the reporting units that we expect to benefit from the respective business combination at the time of acquisition. In addition, for purposes of performing our goodwill impairment tests, assets and liabilities, including corporate assets, which relate to a reporting unit's operations, and would be considered in determining its fair value, are allocated to the individual reporting units. We allocate assets and liabilities not directly related to a specific reporting unit, but from which the reporting unit benefits, based primarily on the respective revenue contribution of each reporting unit.

For our 2016, 2015, and 2014 annual impairment assessments, for those reporting units for which a quantitative test was performed, we used only the income approach, specifically the Discounted Cash Flow (DCF) method, to derive the fair value of each of our reporting units. This approach calculates fair value by estimating the after-tax cash flows attributable to a reporting unit and then discounting these after-tax cash flows to a present value using a risk-adjusted discount rate. We selected this method as being the most meaningful in preparing our goodwill assessments because we believe the income approach most appropriately measures our income producing assets. We have considered using the market approach and cost approach but concluded they are not appropriate in valuing our reporting units given the lack of relevant market comparisons available for application of the market approach and the inability to replicate the value of the specific technology-based assets within our reporting units for application

of the cost approach. Therefore, we believe that the income approach represents the most appropriate valuation technique for which sufficient data are available to determine the fair value of our reporting units.

In applying the income approach to our accounting for goodwill, we make assumptions about the amount and timing of future expected cash flows, terminal value growth rates and appropriate discount rates. The amount and timing of future cash flows within our DCF analysis is based on our most recent operational budgets, long range strategic plans and other estimates. The terminal value growth rate is used to calculate the value of cash flows beyond the last projected period in our DCF analysis and reflects our best estimates for stable, perpetual growth of our reporting units. We use estimates of market-participant risk-adjusted weighted average cost of capital (WACC) as a basis for determining the discount rates to apply to our reporting units' future expected cash flows.

If the carrying value of a reporting unit exceeds its fair value, we then perform the second step of the goodwill impairment test to measure the amount of impairment loss, if any. If the carrying value of a reporting unit is zero or negative, we evaluate whether it is more likely than not that a goodwill impairment exists. If we determine adverse qualitative factors exist that would indicate it is more likely than not an impairment exists, we then perform the second step of the goodwill test. The second step of the goodwill impairment test compares the estimated fair value of a reporting unit's goodwill to its carrying value. If we were unable to complete the second step of the test prior to the issuance of our financial statements and an impairment loss was probable and could be reasonably estimated, we would recognize our best estimate of the loss in our current period financial statements and disclose that the amount is an estimate. We would then recognize any adjustment to that estimate in subsequent reporting periods, once we have finalized the second step of the impairment test. Refer to Note D - Goodwill and Other Intangible Assets to our consolidated financial statements for additional details related to our annual goodwill impairment test.

#### Investments in Publicly Traded and Privately Held Entities

We account for our publicly traded investments as available-for-sale securities based on the quoted market price at the end of the reporting period. Unrealized holding gains or losses during the period, net of tax, are recorded to accumulated other comprehensive income/loss. We compute realized gains and losses on sales of available-for-sale securities at fair value based on the average cost method, adjusted for any other-than-temporary declines in fair value. As of December 31, 2016, we held \$20 million of available-for-sale securities. We held no available-for-sale securities during 2015 and 2014. We account for investments in entities over which we have the ability to exercise significant influence under the equity method if we hold 50 percent or less of the voting stock and the entity is not a VIE in which we are the primary beneficiary in accordance with FASB ASC Topic 323, Investments - Equity Method and Joint Ventures (Topic 323). We record these investments initially at cost, and adjust the carrying amount to reflect our share of the earnings or losses of the investee, including all adjustments similar to those made in preparing consolidated financial statements. We account for investments in entities in which we have less than a 20 percent ownership interest under the cost method of accounting if we do not have the ability to exercise significant influence over the investee in accordance with FASB ASC Topic 325, Investments - Other. In addition, we have notes receivable from certain companies that we account for in accordance with FASB ASC Topic 320, Investments - Debt and Equity Securities (Topic 320). Refer to Note B – Acquisitions and Strategic Investments for additional details on the balances of our equity and cost method investments.

Each reporting period, we evaluate our investments to determine if there are any events or circumstances that are likely to have a significant adverse effect on the fair value of the investment. Examples of such impairment indicators include, but are not limited to: a significant deterioration in earnings performance; recent financing rounds at reduced valuations; a significant adverse change in the regulatory, economic or technological environment of an investee; or a significant doubt about an investee's ability to continue as a going concern. If we identify an impairment indicator, we will estimate the fair value of the investment and compare it to its carrying value. Our estimation of fair value considers all available financial information related to the investee, including valuations based on recent third-party equity investments in the investee. If the fair value of the investment is less than its carrying value, the investment is

impaired and we make a determination as to whether the impairment is other-than-temporary. We deem an impairment to be other-than-temporary unless we have the ability and intent to hold an investment for a period sufficient for a market recovery up to the carrying value of the investment. Further, evidence must indicate that the carrying value of the investment is recoverable within a reasonable period. For other-than-temporary impairments, we recognize an impairment loss equal to the difference between an investment's carrying value and its fair value. Impairment losses on our investments are included in other, net in our consolidated statements of operations.

## Income Taxes

We utilize the asset and liability method of accounting for income taxes. Under this method, we determine deferred tax assets and liabilities based on differences between the financial reporting and tax bases of our assets and liabilities. We measure deferred tax assets and liabilities using the enacted tax rates and laws that will be in effect when we expect the differences to reverse. We reduce our deferred tax assets by a valuation allowance if, based upon the weight of available evidence, it is more likely than not that we will not realize some portion or all of the deferred tax assets. We consider relevant evidence, both positive and negative, to determine the need for a valuation allowance. Information evaluated includes our financial position and results of operations for the current and preceding years, the availability of deferred tax liabilities and tax carrybacks, as well as estimates of the impact of future taxable income and available prudent and feasible tax-planning strategies.

We have not provided U.S. income taxes and foreign withholding taxes on the undistributed earnings of foreign subsidiaries as of December 31, 2016 because we intend to permanently reinvest such earnings outside the U.S. As of December 31, 2016, the cumulative amount of excess financial reporting basis over the tax basis of investments in foreign subsidiaries that is indefinitely reinvested is approximately \$9.8 billion. Generally, such amounts become subject to U.S. taxation upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of deferred tax liability related to investments in these foreign subsidiaries.

We provide for potential amounts due in various tax jurisdictions. In the ordinary course of conducting business in multiple countries and tax jurisdictions, there are many transactions and calculations where the ultimate tax outcome is uncertain. Therefore, judgment is required based on individual facts, circumstances and information available in determining whether or not based on technical merits, the position will be sustained upon examination. In our opinion, we have made adequate provisions for income taxes in determining our worldwide income tax position for all years subject to audit. Although we believe our estimates are reasonable, the final outcome of open tax matters may be different from that which we have reflected in our historical income tax provisions and accruals. Such differences could have a material impact on our income tax provision and operating results. See Note J - Income Taxes for further information and discussion of our income tax provision and balances.

## Legal and Product Liability Costs

In the normal course of business, we are involved in various legal and regulatory proceedings, including intellectual property, breach of contract, securities litigation and product liability suits. In some cases, the claimants seek damages, as well as other relief, which, if granted, could require significant expenditures or impact our ability to sell our products. We are also the subject of certain governmental investigations, which could result in substantial fines, penalties, and administrative remedies. We maintain an insurance policy providing limited coverage against securities claims, and we are substantially self-insured with respect to product liability claims and fully self-insured with respect to intellectual property infringement claims. We accrue anticipated costs of settlement, damages, losses for product liability claims and, under certain conditions, costs of defense, based on historical experience or to the extent specific losses are probable and estimable. Otherwise, we expense these costs as incurred. If the estimate of a probable loss is a range and no amount within the range is more likely, we accrue the minimum amount of the range. We analyze litigation settlements to identify each element of the arrangement. We allocate arrangement consideration to patent licenses received based on estimates of fair value, and capitalize these amounts as assets if the license will provide an on-going future benefit. We record certain legal and product liability charges, credits and costs of defense, which we consider to be unusual or infrequent and significant as litigation-related charges within our consolidated statements of operations; all other legal and product liability charges, credits and costs are recorded within selling, general and administrative expenses. See Note K – Commitments and Contingencies for discussion of our individual material legal proceedings.

## Costs Associated with Exit Activities

We record employee termination costs in accordance with FASB ASC Topic 712, Compensation - Nonretirement and Postemployment Benefits (Topic 712), if we pay the benefits as part of an on-going benefit arrangement, which includes benefits provided as part of our established severance policies or that we provide in accordance with international statutory requirements. We accrue employee termination costs associated with an on-going benefit arrangement if the obligation is attributable to prior services rendered, the rights to the benefits have vested, the payment is probable and we can reasonably estimate the liability. We account for employee termination benefits that represent a one-time benefit in accordance with FASB ASC Topic 420, Exit or Disposal Cost Obligations (Topic 420). We record such costs into expense over the employee's future service period, if any.

Other costs associated with exit activities may include contract termination costs, including costs related to leased facilities to be abandoned or subleased, consultant fees and impairments of long-lived assets. The costs are expensed in accordance with FASB ASC Topic 420 and FASB ASC Topic 360, Property, Plant, and Equipment and are included in restructuring charges in our consolidated statement of operations. Additionally, costs directly related to our active restructuring initiatives, including program

management costs, accelerated depreciation, and costs to transfer product lines among facilities are included within costs of products sold and selling, general and administrative expenses in our consolidated statement of operations. See Note H – Restructuring-related Activities for further information and discussion of our restructuring plans.

#### Translation of Foreign Currency

We translate all assets and liabilities of foreign subsidiaries from local currency into U.S. dollars using the year-end exchange rate, and translate revenues and expenses at the average exchange rates in effect during the year. We show the net effect of these translation adjustments in our consolidated financial statements as a component of accumulated other comprehensive income. For any significant foreign subsidiaries located in highly inflationary economies, we would re-measure their financial statements as if the functional currency were the U.S. dollar. We did not record any highly inflationary economy translation adjustments in 2016, 2015 or 2014.

Foreign currency transaction gains and losses are included in other, net in our consolidated statements of operations, net of losses and gains from any related derivative financial instruments. We recognized net foreign currency transaction losses of \$13 million in 2016, \$21 million in 2015, and \$18 million in 2014.

#### Financial Instruments

We recognize all derivative financial instruments in our consolidated financial statements at fair value in accordance with FASB ASC Topic 815, Derivatives and Hedging (Topic 815), and we present assets and liabilities associated with our derivative financial instruments on a gross basis in our financial statements. In accordance with FASB ASC Topic 815, for those derivative instruments that are designated and qualify as hedging instruments, the hedging instrument must be designated, based upon the exposure being hedged, as a fair value hedge, cash flow hedge, or a hedge of a net investment in a foreign operation. The accounting for changes in the fair value (i.e. gains or losses) of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and, further, on the type of hedging relationship. Our derivative instruments do not subject our earnings or cash flows to material risk, as gains and losses on these derivatives generally offset losses and gains on the item being hedged. We do not enter into derivative transactions for speculative purposes and we do not have any non-derivative instruments that are designated as hedging instruments pursuant to FASB ASC Topic 815. Refer to Note E – Fair Value Measurements for more information on our derivative instruments.

#### Shipping and Handling Costs

We generally do not bill customers for shipping and handling of our products. Shipping and handling costs of \$101 million in 2016, \$93 million in 2015, and \$100 million in 2014 are included in selling, general and administrative expenses.

