MEDTRONIC INC Form 10-K June 28, 2011 Table of Contents

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FO	D.	$\mathbf{M}$	16	$\mathbf{K}$
				/ <b>-</b> N

X	Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934. For the fiscal year ended April 29, 2011.
0	Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.  For the transition period from to

# Medtronic, Inc.

(Exact name of registrant as specified in charter)

Minnesota (State of incorporation)

41-0793183

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

710 Medtronic Parkway Minneapolis, Minnesota 55432 (Address of principal executive offices) (Zip Code) Registrant s telephone number, including area code: (763) 514-4000

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

Title of each class

Common stock, par value \$0.10 per share

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 x No o

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 x No o

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

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 (§ 229.405 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 x No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer x Accelerated filer o Non-accelerated filer o Smaller reporting company o

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

Aggregate market value of voting stock of Medtronic, Inc. held by nonaffiliates of the registrant as of October 29, 2010, based on the closing price of \$35.23, as reported on the New York Stock Exchange: approximately \$38.1 billion. Shares of Common Stock outstanding on June 24, 2011: 1,060,963,265.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s 2011 Annual Report filed as Exhibit 13 hereto are incorporated by reference into Parts I and II hereto and portions of Registrant s Proxy Statement for its 2011 Annual Meeting are incorporated by reference into Part III hereto.

# TABLE OF CONTENTS

Item	Description	Page					
	PART I						
1. 1A. 1B. 2. 3. 4.	Business Risk Factors Unresolved Staff Comments Properties Legal Proceedings Removed and Reserved	1 18 25 25 25 25 25					
	PART II						
5. 6. 7. 7A. 8. 9. 9A. 9B.	Market for Medtronic s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities Selected Financial Data Management s Discussion and Analysis of Financial Condition and Results of Operations Quantitative and Qualitative Disclosures About Market Risk Financial Statements and Supplementary Data Changes in and Disagreements with Accountants on Accounting and Financial Disclosure Controls and Procedures Other Information	25 26 27 27 27 27 27 27 27					
	PART III						
10. 11. 12. 13. 14.	Directors, Executive Officers, and Corporate Governance  Executive Compensation  Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters  Certain Relationships and Related Transactions, and Director Independence  Principal Accounting Fees and Services	28 28 28 28 28					
<u>PART IV</u>							
<u>15.</u>	Exhibits, Financial Statement Schedules	29					

#### Table of Contents

# **Annual Meeting and Record Dates**

Medtronic, Inc. s (Medtronic or the Company) Annual Meeting of Shareholders will be held on Thursday, August 25, 2011 at 10:30 a.m., Central Daylight Time at the Company s World Headquarters, 710 Medtronic Parkway, Minneapolis (Fridley), Minnesota. The record date for the Annual Meeting is June 27, 2011 and all shareholders of record at the close of business on that day will be entitled to vote at the Annual Meeting.

#### **Medtronic Website**

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available through our website (<a href="www.medtronic.com">www.medtronic.com</a> under the Investors caption and Financial Information SEC Filings subcaption) free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (SEC).

Information relating to corporate governance at Medtronic, including our Principles of Corporate Governance, Code of Conduct (including our Code of Ethics for Senior Financial Officers), Code of Business Conduct and Ethics for Members of the Board of Directors and information concerning our executive officers, directors and Board committees (including committee charters) and transactions in Medtronic securities by directors and officers, is available on or through our website at <a href="https://www.medtronic.com">www.medtronic.com</a> under the Investors caption and the Corporate Governance subcaption.

We are not including the information on our website as a part of, or incorporating it by reference into, our Form 10-K.

#### **Available Information**

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public can obtain any documents that the Company files with the SEC at <a href="http://www.sec.gov">http://www.sec.gov</a>. The Company files annual reports, quarterly reports, proxy statements, and other documents with the SEC under the Securities Exchange Act of 1934, as amended (Exchange Act). The public may read and copy any materials that the Company files with the SEC at the SEC s Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

#### PART I

#### Item 1. Business

#### Overview

Medtronic is the global leader in medical technology alleviating pain, restoring health, and extending life for millions of people around the world. Medtronic was founded in 1949, incorporated as a Minnesota corporation in 1957, and today serves physicians, clinicians, and patients in more than 120 countries worldwide. We remain committed to a mission written by our founder over 50 years ago that directs us to contribute to human welfare by the application of biomedical engineering in the research, design, manufacture, and sale of products to alleviate pain, restore health, and extend life.