#### Research and Development

We expense research and development costs, including new product development programs, regulatory compliance and clinical research as incurred. Refer to Indefinite-lived Intangibles, including In-Process Research and Development for our policy regarding in-process research and development acquired in connection with our business combinations and asset purchases.

#### Employee Retirement Plans

Following our 2006 acquisition of Guidant Corporation, we sponsored the Guidant Supplemental Retirement Plan, a frozen, non-qualified defined benefit plan for certain former officers and employees of Guidant. The plan was partially frozen as of September 25, 1995 and completely frozen as of May 31, 2007, and was terminated effective December

1, 2014. During 2015, we finalized the termination process and settled the plan's obligations. As a result, we recorded pension termination charges of \$44 million for the year ended December 31, 2015. The Guidant Supplemental Retirement Plan was partially funded through a Rabbi Trust that contains segregated company assets used to pay the benefit obligations related to the plan.

We also maintain an Executive Retirement Plan, a defined benefit plan covering executive officers and division presidents and certain persons that may have served in these roles. Participants may retire with unreduced benefits once retirement conditions have been satisfied. In addition, we maintain retirement plans covering certain international employees.

We use a December 31 measurement date for these plans and record the underfunded portion as a liability, recognizing changes in the funded status through other comprehensive income (OCI). The outstanding obligation as of December 31, 2016 and 2015 is as follows:

(in millions)	As of December 31, 2016			
	Accumulated Benefit Obligation (ABO)	Projected Benefit Obligation (PBO)	Fair value of Plan Assets	Underfunded PBO Recognized
Executive Retirement Plan	\$15	\$17	\$ —	\$ 17
Guidant Supplemental Retirement Plan (frozen)	32	32	—	32
International Retirement Plans	93	103	54	49
	140	\$ 152	\$ 54	\$ 98
(in millions)	As of December 31, 2015			
	Accumulated Benefit Obligation (ABO)	Projected Benefit Obligation (PBO)	Fair value of Plan Assets	Underfunded PBO Recognized
Executive Retirement Plan	\$12	\$ 14	\$ —	\$ 14
Guidant Supplemental Retirement Plan (frozen)	33	33	—	33
International Retirement Plans	76	84	52	32
	\$121	\$ 131	\$ 52	\$ 79

The value of the Rabbi Trust assets used to pay the Guidant Supplemental Retirement Plan benefits included in our accompanying consolidated financial statements was approximately \$8 million as of December 31, 2016 and \$11 million as of December 31, 2015.

A rollforward of the changes in the pension benefit obligation for our funded retirement plans during 2016 and 2015 is as follows:

(in millions)	Year Ended December 31,	
	2016	2015
Beginning obligations	\$131	\$138
Service and interest costs	10	9
Actuarial gain (loss)	10	(5 )
Plan amendments	7	—
Benefits paid	(5 )	(5 )
Foreign currency exchange	(1 )	(6 )
Ending obligation	\$152	\$131

The critical assumptions associated with our employee retirement plans as of December 31, 2016 are as follows:

	Discount Rate	Expected Return on Plan Assets	Rate of Compensation Increase
Executive Retirement Plan	3.50%		3.00%
Guidant Supplemental Retirement Plan (frozen)	4.00%		
International Retirement Plans	0.50% - 2.13%	3.00% - 4.10%	2.50% - 6.78%

We base our discount rate on the rates of return available on high-quality bonds with maturities approximating the expected period over which benefits will be paid. The rate of compensation increase is based on historical and



expected rate increases. We base our rate of expected return on plan assets on historical experience, our investment guidelines and expectations for long-term rates of return. Our international pension plan assets are invested in a variety of securities, primarily equity securities and government bonds. These securities are considered Level 1 fair value investments and are valued at quoted market prices.

A rollforward of the changes in the fair value of plan assets for our funded retirement plans during 2016 and 2015 is as follows:

	Year Ended	
	December	
	31,	
(in millions)	2016	2015
Beginning fair value	\$52	\$191
Actual return on plan assets	(1 )	1
Employer contributions	7	6
Benefits paid	(5 )	(145 )
Foreign currency exchange	1	(1 )
Ending fair value	\$54	\$52

We also sponsor a voluntary 401(k) Retirement Savings Plan for eligible employees. We match 200 percent of employee elective deferrals for the first two percent of employee eligible compensation, and 50 percent of employee elective deferrals greater than two percent, but not exceeding six percent, of employee eligible compensation. Total expense for our matching contributions to the plan was \$72 million in 2016, \$69 million in 2015, and \$63 million in 2014.

#### Net Income (Loss) per Common Share

We base net income (loss) per common share upon the weighted-average number of common shares and common stock equivalents outstanding during each year. Potential common stock equivalents are determined using the treasury stock method. We exclude stock options whose effect would be anti-dilutive from the calculation.

#### NOTE B – ACQUISITIONS AND STRATEGIC INVESTMENTS

Our consolidated financial statements include the operating results for each acquired entity from its respective date of acquisition. We do not present pro forma financial information for these acquisitions given their results are not material to our consolidated financial statements. Transaction costs associated with these acquisitions were expensed as incurred and are not material for the years ended December 31, 2016, 2015, and 2014.

#### 2016 Acquisitions

##### Neovasc, Inc.'s Advanced Biological Tissue Business

On December 12, 2016, we completed the acquisition of certain manufacturing assets and capabilities of the Neovasc, Inc. (Neovasc) advanced biological tissue business for a total upfront cash payment of \$68 million. With this acquisition, we will integrate certain manufacturing assets and biologic tissue capabilities into our structural heart business for use in the manufacturing of the Lotus™ Valve System and future heart valve technologies within our Interventional Cardiology business. We began the process of integrating Neovasc into our Interventional Cardiology business in the fourth quarter of 2016 and expect to be substantially complete by the end of 2018.

##### EndoChoice Holdings, Inc.

On November 22, 2016, we completed our acquisition of EndoChoice Holdings, Inc. (EndoChoice) for \$8.00 per share or approximately \$214 million. In addition, total consideration for the acquisition also included repayment of EndoChoice's existing senior term loan facility totaling \$43 million, and related acquisition fees and expenses. EndoChoice is an Alpharetta, Georgia based company focused on the development and commercialization of infection control products, pathology services and single-use devices for specialists treating a wide range of gastrointestinal (GI) conditions. We began the process of integrating EndoChoice into our Endoscopy business in the fourth quarter of

2016 and expect to be substantially complete by the end of 2017.

#### Distal Access, LLC's Gynecology and Urology Portfolio

On November 15, 2016, we completed the acquisition of the gynecology and urology portfolio of Distal Access, LLC (Distal), a Salt Lake City based company that designs minimally invasive medical devices for an upfront cash payment of \$20 million plus a potential \$35 million in future consideration based on future sales through 2020 in addition to regulatory and product launch milestones. The portfolio includes the Resectr™ Tissue Resection Device, a single-use solution designed to remove uterine polyps. We began the process of integrating the Resectr device into our Urology and Pelvic Health business during the fourth quarter of 2016 and expect to be substantially complete by the end of 2017.

### LumenR™ Tissue Retractor System

On November 1, 2016, we acquired the LumenR™ Tissue Retractor System from LumenR LLC (LumenR), a privately held Newark, California based company for an upfront cash payment of \$30 million plus a potential \$70 million in future consideration based on future sales through the third quarter of 2026 in addition to development and technology transfer milestones. The LumenR™ Tissue Retractor System is currently in development for use during endoscopic resection of lesions in the colon, esophagus or stomach.

### Cosman Medical, Inc.

On July 27, 2016, we acquired Cosman Medical, Inc. (Cosman), a privately held manufacturer of radiofrequency ablation systems, expanding our Neuromodulation portfolio and offering physicians treating patients with chronic pain a wider choice of non-opioid therapeutic options. Total consideration was comprised of \$71 million in up-front cash plus related fees and expenses, and a potential additional \$20 million in consideration based on future sales through June 30, 2019. We are in the process of integrating Cosman into our Neuromodulation business, and expect the integration to be substantially complete by the end of 2017.

### Purchase Price Allocation

We accounted for these acquisitions as a business combination and, in accordance with FASB ASC Topic 805, Business Combinations (Topic 850), we recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date. The components of the aggregate preliminary purchase price are as follows (in millions):

Cash, net of cash acquired	\$366
Fair value of contingent consideration	50
Fair value of debt repaid	43
	\$459

The following summarizes the preliminary purchase price allocation for our 2016 acquisitions as of December 31, 2016, (in millions):

Goodwill	\$208
Amortizable intangible assets	228
Inventory	11
Property, plant and equipment	6
Other net liabilities	(2 )
Deferred income taxes	8
	\$459

We allocated a portion of the preliminary purchase price to specific intangible asset categories as follows:

	Amount Assigned (in millions)	Weighted Average Amortization Period (in years)	Range of Risk- Adjusted Discount Rates used in Purchase Price Allocation
Amortizable intangible assets:			
Technology-related	\$ 176	9-13	11% - 20%
Customer relationships	51	9-13	11% - 12%
Other intangible assets	1	4	11%
	\$ 228		



## 2015 Acquisitions

### Interventional Radiology Business of CeloNova Biosciences

On December 31, 2015, we completed the acquisition of the interventional radiology business of CeloNova Biosciences (CeloNova), for an upfront payment of \$70 million and additional payments contingent on regulatory and sales milestones. The acquisition includes drug-eluting microspheres designed to be loaded with chemotherapy drugs for delivery to cancerous tumors, and spherical embolic products used to treat uterine fibroids and other conditions. We are in the process of integrating CeloNova into our Peripheral Interventions business and expect to be substantially complete by the second half of 2017.

### AMS Portfolio Acquisition

On August 3, 2015, we completed the acquisition of the American Medical Systems male urology portfolio (AMS Portfolio Acquisition), which includes the men's health and prostate health businesses, from Endo International plc. Total consideration was comprised of \$1.616 billion in up-front cash plus related fees and expenses, and a potential additional \$50 million in consideration based on 2016 sales. The AMS male urology portfolio was integrated with our formerly named Urology and Women's Health business, and the joint businesses became Urology and Pelvic Health. The integration was substantially complete by the end of 2016. In addition, as part of the acquisition agreement, we made a \$60 million Series B non-voting preferred stock investment in the women's health business of Endo Health Solutions, a wholly owned subsidiary of Endo International, plc., representing the remaining Women's Health business of the American Medical Systems' Portfolio. This investment was subsequently repaid in the fourth quarter of 2015.

### Xlumen, Inc.

On April 2, 2015, we acquired Xlumen, Inc. (Xlumen), a medical device company that developed minimally invasive devices for Endoscopic Ultrasound (EUS) guided transluminal drainage of targeted areas within the gastrointestinal tract. The purchase agreement called for an upfront payment of \$63 million, an additional payment of \$13 million upon FDA clearance of the HOT AXIOS™ Product, and further sales-based milestones based on sales achieved through 2018. In 2016, we completed the integration of Xlumen into our Endoscopy business.

In addition, we completed other acquisitions during 2015 for total consideration of \$6 million in cash at closing plus contingent consideration of up to \$1 million.

### Purchase Price Allocation

We accounted for these acquisitions as business combinations and, in accordance with FASB ASC Topic 850, we have recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition dates. The components of the aggregate purchase prices are as follows (in millions):

Cash, net of cash acquired	\$1,735
Fair value of contingent consideration	63
	\$1,798

The following summarizes the aggregate purchase price allocation for the 2015 acquisitions as of December 31, 2015 (in millions):

Goodwill	\$573
Amortizable intangible assets	1,074
Indefinite-lived intangible assets	6
Inventory	103

Property, plant and equipment	43
Other net assets	42
Deferred income taxes	(43 )
	\$1,798

75

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We allocated a portion of the purchase price to specific intangible asset categories as follows:

	Amount Assigned (in millions)	Weighted Average Amortization Period (in years)	Range of Risk- Adjusted Discount Rates used in Purchase Price Allocation
Amortizable intangible assets:			
Technology-related	\$ 431	11-13	14% - 23%
Customer relationships	625	12-13	14% - 15%
Other intangible assets	18	13	14%
Indefinite-lived intangible assets:			
In-process research & development	\$ 6	N/A	17%
	\$ 1,080		

## 2014 Acquisitions

### Interventional Business of Bayer AG

On August 29, 2014, we completed the acquisition of the Interventional Division of Bayer AG (Bayer), for a total cash consideration of \$414 million. We believe that this acquisition enhances our ability to offer physicians and healthcare systems a more complete portfolio of solutions to treat challenging vascular conditions. The transaction includes the AngioJet™ Thrombectomy System and the Fetch® 2 Aspiration Catheter, which are used in endovascular procedures to remove blood clots from blocked arteries and veins, and the JetStream™ Atherectomy System, used to remove plaque and thrombi from diseased arteries. In 2016, we completed the integration of Bayer into our Peripheral Interventions and Interventional Cardiology businesses. IoGyn, Inc.

On May 7, 2014, we completed the acquisition of the remaining fully diluted equity of IoGyn, Inc. (IoGyn). Prior to the acquisition, we held a 28 percent minority interest in IoGyn in addition to notes receivable of approximately \$8 million. Total consideration was comprised of a net cash payment of \$65 million at closing to acquire the remaining 72 percent of IoGyn equity and repay outstanding debt. IoGyn has developed the Symphion™ System, a next generation system for hysteroscopic intrauterine tissue removal including fibroids (myomas) and polyps. In March 2014, IoGyn received U.S. Food & Drug Administration (FDA) approval for the system and in October 2014, we began a limited market release of the system in the United States. We integrated the operations of the IoGyn business into our Urology and Pelvic Health business.

In addition, we completed other acquisitions during 2014 for total consideration of \$7 million cash at closing plus contingent consideration of up to \$4 million.

### Purchase Price Allocation

We accounted for these acquisitions as business combinations and, in accordance with FASB ASC Topic 850, we have recorded the assets acquired and liabilities assumed at their respective fair values as of the acquisition date. The components of the aggregate purchase price for our 2014 acquisitions are as follows (in millions):

Cash, net of cash acquired	\$479
Fair value of prior interests	31
	\$510

In addition, prior to the acquisition of IoGyn, we had an equity interest in IoGyn and held \$8 million of notes receivables. We re-measured our previously-held investments to their estimated acquisition-date fair value of \$31 million and recorded a gain of \$19 million in other, net, in the accompanying consolidated statements of operations



during the second quarter of 2014. We measured the fair values of the previously-held investments based on the liquidation preferences and priority of the equity interest and debt, including accrued interest.

The following summarizes the aggregate purchase price allocation for our 2014 acquisitions as of December 31, 2014:

Goodwill	\$210
Amortizable intangible assets	263
Inventory	23
Property, plant and equipment	17
Prepaid Transaction Service Agreement	5
Other net assets	(1 )
Deferred income taxes	(7 )
	\$510

We allocated a portion of the purchase price to specific intangible asset categories as follows:

	Amount Assigned (in millions)	Weighted Average Amortization Period (in years)	Range of Risk- Adjusted Discount Rates used in Purchase Price Allocation
Amortizable intangible assets:			
Technology-related	\$ 233	10 - 14	14 - 18 %
Customer relationships	29	10	18%
Other intangible assets	1	2	14%
	\$ 263		

For our 2016, 2015 and 2014 acquisitions, our technology-related intangible assets consist of technical processes, intellectual property, and institutional understanding with respect to products and processes that we will leverage in future products or processes and will carry forward from one product generation to the next. We used the income approach and relief from royalty approach to derive the fair value of the technology-related intangible assets, and are amortizing them on a straight-line basis over their assigned estimated useful lives.

In-process research and development represents the estimated fair value of acquired in-process research and development projects that have not yet reached technological feasibility. These indefinite-lived intangible assets are tested for impairment on an annual basis, or more frequently if impairment indicators are present, in accordance with U.S. GAAP and our accounting policies. Upon completion of the associated research and development efforts, we will determine the useful life of the technology and begin amortizing the assets to reflect their use over their remaining lives. The primary basis for determining the technological feasibility or completion of these projects is obtaining regulatory approval to market the underlying products.

Customer relationships represent the estimated fair value of non-contractual customer, payor and distributor relationships. Customer relationships are direct relationships with physicians and hospitals performing procedures with the acquired products, payor relationships are contracts and relationships with healthcare payors relating to reimbursement of services and distributor relationships are relationships with third parties used to sell the acquired products, all as of the acquisition date. These relationships were valued separately from goodwill because there is a history and pattern of conducting business with customers and distributors. We used the income approach or the replacement cost and lost profits methodology to derive the fair value of the customer relationships. The customer relationships intangible assets are amortized on a straight-line basis over their assigned estimated useful lives.

Other intangible assets primarily include acquired tradenames. These tradenames include brand names that we expect to continue using in our product portfolio and related marketing materials. The tradenames are valued using a relief from royalty methodology and are amortized on a straight-line basis over their assigned estimated useful lives.

We believe that the estimated intangible asset values represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the assets. These fair value measurements are based on significant

unobservable inputs, including management estimates and assumptions and, accordingly, are classified as Level 3 within the fair value hierarchy prescribed by FASB ASC Topic 820, Fair Value Measurements and Disclosures.

We recorded the excess of the aggregate purchase price over the estimated fair values of the identifiable assets acquired as goodwill. Goodwill was established due primarily to synergies expected to be gained from leveraging our existing operations as well as revenue and cash flow projections associated with future technologies, and has been allocated to our reportable segments based on the relative expected benefit. Of the goodwill recorded, approximately \$116 million, based on preliminary estimates, related to our 2016 acquisitions is deductible for tax purposes. Of the goodwill recorded related to our 2015 acquisitions \$449 million is deductible for tax purposes and \$160 million of the recorded goodwill related to our 2014 acquisitions is deductible for tax purposes. Refer to Note D - Goodwill and Other Intangible Assets for more information related to goodwill allocated to our reportable segments.

#### Contingent Consideration

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

We recorded a net expense related to the changes in fair value of our contingent consideration liabilities of \$29 million during 2016, net expense related to the changes in fair value of our contingent consideration liabilities of \$123 million during 2015, and a net benefit related to the change in fair value of our contingent consideration liabilities of \$85 million during 2014. We made contingent consideration payments of \$122 million in 2016, \$213 million in 2015 and \$137 million in 2014.

Changes in the fair value of our contingent consideration liabilities were as follows (in millions):

Balance as of December 31, 2014	\$274
Amounts recorded related to new acquisitions	63
Other amounts recorded related to prior acquisitions	(1 )
Fair value adjustment	123
Contingent payments related to prior period acquisition	(213 )
Balance as of December 31, 2015	\$246
Amounts recorded related to new acquisitions	50
Other amounts recorded related to prior acquisitions	1
Fair value adjustment	29
Contingent payments related to prior period acquisition	(122 )
Balance as of December 31, 2016	\$204

As of December 31, 2016, the maximum amount of future contingent consideration (undiscounted) that we could be required to pay was approximately \$1.308 billion.

Contingent consideration liabilities are remeasured to fair value each reporting period using projected revenues, discount rates, probabilities of payment and projected payment dates. The recurring Level 3 fair value measurements of our contingent consideration liabilities include the following significant unobservable inputs:

Contingent Consideration Liability	Fair Value as of December 31, 2016	Valuation Technique	Unobservable Input	Range
R&D and Commercialization-based Milestone	\$46 million	Discounted Cash Flow	Discount Rate	2% - 3%
			Projected Year of Payment	2017 - 2021
	\$60 million	Discounted Cash Flow	Discount Rate	11% - 15%
			Projected Year of Payment	2017 - 2026
Revenue-based Payments	\$98 million	Monte Carlo	Revenue Volatility	25%
			Risk Free Rate	LIBOR Term and Cost of Debt Structure

Projected Year of  
Payment 2017 - 2022

Increases or decreases in the fair value of our contingent consideration can result from changes in discount periods and rates, as well as changes in the timing and amount of revenue estimates or in the timing or likelihood of achieving R&D, regulatory and commercialization-based, and revenue-based milestones. Projected contingent payment amounts related to some of our R&D, regulatory and commercialization-based and revenue-based milestones are discounted back to the current period using a discounted cash flow (DCF) model. Other revenue-based payments are valued using a Monte Carlo valuation model, which simulates future revenues during the earn out-period using management's best estimates. Projected revenues are based on our most recent internal operational budgets and long-range strategic plans. Increases in projected revenues and probabilities of payment may result in higher fair value measurements. Increases in discount rates and the time to payment may result in lower fair value measurements. Increases or decreases in any of those inputs together, or in isolation, may result in a significantly lower or higher fair value measurement.

### Strategic Investments

On April 30, 2015, we acquired a 27 percent ownership interest in Preventice Solutions, Inc. (Preventice), which includes 18.5 percent of Preventice's common stock. Preventice is a privately-held company headquartered in Minneapolis, MN, and a leading developer of mobile health solutions and services. In addition to the equity agreement, we entered into a commercial agreement with Preventice, under which we have become Preventice's exclusive, worldwide sales and marketing representative. In October 2016, we notified Preventice of our intent to terminate the commercial agreement and will transition the sales force back to Preventice in 2017 under the terms of the agreement.

On April 13, 2015, we acquired 25 percent of the common stock of Frankenman Medical Equipment Company (Frankenman). Frankenman is a privately-held company headquartered in Suzhou, China, and is a local market leader in surgical staplers. Additionally, we entered into co-promotional and co-selling agreements with Frankenman to commercialize selected products jointly in China. We believe this alliance will enable us to reach more clinicians and treat more patients in China by providing access to training on less invasive endoscopic technologies with clinical and economic benefits.

We are accounting for our investments in Preventice and Frankenman, as well as certain of our other strategic investments, as equity method investments, in accordance with FASB ASC Topic 323.

The aggregate carrying amount of our strategic investments as of December 31, 2016 and December 31, 2015, were comprised of the following categories:

	As of December 31, 2016	December 31, 2015
Equity method investments	\$265	\$ 173
Cost method investments	20	45
Available-for-sale securities	20	—
Notes receivable	42	30
	\$347	\$ 248

As of December 31, 2016, the book value of our equity method investments exceeded our share of the book value of the investees' underlying net assets by approximately \$200 million, which represents amortizable intangible assets and in-process research and development, corresponding deferred tax liabilities, and goodwill. The net losses from our equity method adjustments, presented within the Other, net caption of our consolidated statement of operations were \$17 million in 2016 and were immaterial in 2015 and 2014.

NOTE C – DIVESTITURES

In January 2011, we closed the sale of our Neurovascular business to Stryker Corporation for a purchase price of \$1.500 billion in cash. At the time of divestiture, due to our continuing involvement in the operations of the Neurovascular business following the transaction, the divestiture did not meet the criteria for presentation as a discontinued operation. Our sales related to our divested Neurovascular business have declined as the various transition services and supply agreements have terminated.