We currently function in two operating segments that manufacture and sell device-based medical therapies. Our operating segments are as follows:

#### Cardiac and Vascular Group

Cardiac Rhythm Disease Management

CardioVascular

Physio-Control

#### **Restorative Therapies Group**

Spinal

Neuromodulation

Diabetes

Surgical Technologies

These two segments resulted from a December 2009 consolidation of our businesses into two operating groups. The creation of these two operating groups did not immediately change how the Company internally managed and reported the results of these businesses until the first quarter of fiscal year 2011 when, due to changes in how the Company internally manages and reports the results of these businesses, the Company began to operate under two reportable segments and two operating segments. During the first quarter of fiscal year 2011, the two operating groups were formally named the Cardiac and Vascular Group (composed of the Cardiac Rhythm Disease Management (CRDM), CardioVascular, and Physio-Control businesses) and the Restorative Therapies Group (composed of the Spinal, Neuromodulation, Diabetes, and Surgical Technologies businesses). The chart above shows the net sales and percentage of total net sales contributed by each of our operating segments for the fiscal year ended April 29, 2011 (fiscal year 2011). Please see note 18 to the consolidated financial statements set forth in Exhibit 13 hereto and included in our 2011 Annual Report for more information on our operating segments.

With innovation and market leadership, we have pioneered advances in medical technology in all of our businesses and enjoyed steady overall growth. Over the last five years, our net sales on a compounded annual growth basis have increased more than 7 percent, from \$11.292 billion in fiscal year 2006 to \$15.933 billion in fiscal year 2011. We attribute this growth to our commitment to develop and acquire new products to treat an expanding array of medical conditions.

We will accomplish this commitment by reaching within and across our operating segments to make the whole of Medtronic greater than the sum of its parts. The main tenets of this approach are:

Driving sustainable long-term growth through innovation,

Maintaining a strong focus on improving operating margins,

Delivering earnings per share growth and disciplined capital allocation, and

Aligning the organization for market-leading and consistent execution.

Our primary customers include hospitals, clinics, third-party health care providers, distributors, and other institutions, including governmental health care programs and group purchasing organizations.

1

#### CARDIAC AND VASCULAR GROUP

# **Cardiac Rhythm Disease Management**

CRDM develops, manufactures, and markets products for the diagnosis, treatment, and management of heart rhythm disorders and heart failure, including implantable devices, leads and delivery systems, products for the treatment of atrial fibrillation (AF), and information systems for the management of patients with CRDM devices.

The following are the principal products offered by our CRDM business:

Implantable Cardiac Pacemakers (Pacemakers). A pacemaker is a battery-powered device implanted in the chest that delivers electrical impulses to treat bradycardia, a condition of abnormally slow heart rhythms, usually less than 60 beats per minute, or unsteady heart rhythms that cause symptoms such as dizziness, fainting, fatigue, and shortness of breath. Our latest generation of pacemaker systems is compatible with certain MRI machines. This includes the Revo MRI SureScan with U.S. Food and Drug Administration (FDA) approval and Advisa and Ensura MRI SureScan models with Conformité Européene (CE) Mark approval. Medtronic also continues to market the Adapta product family, which includes the Adapta, Versa, Sensia, and Relia models.

Implantable Cardioverter Defibrillators (ICDs). An ICD continually monitors the heart and delivers therapy when an abnormal heart rhythm, such as tachyarrhythmia, or rapid heart rhythm, occurs and leads to sudden cardiac arrest. Medtronic s latest generation of ICDs is the Protecta family with SmartShock technology. Devices in this family are the Protecta XT, Protecta, Cardia, and Egida models. Medtronic also continues to market the Virtuoso II, Maximo II, and Secura devices.

Implantable Cardiac Resynchronization Therapy Devices (CRT-Ds and CRT-Ps). Implantable cardiac resynchronization therapy devices may be combined with defibrillation (CRT-D) or be pacing-only (CRT-P). These devices treat heart failure patients by altering the abnormal electrical sequence of cardiac contractions by sending tiny electrical impulses to the lower chambers of the heart to help them beat in a more synchronized fashion. Medtronic s latest generation of CRT-Ds is the Protecta family with SmartShock technology. Devices in this family are the Protecta XT, Protecta, Cardia, and Egida models. Medtronic also continues to market the Consulta, Concerto II, and Maximo II models. Our CRT-P portfolio includes the Consulta, Syncra, and InSync III products. In addition to these devices, Medtronic has a unique offering of left heart leads and delivery catheters with its Attain family of products.