We recorded a gain of \$12 million during 2014 associated with the transaction and we recorded revenue related to the Neurovascular business following its divestiture of \$4 million in 2014.

## NOTE D – GOODWILL AND OTHER INTANGIBLE ASSETS

The gross carrying amount of goodwill and other intangible assets and the related accumulated amortization for intangible assets subject to amortization and accumulated write-offs of goodwill as of December 31, 2016 and 2015 are as follows:

(in millions)	As of December 31, 2016		As of December 31, 2015	
	Gross Carrying Amount	Accumulated Amortization/Write-offs	Gross Carrying Amount	Accumulated Amortization/Write-offs
Amortizable intangible assets				
Technology-related	\$9,123	\$ (4,468 )	\$8,948	\$ (4,054 )
Patents	529	(374 )	520	(358 )
Other intangible assets	1,583	(722 )	1,529	(610 )
	\$11,235	\$ (5,564 )	\$10,997	\$ (5,022 )
Unamortizable intangible assets				
Goodwill	\$16,578	\$ (9,900 )	\$16,373	\$ (9,900 )
In-process research and development (IPR&D)	92	—	99	—
Technology-related	120	—	120	—
	\$16,790	\$ (9,900 )	\$16,592	\$ (9,900 )

Our technology-related intangible assets that are not subject to amortization represent technical processes, intellectual property and/or institutional understanding acquired through business combinations that are fundamental to the on-going operations of our business and have no limit to their useful life. Our technology-related intangible assets that are not subject to amortization are comprised primarily of certain acquired balloon and other technology, which is foundational to our continuing operations within the Cardiovascular market and other markets within interventional medicine. We assess our indefinite-lived intangible assets at least annually for impairment and reassess their classification as indefinite-lived assets. We assess qualitative factors to determine whether the existence of events and circumstances indicate that it is more likely than not that our indefinite-lived intangible assets are impaired. If we conclude that it is more likely than not that the asset is impaired, we then determine the fair value of the intangible asset and perform the quantitative impairment test by comparing the fair value with the carrying value in accordance with FASB ASC Topic 350.

The following represents our goodwill balance by global reportable segment:

(in millions)	Cardiovascular	Rhythm Management	MedSurg	Total
Balance as of December 31, 2014	\$ 3,426	\$ 290	\$ 2,182	\$5,898
Purchase price adjustments	2	2	(2 )	2
Goodwill acquired	23	—	550	573
Balance as of December 31, 2015	\$ 3,451	\$ 292	\$ 2,730	\$6,473
Purchase price adjustments	—	(2 )	(1 )	(3 )
Goodwill acquired	62	—	146	208
Balance as of December 31, 2016	\$ 3,513	\$ 290	\$ 2,875	\$6,678

The 2016 and 2015 purchase price adjustments relate primarily to adjustments in taxes payable and deferred income taxes, including changes in the liability for unrecognized tax benefits.

## Goodwill Impairment Testing



We test our goodwill balances during the second quarter of each year for impairment, or more frequently if indicators are present or changes in circumstances suggest that impairment may exist.

In performing the goodwill impairment assessment, we utilize both the optional qualitative assessment and the two-step approach prescribed under FASB ASC Topic 350. Beginning in 2016, the qualitative assessment was used for testing certain reporting units where fair value has historically exceeded the carrying value by greater than 100%. All other reporting units were tested using the two-step approach. In 2016, for all reporting units tested using the optional qualitative assessment, we concluded that it was not necessary to perform the first step of the two-step goodwill test. For all reporting units tested under the two step approach, we concluded that the fair value of each reporting unit exceeded its carrying value. Because our global Electrophysiology reporting

unit was identified as being at higher risk of potential goodwill impairment during our 2015 annual test, it was tested for impairment on a stand-alone basis in the second quarter of 2016, immediately prior to aggregating it with our global Cardiac Rhythm Management reporting unit. The fair value of the stand-alone global Electrophysiology reporting unit exceeded the carrying value by approximately 36 percent. In comparison, the global Electrophysiology reporting unit had excess fair value of approximately 28 percent as of our 2015 annual test. As of the date of our 2016 annual goodwill impairment test, the aggregated global Electrophysiology and Cardiac Rhythm Management operating segment (Rhythm Management) had excess fair value over carrying value of approximately 70 percent and held \$292 million of allocated goodwill. As such, it was not deemed at higher risk of future impairment. Changes in our reporting units or in the structure of our business as a result of future reorganizations, acquisitions or divestitures of assets or businesses could result in future impairments of goodwill within our reporting units.

Refer to Note A - Significant Accounting Policies and Critical Accounting Policies and Estimates within Management's Discussion and Analysis of Financial Condition and Results of Operations contained in Item 7 of this Annual Report on Form 10-K for a discussion of key assumptions used in our testing.

On a quarterly basis, we monitor the key drivers of fair value to detect events or other changes that would warrant an interim impairment test of our goodwill. The key variables that drive the cash flows of our reporting units and amortizable intangibles are estimated revenue growth rates and levels of profitability. Terminal value growth rate assumptions, as well as the weighted average cost of capital (WACC) rate applied, are additional key variables for reporting unit cash flows. These assumptions are subject to uncertainty, including our ability to grow revenue and improve profitability levels. Relatively small declines in the future performance and cash flows of a reporting unit or asset group or small changes in other key assumptions may result in the recognition of significant goodwill impairment charges. For example, as of the date of our annual goodwill impairment test, keeping all other variables constant, a combined increase of 50 basis points in the WACC along with a simultaneous decrease of 150 basis points in the long term growth rate applied would require that we perform the second step of the goodwill impairment test for our global Electrophysiology reporting unit. The estimates used for our future cash flows and discount rates represent management's best estimates, which we believe to be reasonable, but future declines in business performance may result in impairment of our goodwill. Future events or factors could have a negative impact on the levels of excess fair value over carrying value of our reporting units and negative changes in one or more of these events or factors could result in impairment charges.

The following is a rollforward of accumulated goodwill write-offs by global reportable segment:

(in millions)	Cardiovascular	Rhythm Management	MedSurg	Total
Accumulated write-offs as of December 31, 2014	\$ (1,479 )	\$ (6,960 )	\$ (1,461 )	\$ (9,900)
Goodwill written off	—	—	—	—
Accumulated write-offs as of December 31, 2015	\$ (1,479 )	\$ (6,960 )	(1,461 )	\$ (9,900)
Goodwill written off	—	—	—	—
Accumulated write-offs as of December 31, 2016	\$ (1,479 )	\$ (6,960 )	\$ (1,461 )	\$ (9,900)

#### Intangible Asset Impairment Charges

Unamortizable intangible assets are tested for impairment on an annual basis during the third quarter of each year, or more frequently if impairment indicators are present, in accordance with U.S. GAAP and our accounting policies described in Note A – Significant Accounting Policies of this Annual Report on Form 10-K. In addition, on a quarterly basis, we monitor all intangible assets for events or other potential indicators of impairment that would warrant an interim impairment test.

The intangible asset category and associated write downs recorded in 2016, 2015 and 2014 were as follows:

(in millions)	Year Ended		
	December 31,		
	2016	2015	2014
Amortizable intangible assets	\$4	\$ 9	\$107
In-process research and development	7	10	88
	\$11	19	\$195

## 2014 Charges

During the fourth quarter of 2014, as a result of revised estimates in conjunction with our annual operating plan, we performed an interim impairment test of in-process research and development projects associated with certain of our acquisitions. Based on our impairment assessment, and lower expected future cash flows associated with our intangible assets, we recorded an impairment charge of \$18 million to write-down the balances of these in-process projects to their fair value, which was determined to be zero.

During the third quarter of 2014, we performed our annual impairment test of all in-process research and development projects, and our indefinite lived core technology assets. Based on the results of our annual test, we recorded total impairment charges of \$4 million to write-down the balances of certain in-process projects to their fair value. In addition, as a result of revised estimates in conjunction with our annual operating plan, we performed an interim impairment test of core technology associated with certain of our acquisitions, and recorded an impairment charge of \$8 million, for a total of \$12 million of impairment charges in the third quarter of 2014.

During the second quarter of 2014, as a result of revised estimates developed in conjunction with our annual strategic planning process and annual goodwill impairment test, we performed an interim impairment test of our in-process research and development projects and core technology assets associated with certain of our acquisitions. Based on our impairment assessment, and lower expected future cash flows associated with our intangible assets, we recorded impairment charges of \$110 million. The impairment charges were due to changes in our clinical strategy and lower estimates of the European and global hypertension markets, and the resulting amount of future revenue and cash flows associated with our hypertension technology; as a result, we recorded impairment charges of \$67 million related to these technology intangible assets. In addition, in the second quarter of 2014, due to revised expectations and timing as a result of the announcement of a third FDA Circulatory System Devices Panel, we recorded impairment charges of \$35 million related to the in-process research and development intangible assets acquired from Atritech, Inc. (Atritech). We also recorded an \$8 million intangible asset impairment charge associated with changes in the amount of the expected cash flows related to certain other acquired in-process research and development projects.

During the first quarter of 2014, as a result of lower estimates of the resistant hypertension market following the announcement of data from a competitor's clinical trial, we performed an interim impairment test of our hypertension-related in-process research and development projects and core technology assets. The impairment assessments were based upon probability-weighted cash flows of potential future scenarios. Based on our impairment assessment, and lower expected future cash flows associated with our hypertension-related intangible assets, we recorded impairment charges of \$55 million in the first quarter of 2014 to write-down the balance of these intangible assets to their fair value.

The nonrecurring Level 3 fair value measurements of our intangible asset impairment analysis included the following significant unobservable inputs:

Intangible Asset	Valuation Date	Fair Value	Valuation Technique	Unobservable Input	Rate
Technology-related (amortizable)	September 30, 2015	\$8 million	Income Approach - Excess Earnings Method	Discount Rate	10%
In-Process R&D	June 30, 2015	\$6 million	Income Approach - Excess Earnings Method	Discount Rate	16.5 - 20%
In-Process R&D	September 30, 2014	\$16 million	Income Approach - Excess Earnings Method	Discount Rate	16.5 - 20%
In-Process R&D	June 30, 2014	\$83 million	Income Approach - Excess Earnings Method	Discount Rate	16.5 - 20%
Technology-related (amortizable)	June 30, 2014	\$8 million	Income Approach - Excess Earnings Method	Discount Rate	15%
In-Process R&D	March 31, 2014	\$6 million	Income Approach - Excess Earnings Method	Discount Rate	20%
Technology-related (amortizable)	March 31, 2014	\$64 million	Income Approach - Excess Earnings Method	Discount Rate	15%

Estimated amortization expense for each of the five succeeding fiscal years based upon our intangible asset portfolio as of December 31, 2016 is as follows:

Fiscal Year	Estimated Amortization Expense (in millions)
2017	\$ 535
2018	525
2019	523
2020	519
2021	481

#### NOTE E – FAIR VALUE MEASUREMENTS

##### Derivative Instruments and Hedging Activities

We address market risk from changes in foreign currency exchange rates and interest rates through a risk management program that includes the use of derivative financial instruments, and we operate the program pursuant to documented corporate risk management policies. Our derivative instruments do not subject our earnings or cash flows to material risk, as gains and losses on these derivatives generally offset losses and gains on the item being hedged. We do not enter into derivative transactions for speculative purposes and we do not have any non-derivative instruments that are designated as hedging instruments pursuant to FASB ASC Topic 815.

### Currency Hedging

We are exposed to currency risk consisting primarily of foreign currency denominated monetary assets and liabilities, forecasted foreign currency denominated intercompany transactions and third-party transactions and net investments in certain subsidiaries. We manage our exposure to changes in foreign currency exchange rates on a consolidated basis to take advantage of offsetting transactions. We use derivative instruments, and non-derivative transactions to reduce the risk that our earnings and cash flows associated with these foreign currency denominated balances and transactions will be adversely affected by foreign currency exchange rate changes.

### Currently or Previously Designated Foreign Currency Hedges

All of our designated currency hedge contracts outstanding as of December 31, 2016 and December 31, 2015 were cash flow hedges under Topic 815 intended to protect the U.S. dollar value of our forecasted foreign currency denominated transactions. We record the effective portion of any change in the fair value of foreign currency cash flow hedges in other comprehensive income (OCI) until the related third-party transaction occurs. Once the related third-party transaction occurs, we reclassify the effective portion of any related gain or loss on the foreign currency cash flow hedge to earnings. In the event the hedged forecasted transaction does not occur, or it becomes no longer probable that it will occur, we reclassify the amount of any gain or loss on the related cash flow hedge to earnings at that time. We had currency derivative instruments designated as cash flow hedges outstanding in the contract amount of \$2.271 billion as of December 31, 2016 and \$1.458 billion as of December 31, 2015.

We recognized net gains of \$133 million during 2016 on our cash flow hedges, as compared to \$213 million of net gains during 2015, and \$105 million of net gains during 2014. All currency cash flow hedges outstanding as of December 31, 2016 mature within 60 months. As of December 31, 2016, \$102 million of net gains, net of tax, were recorded in accumulated other comprehensive income (AOCI) to recognize the effective portion of the fair value of any currency derivative instruments that are, or previously were, designated as foreign currency cash flow hedges, as compared to net gains of \$145 million as of December 31, 2015. As of December 31, 2016, \$63 million of net gains, net of tax, may be reclassified to earnings within the next twelve months.

The success of our hedging program depends, in part, on forecasts of transaction activity in various currencies (primarily British pound sterling, Euro and Japanese yen). We may experience unanticipated currency exchange gains or losses to the extent that there are differences between forecasted and actual activity during periods of currency volatility. In addition, changes in foreign currency exchange rates related to any unhedged transactions may impact our earnings and cash flows.

### Non-designated Foreign Currency Contracts

We use currency forward contracts as a part of our strategy to manage exposure related to foreign currency denominated monetary assets and liabilities. These currency forward contracts are not designated as cash flow, fair value or net investment hedges under FASB ASC Topic 815; are marked-to-market with changes in fair value recorded to earnings; and are entered into for periods consistent with currency transaction exposures, generally less than one year. We had currency derivative instruments not designated as hedges under FASB ASC Topic 815 outstanding in the contract amount of \$1.830 billion as of December 31, 2016 and \$2.090 billion as of December 31, 2015.

### Interest Rate Hedging

Our interest rate risk relates primarily to U.S. dollar borrowings, partially offset by U.S. dollar cash investments. We have historically used interest rate derivative instruments to manage our earnings and cash flow exposure to changes in interest rates by converting fixed-rate debt into floating-rate debt or floating-rate debt into fixed-rate debt. We had no interest rate derivative instruments outstanding as of December 31, 2016 and December 31, 2015.

We designate these derivative instruments either as fair value or cash flow hedges under FASB ASC Topic 815. We record changes in the value of fair value hedges in interest expense, which is generally offset by changes in the fair value of the hedged debt obligation. Interest payments made or received related to our interest rate derivative instruments are included in interest expense. We record the effective portion of any change in the fair value of derivative instruments designated as cash flow hedges as unrealized gains or losses in OCI, net of tax, until the hedged cash flow occurs, at which point the effective portion of any gain or loss is reclassified to earnings. We record the ineffective portion of our cash flow hedges in interest expense. In the event the hedged cash flow does not occur, or it

becomes no longer probable that it will occur, we reclassify the amount of any gain or loss on the related cash flow hedge to interest expense at that time.

During the first quarter of 2015, we terminated interest rate derivative contracts designated as fair value hedges having a notional amount of \$450 million to convert fixed-rate debt into floating-rate debt and received total proceeds of approximately \$35 million, which included approximately \$7 million of net accrued interest receivable. We assessed at inception, and re-assessed on an

ongoing basis, whether the interest rate derivative contracts were highly effective in offsetting changes in the fair value of the hedged fixed rate debt. We had no fair value hedges outstanding during 2016 and recognized no gains or losses in interest expense during 2016. During 2015, we recognized, in interest expense, an \$8 million loss on our hedged debt and an \$8 million gain on the related interest rate derivatives contracts. This resulted in immaterial net gains recorded in earnings due to ineffectiveness in 2015.

During the second quarter of 2015, we entered into forward starting interest rate derivative contracts having a notional amount of \$450 million to hedge interest rate risk associated with a planned issuance of fixed-rate senior notes, which we designated as cash flow hedges. These hedges were terminated during the second quarter at the time we issued the fixed-rate senior notes and we received total proceeds of approximately \$11 million. We had no amount outstanding under these hedges as of December 31, 2016 and December 31, 2015. We assessed, at inception, and re-assessed, on an ongoing basis, whether the cash flow derivative contracts were highly effective in offsetting changes in interest rates. The gain on this derivative contract was recorded within accumulated other comprehensive income, and is being amortized into earnings as a reduction to interest expense over the life of the related senior notes.

We are amortizing the gains and losses on previously terminated interest rate derivative instruments, including fixed-to-floating interest rate contracts designated as fair value hedges, and forward starting interest rate derivative contracts and treasury locks designated as cash flow hedges into earnings as a component of interest expense over the remaining term of the hedged debt, in accordance with Topic 815. The carrying amount of certain of our senior notes included unamortized gains of \$51 million as of December 31, 2016 and \$63 million as of December 31, 2015, and immaterial unamortized losses as of December 31, 2016 and December 31, 2015. In addition, we had pre-tax net gains within AOCI related to terminated forward starting interest rate derivative contracts and treasury locks of \$9 million as of December 31, 2016, and \$10 million as of December 31, 2015. The net gains that we recognized in earnings related to previously terminated interest rate derivatives were \$13 million in 2016, \$13 million in 2015, and \$9 million in 2014. As of December 31, 2016, \$13 million of net gains may be reclassified to earnings within the next twelve months from amortization of our previously terminated interest rate derivative contracts.

#### Counterparty Credit Risk

We do not have significant concentrations of credit risk arising from our derivative financial instruments, whether from an individual counterparty or a related group of counterparties. We manage our concentration of counterparty credit risk on our derivative instruments by limiting acceptable counterparties to a diversified group of major financial institutions with investment grade credit ratings, limiting the amount of credit exposure to each counterparty, and by actively monitoring their credit ratings and outstanding fair values on an on-going basis. Furthermore, none of our derivative transactions are subject to collateral or other security arrangements and none contain provisions that are dependent on our credit ratings from any credit rating agency.

We also employ master netting arrangements that reduce our counterparty payment settlement risk on any given maturity date to the net amount of any receipts or payments due between us and the counterparty financial institution. Thus, the maximum loss due to counterparty credit risk is limited to the unrealized gains in such contracts net of any unrealized losses should any of these counterparties fail to perform as contracted. Although these protections do not eliminate concentrations of credit risk, as a result of the above considerations, we do not consider the risk of counterparty default to be significant.



## Fair Value of Derivative Instruments

The following presents the effect of our derivative instruments designated as cash flow hedges under Topic 815 on our accompanying consolidated statements of operations during 2016, 2015 and 2014 (in millions):

	Amount of Pre-tax Gain (Loss) Recognized in OCI (Effective Portion)	Amount of Pre-tax Gain (Loss) Reclassified from AOCI into Earnings (Effective Portion)	Location in Statement of Operations
Year Ended December 31, 2016			
Interest rate contracts	\$ —	\$ 1	Interest expense
Currency hedge contracts	65	133	Cost of products sold
	\$ 65	\$ 134	
Year Ended December 31, 2015			
Interest rate contracts	\$ 11	\$ 2	Interest expense
Currency hedge contracts	98	213	Cost of products sold
	\$ 109	\$ 215	
Year Ended December 31, 2014			
Interest rate contracts	\$ —	\$ 1	Interest expense
Currency hedge contracts	227	105	Cost of products sold
	\$ 227	\$ 106	

The amount of gain (loss) recognized in earnings related to the ineffective portion of hedging relationships was immaterial in all periods presented.

Net gains and losses on currency hedge contracts not designated as hedging instruments were offset by net losses and gains from foreign currency transaction exposures, as shown in the following table:

(in millions)	Year Ended December 31, 2016 2015 2014			Location in Statement of Operations
Gain (loss) on currency hedge contracts	\$(20)	\$48	\$52	Other, net
Gain (loss) on foreign currency transaction exposures	7	(69)	(70)	Other, net
Net foreign currency gain (loss)	\$(13)	\$(21)	\$(18)	

FASB ASC Topic 815 requires all derivative instruments to be recognized at their fair values as either assets or liabilities on the balance sheet. We determine the fair value of our derivative instruments using the framework prescribed by FASB ASC Topic 820, by considering the estimated amount we would receive or pay to transfer these instruments at the reporting date and by taking into account current interest rates, foreign currency exchange rates, the creditworthiness of the counterparty for the assets and our creditworthiness for liabilities. In certain instances, we may utilize financial models to measure fair value. In doing so, we use inputs that include quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; other observable inputs for the asset or liability; and inputs derived principally from, or corroborated by, observable market data by correlation or other means. As of December 31, 2016 we have classified all of our derivative assets and liabilities within Level 2 of the fair value hierarchy prescribed by Topic 820, as discussed below, because these

observable inputs are available for substantially the full term of our derivative instruments.

The following are the balances of our derivative assets and liabilities as of December 31, 2016 and December 31, 2015:

		As of	
		December	December
		31, 2016	31, 2015
(in millions)	Location in Balance Sheet (1)		
<b>Derivative Assets:</b>			
<b>Designated Hedging Instruments</b>			
Currency hedge contracts	Other current assets	\$98	\$ 138
Currency hedge contracts	Other long-term assets	65	66
		163	204
<b>Non-Designated Hedging Instruments</b>			
Currency hedge contracts	Other current assets	36	33
<b>Total Derivative Assets</b>		<b>\$199</b>	<b>\$ 237</b>
<b>Derivative Liabilities:</b>			
<b>Designated Hedging Instruments</b>			
Currency hedge contracts	Other current liabilities	\$3	\$ 1
Currency hedge contracts	Other long-term liabilities	4	—
		7	1
<b>Non-Designated Hedging Instruments</b>			
Currency hedge contracts	Other current liabilities	19	22
<b>Total Derivative Liabilities</b>		<b>\$26</b>	<b>\$ 23</b>

(1) We classify derivative assets and liabilities as current when the remaining term of the derivative contract is one year or less.

#### Other Fair Value Measurements

##### Recurring Fair Value Measurements

On a recurring basis, we measure certain financial assets and financial liabilities at fair value based upon quoted market prices, where available. Where quoted market prices or other observable inputs are not available, we apply valuation techniques to estimate fair value. Topic 820 establishes a three-level valuation hierarchy for disclosure of fair value measurements. The categorization of financial assets and financial liabilities within the valuation hierarchy is based upon the lowest level of input that is significant to the measurement of fair value. The three levels of the hierarchy are defined as follows:

Level 1 – Inputs to the valuation methodology are quoted market prices for identical assets or liabilities.