AF Products. AF is a condition in which the atrium quivers instead of pumping blood effectively. Our portfolio of AF products includes the Arctic Front Cardiac CryoAblation Catheter designed specifically to treat paroxysmal AF by performing pulmonary vein isolation. Additionally, we have a portfolio of anatomically-shaped ablation catheters that use a duty cycled, phased radio frequency energy system for the treatment of permanent and persistent AF, all of which are CE Mark approved. We also offer the Reveal XT Insertable Cardiac Monitor, which is designed to identify and quantify episodes of AF.

*Diagnostics and Monitoring Devices.* The Reveal DX and Reveal XT Insertable Cardiac Monitors are small, memory-stick sized devices that are placed under the skin and can continuously monitor the heart. The devices are used to record the heart selectrical activity before, during, and after transient symptoms such as syncope (i.e., fainting) and palpitations to help provide a diagnosis. The latest generation product, Reveal XT, adds the capability to detect AF and provides long-term trending information to help inform the ongoing management of AF.

Patient Management Tools. We have a number of patient management tools, such as CareLink, Paceart, and CardioSight Service. CareLink enables patients to transmit data from their pacemaker, ICD, or CRT-D using a portable monitor that is connected to a standard telephone line. Paceart organizes and archives data for cardiac devices from major device manufacturers, serving as the central hub for patients device data. CardioSight Service is an in-clinic data access tool available to physicians treating heart failure patients who have one of several types of Medtronic CRT-Ds or ICDs.

#### Table of Contents

The charts below set forth net sales of our CRDM products as a percentage of our total net sales for each of the last three fiscal years:

#### **Customers and Competitors**

The primary medical specialists who use our CRDM products include electrophysiologists, implanting cardiologists, heart failure specialists, and cardiovascular surgeons. Our primary competitors in the CRDM business are St. Jude Medical, Inc., Boston Scientific Corporation, Biotronik, Inc., and Sorin Group.

#### CardioVascular

CardioVascular is comprised of three businesses: the Coronary and Peripheral business, the Endovascular business, and the Structural Heart business.

The Coronary and Peripheral business is comprised of therapies to treat coronary artery disease (CAD), peripheral vascular disease (PVD), and hypertension. The products contained within this business include coronary and peripheral stents and related delivery systems, along with a broad line of balloon angioplasty catheters, guide catheters, guidewires, diagnostic catheters, and accessories. The following are our principal products offered by our Coronary and Peripheral business:

**Percutaneous Coronary Intervention (PCI).** PCI encompasses a variety of procedures used to treat patients with CAD. CAD is commonly treated with balloon angioplasty, which is performed to open narrowed heart vessels by inserting a balloon catheter into the vessel and advancing it to the site of the blockage where it is inflated to widen the obstructed vessel. Balloon angioplasty can be followed up with a coronary stent, a support device which works as scaffolding to keep the vessel open following the intervention. Our PCI stent products include our Integrity, Driver, and Micro-Driver bare metal stent systems as well as our Resolute Integrity, Resolute, and Endeavor drug-eluting coronary stent systems.

Peripheral Vascular Intervention (PVI). PVI encompasses a variety of procedures to treat patients with PVD, a narrowing or blockage of vessels outside the heart which impedes blood supply to the brain, kidneys, legs, and other vital organs. Similar to CAD, PVD is commonly treated with balloon angioplasty which can be followed up with a peripheral stent. Our PVI products include the Complete SE stent and Pioneer Plus lumen re-entry device as well as various angioplasty balloons. In April 2010, we completed the acquisition of Invatec, S.p.A. (Invatec), a developer of innovative medical technologies for the interventional treatment of cardiovascular disease. Through this acquisition, we have obtained a portfolio of innovative solutions for both coronary and peripheral vascular disease, including percutaneous angioplasty balloons and stents for use below-the-knee. This portfolio also features drug-eluting balloons for coronary and lower-extremity vessels as well as embolic protection devices and stents for the treatment of carotid artery disease.

**Renal Denervation.** In January 2011, Medtronic acquired Ardian, Inc. (Ardian) and its Symplicity Catheter System, which is designed to treat chronic uncontrolled hypertension by delivering radio frequency energy through the renal artery walls to denervate the renal nerves, or ablate the nerves lining the renal arteries. This technology has received CE Mark approval and is available in select markets.