Level 2 – Inputs to the valuation methodology are other observable inputs, including quoted market prices for similar assets or liabilities and market-corroborated inputs.

Level 3 – Inputs to the valuation methodology are unobservable inputs based on management's best estimate of inputs market participants would use in pricing the asset or liability at the measurement date, including assumptions about risk.

Assets and liabilities measured at fair value on a recurring basis consist of the following as of December 31, 2016 and December 31, 2015:

(in millions)	As of December 31, 2016				As of December 31, 2015			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>Assets</b>								
Money market and government funds	\$42	\$—	\$—	\$42	\$118	\$—	\$—	\$118
Available-for-sale-securities	20	—	—	20	—	—	—	—
Currency hedge contracts	—	199	—	199	—	237	—	237
	\$62	\$199	\$—	\$261	\$118	\$237	\$—	\$355
<b>Liabilities</b>								
Currency hedge contracts	\$—	\$26	\$—	\$26	\$—	\$23	\$—	\$23
Accrued contingent consideration	—	—	204	\$204	—	—	246	246
	\$—	\$26	\$204	\$230	\$—	\$23	\$246	\$269

Our investments in money market and government funds are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. These investments are classified as cash and cash equivalents within our accompanying consolidated balance sheets, in accordance with U.S. GAAP and our accounting policies. In addition to \$42 million invested in money market and government funds as of December 31, 2016, we had \$19 million in short-term time deposits and \$135 million in interest bearing and non-interest bearing bank accounts. In addition to \$118 million invested in money market and government funds as of December 31, 2015, we had \$31 million in short-term time deposits and \$170 million in interest bearing and non-interest bearing bank accounts.

On December 1, 2016, we signed a subscription agreement to acquire 11,817,000 shares of Neovasc's common stock for \$0.60 per share or \$7 million. The subscription agreement was accounted for as a derivative forward contract, in accordance with FASB ASC Topic 815, until the settlement date. On December 12, 2016, the contract was settled, and we acquired the shares of Neovasc's common stock for \$7 million. The fair value of the shares purchased on the settlement date was \$26 million. Therefore, we recognized a gain of \$12 million, net of tax, in earnings on the forward contract during 2016. Subsequently, we are accounting for the investment as an available-for-sale security, in accordance with FASB ASC Topic 320.

Our recurring fair value measurements using significant unobservable inputs (Level 3) relate solely to our contingent consideration liability. Refer to Note B – Acquisitions and Strategic Investments for a discussion of the changes in the fair value of our contingent consideration liability and additional details on our Neovasc strategic investment.

#### Non-Recurring Fair Value Measurements

We hold certain assets and liabilities that are measured at fair value on a non-recurring basis in periods subsequent to initial recognition. The fair value of a cost method investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. Refer to Note B - Acquisitions and Strategic Investments for a discussion of our strategic investments.

The fair value of our outstanding debt obligations was \$5.739 billion as of December 31, 2016 and \$5.887 billion as of December 31, 2015, which was determined by using quoted market prices for our publicly-registered senior notes, classified as Level 1 within the fair value hierarchy. Refer to Note F – Borrowings and Credit Arrangements for a discussion of our debt obligations.

## NOTE F – BORROWINGS AND CREDIT ARRANGEMENTS

We had total debt of \$5.484 billion as of December 31, 2016 and \$5.677 billion as of December 31, 2015. The debt maturity schedule for the significant components of our debt obligations as of December 31, 2016 is as follows:

(in millions)	2017	2018	2019	2020	2021	Thereafter	Total
Senior notes	\$250	\$600	\$—	\$1,450	\$—	\$2,350	\$4,650
Term loans	—	225	150	375	—	—	750
	\$250	\$825	\$150	\$1,825	\$—	\$2,350	\$5,400

Note: The table above does not include unamortized discounts associated with our senior notes, or amounts related to interest rate contracts used to hedge the fair value of certain of our senior notes or debt issuance costs.

## Revolving Credit Facility

On April 10, 2015, we entered into a new \$2.000 billion revolving credit facility (the 2015 Facility) with a global syndicate of commercial banks and terminated our previous \$2.000 billion revolving credit facility. The 2015 Facility matures on April 10, 2020. Eurodollar and multicurrency loans under the 2015 Facility bear interest at LIBOR plus an interest margin of between 0.900 percent and 1.500 percent, based on our corporate credit ratings and consolidated leverage ratio (1.300 percent as of December 31, 2016). In addition, we are required to pay a facility fee based on our credit ratings, consolidated leverage ratio, and the total amount of revolving credit commitments, regardless of usage, under the agreement (0.200 percent as of December 31, 2016). The 2015 Facility contains covenants which, among other things, require that we maintain a minimum interest coverage ratio of 3.0 times consolidated EBITDA and a maximum leverage ratio of 4.5 times consolidated EBITDA for the first four fiscal quarter-ends following the closing of the AMS Portfolio Acquisition on August 3, 2015, and decreasing to 4.25 times, 4.00 times, and 3.75 times consolidated EBITDA for the next three fiscal quarter-ends after such four fiscal quarter-ends, respectively, and then to 3.50 times for each fiscal quarter-end thereafter. There were no amounts borrowed under our current and prior revolving credit facilities as of December 31, 2016 or December 31, 2015.

Our revolving credit facility agreement in place as of December 31, 2016 requires that we maintain certain financial covenants, as follows:

	Covenant Requirement as of December 31, 2016	Actual as of December 31, 2016
Maximum leverage ratio (1)	4.0 times	2.4 times
Minimum interest coverage ratio (2)	3.0 times	9.8 times

(1) Ratio of total debt to consolidated EBITDA, as defined by the credit agreement, for the preceding four consecutive fiscal quarters.

(2) Ratio of consolidated EBITDA, as defined by the credit agreement, to interest expense for the preceding four consecutive fiscal quarters.

The credit agreement for the 2015 Facility provides for an exclusion from the calculation of consolidated EBITDA, as defined by the credit agreement, through the credit agreement maturity, of any non-cash charges and up to \$620 million in restructuring charges and restructuring-related expenses related to our current or future restructuring plans. As of December 31, 2016, we had \$485 million of the restructuring charge exclusion remaining. In addition, any cash litigation payments (net of any cash litigation receipts), as defined by the agreement, are excluded from the calculation of consolidated EBITDA and any new debt issued to fund any tax deficiency payments is excluded from consolidated total debt, as defined in the agreement, provided that the sum of any excluded net cash litigation payments and any new debt issued to fund any tax deficiency payments not exceed \$2.000 billion in the aggregate. As of December 31, 2016, we had approximately \$885 million of the combined legal and debt exclusion remaining.

As of and through December 31, 2016, we were in compliance with the required covenants.

Any inability to maintain compliance with these covenants could require us to seek to renegotiate the terms of our credit facility or seek waivers from compliance with these covenants, both of which could result in additional borrowing costs. Further, there can be no assurance that our lenders would agree to such new terms or grant such waivers.



## Term Loans

As of December 31, 2016, we had an aggregate \$750 million outstanding under our unsecured term loan facilities and \$1.000 billion outstanding under these facilities as of December 31, 2015. These facilities include an unsecured term loan facility entered into in August 2013 (2013 Term Loan) which had \$150 million outstanding as of December 31, 2016 and \$250 million outstanding as of December 31, 2015, along with an unsecured term loan credit facility entered into in April 2015 (2015 Term Loan) which had \$600 million outstanding as of December 31, 2016 and \$750 million outstanding as of December 31, 2015.

Borrowings under the 2013 Term Loan bear interest at LIBOR plus an interest margin of between 1.0 percent and 1.75 percent (currently 1.5 percent), based on our corporate credit ratings and consolidated leverage ratio. We repaid \$150 million of our 2013 Term Loan facility in the fourth quarter of 2015 and repaid an additional \$100 million during the second quarter of 2016. As a result and in accordance with the credit agreement, the outstanding balance of \$150 million is the remaining principal amount due at the final maturity date in August 2018. The 2013 Term Loan borrowings are repayable at any time without premium or penalty. Our term loan facility requires that we comply with certain covenants, including financial covenants with respect to maximum leverage and minimum interest coverage, consistent with the 2015 Term Loan Facility. The maximum leverage ratio requirement is 4.0 times, our actual leverage ratio as of December 31, 2016 is 2.4 times, and the minimum interest coverage ratio requirement is 3.0 times, our actual interest coverage ratio as of December 31, 2016 is 9.8 times.

On April 10, 2015, we entered into a new \$750 million unsecured term loan credit facility which matures on August 3, 2020. The 2015 Term Loan was funded on August 3, 2015 and was used to partially fund the AMS Portfolio Acquisition, including the payment of fees and expenses. Term loan borrowings under this facility bear interest at LIBOR plus an interest margin of between 1.00 percent and 1.75 percent (currently 1.50 percent), based on our corporate credit ratings and consolidated leverage ratio. We repaid \$150 million of our 2015 Term Loan during the second quarter of 2016. The remaining 2015 Term Loan requires quarterly principal payments of \$38 million commencing in the third quarter of 2018, and the remaining principal amount is due at the final maturity date of August 3, 2020. The 2015 Term Loan agreement requires that we comply with certain covenants, including financial covenants with respect to maximum leverage and minimum interest coverage, consistent with our revolving credit facility. The maximum leverage ratio requirement is 4.0 times, our actual leverage ratio as of December 31, 2016 is 2.4 times, and the minimum interest coverage ratio requirement is 3.0 times, our actual interest coverage ratio as of December 31, 2016 is 9.8 times.

## Senior Notes

We had senior notes outstanding of \$4.650 billion as of December 31, 2016 and December 31, 2015. In May 2015, we completed the offering of \$1.850 billion in aggregate principal amount of senior notes consisting of \$600 million in aggregate principal amount of 2.850% notes due 2020, \$500 million in aggregate principal amount of 3.375% notes due 2022 and \$750 million in aggregate principal amount of 3.850% notes due 2025. The net proceeds from the offering of the notes, after deducting underwriting discounts and estimated offering expenses, were approximately \$1.830 billion. We used a portion of the net proceeds from the senior notes offering to redeem \$400 million aggregate principal amount of our 5.500% notes due November 2015 and \$600 million aggregate principal amount of our 6.400% notes due June 2016. The remaining senior notes offering proceeds, together with the 2015 Term Loan, were used to fund the AMS Portfolio Acquisition. We recorded a charge of \$45 million in interest expense, during the second quarter of 2015, for premiums, accelerated amortization of debt issuance costs, and investor discount costs net of interest rate hedge gains related to the early debt extinguishment.

Our senior notes were issued in public offerings, are redeemable prior to maturity and are not subject to any sinking fund requirements. Our senior notes are unsecured, unsubordinated obligations and rank on parity with each other. These notes are effectively junior to borrowings under our credit and security facility, to the extent if borrowed by our subsidiaries, and to liabilities of our subsidiaries (see Other Arrangements below).

On January 12, 2017, we used our existing credit facilities to repay the \$250 million plus interest of our senior notes due in January 2017.





Our senior notes consist of the following as of December 31, 2016:

	Amount (in millions)	Issuance Date	Maturity Date	Semi-annual Coupon Rate
January 2017 Notes	\$ 250	November 2004	January 2017	5.125%
October 2018 Notes	600	August 2013	October 2018	2.650%
January 2020 Notes	850	December 2009	January 2020	6.000%
May 2020 Notes	600	May 2015	May 2020	2.850%
May 2022 Notes	500	May 2015	May 2022	3.375%
May 2025 Notes	750	May 2015	May 2025	3.850%
October 2023 Notes	450	August 2013	October 2023	4.125%
November 2035 Notes	350	November 2005	November 2035	6.250%
January 2040 Notes	300	December 2009	January 2040	7.375%
	\$ 4,650			

Our \$4.050 billion of senior notes issued in 2009, 2013 and 2015 contain a change-in-control provision, which provides that each holder of the senior notes may require us to repurchase all or a portion of the notes at a price equal to 101 percent of the aggregate repurchased principal, plus accrued and unpaid interest, if a rating event, as defined in the indenture, occurs as a result of a change-in-control, as defined in the indenture. Any other credit rating changes may impact our borrowing cost, but do not require us to repay any borrowings.

The interest rate payable on our November 2035 Notes is currently 7.00 percent. Corporate credit rating improvements may result in a decrease in the adjusted interest rate on our November 2035 Notes to the extent that our lowest credit rating is above BBB- or Baa3. The interest rates on our November 2035 Notes will be permanently reinstated to the issuance rate if the lowest credit ratings assigned to these senior notes is either A- or A3 or higher.

#### Other Arrangements

We maintained a \$300 million credit and security facility secured by our U.S. trade receivables maturing on June 9, 2017. The credit and security facility required that we maintain a maximum leverage covenant consistent with our revolving credit facility. The maximum leverage ratio requirement was 4.0 times and our actual leverage ratio as of December 31, 2016 was 2.4 times. We had borrowings of \$60 million outstanding under this facility as of December 31, 2016 and no borrowings outstanding as of December 31, 2015. On February 7, 2017, we amended the terms of this credit and security facility, including increasing the facility size to \$400 million. This amendment retained a similar maximum leverage ratio requirement and extended the facility maturity to February 2019.

We have accounts receivable factoring programs in certain European countries that we account for as sales under FASB ASC Topic 860, Transfers and Servicing. These agreements provide for the sale of accounts receivable to third parties, without recourse, of up to approximately \$391 million as of December 31, 2016. We have no retained interests in the transferred receivables, other than collection and administrative responsibilities and, once sold, the accounts receivable are no longer available to satisfy creditors in the event of bankruptcy. We de-recognized \$152 million of receivables as of December 31, 2016 at an average interest rate of 1.8 percent, and \$151 million as of December 31, 2015 at an average interest rate of 2.4 percent.

In addition, we have uncommitted credit facilities with a commercial Japanese bank that provide for borrowings, promissory notes discounting and receivables factoring of up to 21.0 billion Japanese yen (approximately \$180 million as of December 31, 2016). We de-recognized \$149 million of notes receivable as of December 31, 2016 at an average interest rate of 1.6 percent and \$132 million of notes receivable as of December 31, 2015 at an average interest rate of 1.6 percent. De-recognized accounts and notes receivable are excluded from trade accounts receivable, net in the accompanying consolidated balance sheets.

As of December 31, 2016 and December 31, 2015, we had outstanding letters of credit of \$44 million which consisted primarily of bank guarantees and collateral for workers' compensation insurance arrangements. As of December 31, 2016 and 2015, none of the beneficiaries had drawn upon the letters of credit or guarantees; accordingly, we have not recognized a related liability for our outstanding letters of credit in our consolidated balance sheets as of

December 31, 2016 or 2015.

**NOTE G – LEASES AND OTHER PURCHASE OBLIGATIONS**

Rent expense amounted to \$80 million in 2016, \$76 million in 2015 and \$76 million in 2014.

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Future minimum rental commitments as of December 31, 2016 under all noncancellable lease agreements, including capital leases, were as follows (in millions):

2017	\$66
2018	60
2019	42
2020	34
2021	25
Thereafter	64
	\$291

Future minimum purchase obligations as of December 31, 2016, were as follows (in millions):

2017	\$321
2018	52
2019	39
2020	19
2021	12
Thereafter	15
	\$458

#### NOTE H – RESTRUCTURING-RELATED ACTIVITIES

We monitor the dynamics of the economy, the healthcare industry, and the markets in which we compete and assess opportunities for improved operational effectiveness and efficiency, and better alignment of expenses with revenues, while preserving our ability to make the investments in research and development projects, capital, our people that we believe are essential to our long-term success. As a result of these assessments, we have undertaken various restructuring initiatives in order to enhance our growth potential and position us for long-term success. These initiatives are described below.

##### 2016 Restructuring Plan

On June 6, 2016, our Board of Directors approved, and we committed to, a restructuring initiative (the 2016 Restructuring Plan). The 2016 Restructuring Plan is intended to develop global commercialization, technology and manufacturing capabilities in key growth markets, build on our Plant Network Optimization (PNO) strategy which is intended to simplify our manufacturing plant structure by transferring certain production lines among facilities, and expand operational efficiencies in support of our operating income margin goals. Key activities under the 2016 Restructuring Plan include strengthening global infrastructure through evolving global real estate and workplaces, developing global commercial and technical competencies, enhancing manufacturing and distribution expertise in certain regions, and continuing implementation of our PNO strategy. These activities initiated in the second quarter of 2016 and are expected to be substantially completed by the end of 2018.

The implementation of the 2016 Restructuring Plan is expected to result in total pre-tax charges of approximately \$175 million to \$225 million, and approximately \$160 million to \$210 million of these charges are estimated to result in cash outlays, of which we have made payments of \$27 million in 2016. We have recorded related costs of \$47 million in 2016, and recorded a portion of these expenses as restructuring charges and the remaining portion through other lines within our consolidated statements of operations.



The following table provides a summary of our estimates of costs associated with the 2016 Restructuring Plan through the end of 2018 by major type of cost:

Type of cost	Total estimated amount expected to be incurred
Restructuring charges:	
Termination benefits	\$65 million to \$80 million
Other (1)	\$15 million to \$25 million
Restructuring-related expenses:	
Other (2)	\$95 million to \$120 million
	\$175 million to \$225 million

(1) Consists primarily of consulting fees and costs associated with contract cancellations.

(2) Comprised of other costs directly related to the 2016 Restructuring Plan, including program management, accelerated depreciation, and costs to transfer product lines among facilities.

#### 2014 Restructuring Plan

On October 22, 2013, our Board of Directors approved, and we committed to, a restructuring initiative (the 2014 Restructuring Plan). The 2014 Restructuring Plan built on the progress we made to address financial pressures in a changing global marketplace, further strengthened our operational effectiveness and efficiency and supported new growth investments. Key activities under the plan included continued implementation of our PNO strategy, continued focus on driving operational effectiveness and efficiencies and business and commercial model changes. The PNO strategy simplified our manufacturing plant structure by transferring certain production lines among facilities. Other activities involved rationalizing organizational reporting structures to streamline various functions, eliminate bureaucracy, increase productivity and better align resources to business strategies and marketplace dynamics. These activities were initiated in the fourth quarter of 2013 and were substantially completed by the end of 2015, except for certain actions associated with our PNO strategy, which were completed by the end of 2016.

The implementation of the 2014 Restructuring Plan resulted in total pre-tax charges of \$261 million and \$244 million of cash outlays. We recorded a portion of these expenses as restructuring charges and the remaining portion through other lines within our consolidated statements of operations.

The following table provides a summary of our total costs associated with the 2014 Restructuring plan through December 31, 2016 by major type of cost:

Type of cost	Total amount incurred
Restructuring charges:	
Termination benefits	\$91 million
Other (1)	\$34 million
Restructuring-related expenses:	
Other (2)	\$136 million
	\$261 million

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

(2) Comprised of other costs directly related to the 2014 Restructuring plan, including program management, accelerated depreciation, and costs to transfer product lines among facilities.

We recorded restructuring charges pursuant to our restructuring plans of \$28 million during 2016, \$26 million during 2015, and \$69 million during 2014. In addition, we recorded expenses within other lines of our accompanying consolidated statements of operations related to our restructuring initiatives of \$50 million during 2016, \$57 million during 2015, and \$48 million during 2014.

The following presents these costs (credits) by major type and line item within our accompanying consolidated statements of operations, as well as by program:

Year Ended December 31, 2016

(in millions)	Termination Benefits	Accelerated Depreciation	Transfer Costs	Fixed Asset Write-Offs	Other	Total
Restructuring charges	\$ 19	\$ —	\$ —	\$ 2	\$ 7	\$ 28
Restructuring-related expenses:						
Cost of products sold	—	—	34	—	—	34
Selling, general and administrative expenses	—	5	—	—	11	16
	—	5	34	—	11	50
	\$ 19	\$ 5	\$ 34	\$ 2	\$ 18	\$ 78

(in millions)	Termination Benefits	Accelerated Depreciation	Transfer Costs	Fixed Asset Write-Offs	Other	Total
2016 Restructuring plan	\$ 24	\$ 1	\$ 15	\$ —	\$ 7	\$ 47
2014 Restructuring plan	\$ (5 )	\$ 4	19	\$ 2	\$ 11	\$ 31
	\$ 19	\$ 5	\$ 34	\$ 2	\$ 18	\$ 78

Year Ended December 31, 2015

(in millions)	Termination Benefits	Accelerated Depreciation	Transfer Costs	Other	Total
Restructuring charges	\$ 23	\$ —	\$ —	\$ 3	\$ 26
Restructuring-related expenses:					
Cost of products sold	—	—	31	—	31
Selling, general and administrative expenses	—	3	—	23	26
	—	3	31	23	57
	\$ 23	\$ 3	\$ 31	\$ 26	\$ 83

(in millions)	Termination Benefits	Accelerated Depreciation	Transfer Costs	Other	Total
2014 Restructuring plan	\$ 27	\$ 3	\$ 31	\$ 26	\$ 87
Substantially complete restructuring plan	(4 )	—	—	—	(4 )
	\$ 23	\$ 3	\$ 31	\$ 26	\$ 83

## Year Ended December 31, 2014

(in millions)	Termination Benefits	Accelerated Depreciation	Transfer Costs	Other	Total
Restructuring charges	\$ 42	\$ —	\$ —	\$ 27	\$69
Restructuring-related expenses:					
Cost of products sold	—	—	24	—	24
Selling, general and administrative expenses	—	5	—	19	24
	—	5	24	19	48
	\$ 42	\$ 5	\$ 24	\$ 46	\$117

(in millions)	Termination Benefits	Accelerated Depreciation	Transfer Costs	Other	Total
2014 Restructuring plan	\$ 41	\$ 5	\$ 24	\$ 43	\$113
Substantially complete restructuring plan	1	—	—	3	4
	\$ 42	\$ 5	\$ 24	\$ 46	\$117

Termination benefits represent amounts incurred pursuant to our benefit arrangements and amounts for “one-time” involuntary termination benefits, and have been recorded in accordance with FASB ASC Topic 712 and FASB ASC Topic 420. Other restructuring costs, which represent primarily consulting fees and costs related to contract cancellations, are being recorded as incurred in accordance with FASB ASC Topic 420. Accelerated depreciation is being recorded over the adjusted remaining useful life of the related assets and production line transfer costs are being recorded as incurred.