The Endovascular business is comprised of a comprehensive line of products and therapies to treat abdominal and thoracic aortic aneurysms. Our products include endovascular stent graft systems, distal embolic protection systems, perfusion systems, positioning and stabilization systems for beating heart revascularization surgery, products for the repair and replacement of heart valves, and surgical ablation products. The following are our principal products offered by our Endovascular business:

#### Table of Contents

Endovascular Stent Grafts. An endovascular stent graft is a minimally invasive device to repair an aortic aneurysm, which is a weakened and bulging area in the aorta, the major blood vessel that feeds blood to the body. Our product line includes a range of endovascular stent grafts including the market-leading Talent and Endurant abdominal stent grafts for minimally invasive abdominal aortic aneurysm repair and the Talent and Valiant (available in select markets outside the United States (U.S.)) thoracic stent grafts for minimally invasive thoracic aortic aneurysm repair.

The Structural Heart business offers a comprehensive line of products and therapies to treat a variety of heart valve disorders. Our products include products for the repair and replacement of heart valves, perfusion systems, positioning and stabilization systems for beating heart revascularization surgery, and surgical ablation products. The following are our principal products offered by our Structural Heart business:

Heart Valves. We offer a complete line of surgical valve replacement and repair products for damaged or diseased heart valves. Our replacement products include both tissue and mechanical valves. Our replacement tissue valve product offerings include the Mosaic bioprosthetic stented, Freestyle stentless, and Hancock II stented valves. In August 2010, we acquired ATS Medical, Inc. (ATS Medical) and its portfolio of valves including the Open Pivot mechanical valve, 3f Biological tissue valve, and minimally invasive 3f Enable Aortic Bioprosthesis sutureless tissue valve. Our existing valve repair products, including the Duran Flexible and CG Future Band, the CG Composite Annuloplasty Systems, and the Profile 3D Annuloplasty Ring, were supplemented with the addition of ATS Medical s Simulus Ring portfolio.

*Transcatheter Heart Valves*. Transcatheter valve (TCV) technology represents a less invasive means to treat heart valve disease and is designed to allow physicians to deliver replacement valves via a catheter through the body s cardiovascular system, eliminating the need to open the chest. Our TCVs include the Melody pulmonary valve and the CoreValve aortic valve. The Melody has received CE Mark approval as well as FDA approval under a Humanitarian Device Exemption (HDE). CoreValve has received CE Mark approval.

Arrested Heart Surgery. In conventional coronary artery bypass graft procedures and heart valve surgery, the patient s heart is temporarily stopped, or arrested. The patient is placed on a circulatory support system that temporarily functions as the patient s heart and lungs and provides blood flow to the body. We offer a complete line of blood-handling products that form this circulatory support system and maintain and monitor blood circulation and coagulation status, oxygen supply, and body temperature during arrested heart surgery.

**Beating Heart Surgery** To assist physicians performing beating heart surgery, we offer positioning and stabilization technologies. These technologies include our Starfish 2 and Urchin heart positioners, which are designed to work in concert with our family of Octopus tissue stabilizers.

**Surgical Ablation.** Our Cardioblate surgical ablation system, which includes the Cardioblate LP surgical ablation system and Cardioblate navigator tissue dissector, allows cardiac surgeons to create ablation lines during cardiac surgery. In addition, Medtronic acquired ATS Medical surgical cryoablation system.

The charts below set forth net sales of our CardioVascular products as a percentage of our total net sales for each of the last three fiscal years:

#### **Customers and Competitors**

The primary medical specialists who use our Coronary products are interventional cardiologists, while products in our Peripheral and Endovascular businesses may be used by interventional radiologists, vascular surgeons, cardiac surgeons, and interventional cardiologists. Our primary competitors in the Coronary and Peripheral business are Abbott Laboratories, Boston Scientific Corporation, and Johnson & Johnson. Our primary competitors in the Endovascular business are Cook, Inc., W. L. Gore & Associates, Inc., and Endologix, Inc. The principal medical specialists who use our Structural Heart products are cardiac surgeons and interventional cardiologists. Our primary competitors in the Structural Heart business are Edwards LifeSciences Corporation, St. Jude Medical, Inc., Terumo Medical Corporation, and Sorin Group.