As of December 31, 2016, we have incurred cumulative restructuring charges related to our 2016 Restructuring Plan and our 2014 Restructuring Plan of \$153 million and restructuring-related costs of \$155 million since we committed to the plans. The following presents these costs by major type and by plan:

(in millions)	2016 Restructuring Plan	2014 Restructuring Plan	Total
Termination benefits	24	\$ 91	\$115
Fixed asset write-offs	—	2	2
Other	4	32	36
Total restructuring charges	28	125	153
Accelerated depreciation	1	12	13
Transfer costs	15	75	90
Other	3	49	52
Restructuring-related expenses	19	136	155
	\$ 47	\$ 261	\$308

We made cash payments of \$82 million in 2016 associated with restructuring initiatives, and as of December 31, 2016 we had made total cash payments of \$271 million related to our 2016 Restructuring Plan and 2014 Restructuring Plan since committing to the plans. These payments were made using cash generated from operations, and are comprised of the following:

(in millions)	2016 Restructuring Plan	2014 Restructuring Plan	Total
Year Ended December 31, 2016			
Termination benefits	8	\$ 24	\$32
Transfer costs	15	19	34
Other	4	12	16
	\$ 27	\$ 55	\$82

Program to Date			
Termination benefits	8	93	\$101
Transfer costs	15	74	89
Other	4	77	81
	\$ 27	\$ 244	\$271

Our restructuring liability is primarily comprised of accruals for termination benefits. The following is a rollforward of the termination benefit liability associated with our 2016 Restructuring Plan, our 2014 Restructuring Plan and our substantially complete restructuring plan, which is reported as a component of accrued expenses included in our accompanying consolidated balance sheets:

(in millions)	Restructuring Plan Termination Benefits			Substantially complete restructuring plan	Total
	2016 Restructuring Plan	2014 Restructuring Plan			
Accrued as of December 31, 2014	—	39		4	43
Charges	—	27		(4 )	23
Cash payments	—	(37 )		—	(37 )
Accrued as of December 31, 2015	—	29		—	29
Charges	24	(5 )		—	19
Cash payments	(8 )	(24 )		—	(32 )
Accrued as of December 31, 2016	\$16	\$ —		\$ —	\$16

In addition to our accrual for termination benefits, we had a \$6 million liability as of December 31, 2016 and a \$3 million liability as of December 31, 2015 for other restructuring-related items.

#### NOTE I – SUPPLEMENTAL BALANCE SHEET INFORMATION

Components of selected captions in our accompanying consolidated balance sheets are as follows:

Trade accounts receivable, net

(in millions)	As of	
	December 31, 2016	December 31, 2015
Accounts receivable	\$1,591	\$ 1,394
Less: allowance for doubtful accounts	(73 )	(75 )
Less: allowance for sales returns	(46 )	(44 )
	\$1,472	\$ 1,275





The following is a rollforward of our allowance for doubtful accounts for 2016, 2015 and 2014:

	Year Ended		
	December 31,		
(in millions)	2016	2015	2014
Beginning balance	\$75	\$76	\$81
Net charges to expenses	9	15	10
Utilization of allowances	(11)	(16)	(15)
Ending balance	\$73	\$75	\$76

#### Inventories

	As of	
	December 31,	
(in millions)	2016	2015
Finished goods	\$625	\$706
Work-in-process	94	102
Raw materials	236	208
	\$955	\$1,016

#### Prepaids and other current assets

	As of	
	December 31,	
(in millions)	2016	2015
Prepaid expenses	\$58	\$57
Restricted cash	243	54
Other	240	254
	\$541	\$365

#### Property, plant and equipment, net

	As of	
	December 31,	
(in millions)	2016	2015
Land	\$91	\$86
Buildings and improvements	981	981
Equipment, furniture and fixtures	2,955	2,793
Capital in progress	338	202
	4,365	4,062
Less: accumulated depreciation	2,735	2,572
	\$1,630	\$1,490

#### Accrued expenses

	As of	
	December 31,	
(in millions)	2016	2015
Legal reserves	\$1,062	\$773
Payroll and related liabilities	572	504
Accrued contingent consideration	63	119
Other	615	574
	\$2,312	\$1,970

## Other long-term liabilities

(in millions)	As of	
	December 31, 2016	December 31, 2015
Accrued income taxes	\$781	\$ 1,253
Legal reserves	961	1,163
Accrued contingent consideration	141	127
Other long-term liabilities	455	431
	\$2,338	\$ 2,974

## NOTE J – INCOME TAXES

Our income (loss) before income taxes consisted of the following:

(in millions)	Year Ended December 31,		
	2016	2015	2014
Domestic	\$(1,019)	\$(1,623)	\$(1,263)
Foreign	1,196	973	754
	\$177	\$(650)	\$(509)

The related benefit for income taxes consisted of the following:

(in millions)	Year Ended December 31,		
	2016	2015	2014
Current			
Federal	\$31	\$59	\$(2)
State	6	3	(5)
Foreign	136	132	111
	173	194	104
Deferred			
Federal	(337)	(545)	(458)
State	(14)	(41)	(23)
Foreign	8	(19)	(13)
	(343)	(605)	(494)
	\$(170)	\$(411)	\$(390)

The reconciliation of income taxes at the federal statutory rate to the actual benefit for income taxes is as follows:

	Year Ended December			
	31,			
	2016	2015	2014	
U.S. federal statutory income tax rate	35.0	% (35.0)%	(35.0)%	
State income taxes, net of federal benefit	(1.7)	)% (4.8	)% (6.5	)%
Effect of foreign taxes	(99.1)	)% (34.4)%	(29.1)	)%
Acquisition-related	9.4	% 6.0	% (7.5	)%
Research credit	(15.0)	)% (4.4	)% (7.0	)%
Valuation allowance	(42.2)	)% 2.3	% 4.0	%
Compensation-related	6.4	% 1.6	% 0.7	%
Non-deductible expenses	9.3	% 2.4	% 1.9	%
Uncertain domestic tax positions	5.5	% 2.7	% 2.0	%
Other, net	(3.5)	)% 0.4	% (0.2	)%
	(95.9)	)% (63.2)%	(76.7)%	

We had net deferred tax assets of \$62 million as of December 31, 2016 and net deferred tax liabilities of \$264 million as of December 31, 2015. Gross deferred tax liabilities of \$1.760 billion as of December 31, 2016 and \$1.875 billion as of December 31, 2015 relate primarily to goodwill and intangible assets acquired in connection with our prior acquisitions. Gross deferred tax assets of \$1.822 billion as of December 31, 2016 and \$1.611 billion as of December 31, 2015 relate primarily to the establishment of inventory and product-related reserves; litigation, product liability and other reserves and accruals; compensation related accruals; net operating loss carryforwards and tax credit carryforwards; and the federal benefit of uncertain tax positions.

Significant components of our deferred tax assets and liabilities are as follows:

(in millions)	As of December 31,	
	2016	2015
Deferred Tax Assets:		
Inventory costs and related reserves	\$37	\$49
Tax benefit of net operating loss and credits	798	742
Reserves and accruals	228	232
Restructuring-related charges	14	17
Litigation and product liability reserves	752	689
Investment write-down	17	7
Compensation related	142	138
Federal benefit of uncertain tax positions	238	197
Other	42	39
	2,268	2,110
Less valuation allowance	(446 )	(499 )
	1,822	1,611
Deferred Tax Liabilities:		
Property, plant and equipment	42	44
Unrealized gains and losses on derivative financial instruments	67	82
Intangible assets	1,651	1,749
	1,760	1,875
Net Deferred Tax Assets / (Liabilities)	62	(264 )
Prepaid on intercompany profit	75	63
Net Deferred Tax Assets / (Liabilities) and Prepaid on Intercompany Profit	\$137	\$(201)
Our deferred tax assets, deferred tax liabilities and prepaid on intercompany profit, are included in the following locations within our accompanying consolidated balance sheets (in millions):		
Component	Location in As of December 31,	
	Balance Sheet	2016 2015
Current deferred tax asset and prepaid on intercompany profit	Deferred income taxes	\$ 75 \$ 496
Non-current deferred tax asset	Other long-term assets	80 40
Deferred Tax Assets and Prepaid on Intercompany Profit		155 536
Current deferred tax liability	Other current liabilities	— 2
Non-current deferred tax liability	Deferred income taxes	18 735
Deferred Tax Liabilities		18 737
Net Deferred Tax Assets / (Liabilities) and Prepaid on Intercompany Profit		\$ 137 \$ (201 )

As of December 31, 2016, we had U.S. federal and state tax net operating loss carryforwards and tax credits, the tax effect of which was \$724 million. As of December 31, 2015, we had U.S. federal and state tax net operating loss carryforwards and tax credits, the tax effect of which was \$500 million. In addition, we had foreign tax net operating loss carryforwards and tax credits, the tax effect of which was \$172 million as of December 31, 2016, as compared to \$273 million as of December 31, 2015. These tax attributes will expire periodically beginning in 2017. The tax effect of both U.S. federal and state tax net operating loss carryforwards and tax credits and foreign tax net operating loss carryforwards and tax credits as of December 31, 2015 was

previously disclosed in the amounts of \$624 million and \$288 million, respectively. We are updating these amounts to reflect unrecognized tax benefits that reduce the amounts.

The current accounting standard for stock-based compensation prohibits the recognition of windfall tax benefits from stock-based compensation deducted for tax return purposes until realized through a reduction of income taxes payable. We have \$76 million and \$32 million of U.S. tax net operating loss and credits as of December 31, 2016 and December 31, 2015, respectively. These amounts were not included in the gross deferred tax balances as of December 31, 2016 and December 31, 2015.

After consideration of all positive and negative evidence, we believe that it is more likely than not that a portion of the deferred tax assets will not be realized. As a result, we established a valuation allowance of \$446 million as of December 31, 2016 and \$499 million as of December 31, 2015, representing a decrease of \$53 million. The decrease in the valuation allowance as of December 31, 2016, as compared to December 31, 2015, is primarily attributable to the release of valuation allowance related to certain foreign tax net operating losses which expired in 2016. The release was offset by an increase to the valuation allowance related to federal and state tax credits and state tax net operating loss carryforwards. The income tax impact of the unrealized gain or loss component of other comprehensive income and stockholders' equity was a charge of \$9 million in 2016, a charge of \$25 million in 2015, and a charge of \$21 million in 2014.

We have not provided U.S. income taxes and foreign withholding taxes on the undistributed earnings of foreign subsidiaries as of December 31, 2016 because we intend to permanently reinvest such earnings outside the U.S. As of December 31, 2016, the cumulative amount of excess financial reporting basis over the tax basis of investments in foreign subsidiaries that is indefinitely reinvested is approximately \$9.8 billion. Generally, such amounts become subject to U.S. taxation upon the remittance of dividends and under certain other circumstances. It is not practicable to estimate the amount of deferred tax liability related to investments in these foreign subsidiaries.

We obtain tax incentives through Free Trade Zone Regime offered in Costa Rica which allows 100% exemption from income tax in the first eight years of operations and 50% exemption in the following four years. This tax incentive resulted in income tax savings of \$123 million for 2016, \$7 million for 2015, and \$7 million for 2014. The tax incentive for 100% exemption from income tax is expected to expire in 2023. The impact of per share earnings is \$0.09 for 2016 and immaterial for 2015 and 2014.

As of December 31, 2016, we had \$1.095 billion of gross unrecognized tax benefits, of which a net \$1.006 billion, if recognized, would affect our effective tax rate. As of December 31, 2015, we had \$1.056 billion of gross unrecognized tax benefits, of which a net \$900 million, if recognized, would affect our effective tax rate. As of December 31, 2014, we had \$1.047 billion of gross unrecognized tax benefits, of which a net \$903 million, if recognized, would affect our effective tax rate. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in millions):

	Year Ended December 31,		
	2016	2015	2014
Beginning Balance	\$1,056	\$1,047	\$1,102
Additions based on positions related to the current year	47	32	44
Additions based on positions related to prior years	14	38	3
Reductions for tax positions of prior years	(17)	(36)	(87)
Settlements with taxing authorities	(3)	(18)	(5)
Statute of limitation expirations	(2)	(7)	(10)
Ending Balance			