#### **Physio-Control**

Physio-Control develops, manufactures, and markets a full range of services and complementary products that form an emergency response solution. Our primary offerings are external defibrillators, including advanced monitor/defibrillators used by emergency response and hospital personnel and automated external defibrillators (AEDs) used in commercial (workplace) and public settings for the treatment of sudden cardiac arrest. Our principal products include our LIFEPAK products, including the LIFEPAK 15 and LIFEPAK 20e monitor/defibrillators with advanced monitoring parameters (12-lead ECG, EtCO2, SpO2, and temperature) for emergency care settings. In February 2011, the Company acquired Jolife AB (Jolife) and its innovative LUCAS Chest Compression System, a device that administers uninterrupted and high-quality chest compressions during resuscitation. In addition to the portfolio of external defibrillation and emergency response products and support services, we offer the LIFENET System which provides a reliable and secure web-based platform linking care teams with critical information for emergent patient data and post-event review.

In February 2011, Medtronic reiterated its intention to divest the Physio-Control business. Medtronic first announced plans for divestiture of the Physio-Control business in 2006. Medtronic believes the timing is right to move forward with the divestiture due to the stabilizing economic environment and regulatory developments Physio-Control received notice from the FDA in fiscal year 2010 that it successfully met requirements for improvements to the quality system, and resumed full shipments.

The charts below set forth net sales of our Physio-Control products as a percentage of our total net sales for each of the last three fiscal years:

#### **Customers and Competitors**

The primary customers for our manual external defibrillators are emergency medical services personnel, emergency care doctors, and highly-trained nurses. Our primary competitors in the manual external defibrillator business are ZOLL Medical Corporation and Philips Medical Systems.

The primary customers for our AED products are hospitals, schools, governments, businesses, and any other public facilities. Our primary competitors in the AED business are Cardiac Science, Inc., ZOLL Medical Corporation, Philips Medical Systems, and Defibtech, LLC.

Table of Contents

#### RESTORATIVE THERAPIES GROUP

#### **Spinal**

Our Spinal business develops, manufactures, and markets a comprehensive line of medical devices and implants used in the treatment of the spine and the musculoskeletal system. Our products and therapies treat a variety of conditions affecting the spine, including degenerative disc disease, spinal deformity, spinal tumors, fractures of the spine, and stenosis. Our Spinal business also provides biologic solutions for the dental and orthopedic markets.

Today, we offer one of the industry s broadest lines of devices, including a wide range of sophisticated internal spinal stabilization devices, instruments, and biomaterials used in the treatment of spinal conditions. Our Spinal products are used in spinal fusion of both the thoracolumbar region, referring to the mid to lower vertebrae, as well as of the cervical region, or upper spine and neck vertebrae. Products used to treat spinal conditions include rods, pedicle screws, hooks, plates, and interbody devices, such as cages, as well as biologics products, which include bone growth substitutes, dowels, and wedges.

The following are the principal products offered by our Spinal business:

Thoracolumbar Products. Products used to treat conditions in this region of the spine include the CD HORIZON SOLERA and LEGACY Systems, the TSRH 3Dx System, and the T2 SCEPTOR and XVBR Systems. In addition, Medtronic offers a number of products that facilitate less invasive thoracolumbar surgeries, including the CD HORIZON SEXTANT and LONGITUDE Percutaneous Fixation Systems, the Direct Lateral Access System and corresponding CLYDESDALE Interbody Implant, Balloon Kyphoplasty for vertebral compression fractures, the METRx System, and the NIM-ECLIPSE Spinal System.

*Cervical Products.* Products used to treat conditions in this region of the spine include the ATLANTIS VISION ELITE Anterior Cervical Plate System, the VERTEX SELECT Reconstruction System, and the PRESTIGE and BRYAN Cervical Discs.

*Biologics Products*. Products in our Biologics platform include INFUSE Bone Graft, which contains a recombinant human bone morphogenetic protein, rhBMP-2, for spinal, trauma, and oral maxillofacial applications, PROGENIX Demineralized Bone Matrix (DBM), a bone graft substitute and bone void filler, and the MASTERGRAFT family of synthetic bone graft products Matrix, Putty, and Granules. In November 2010, Medtronic acquired Osteotech, Inc. (Osteotech), which has broadened our Biologics product platform, primarily DBMs, to include Grafton/Grafton Plus, MagniFuse Biologic Spine Implant, and Graftech Structural Allografts.

The charts below set forth net sales of our Spinal products as a percentage of our total net sales for each of the last three fiscal years:

#### **Customers and Competitors**

The primary medical specialists who use our Spinal products are spinal surgeons, orthopedic surgeons, neurosurgeons, and interventional radiologists. Competitors in this business include DePuy Spine, Inc., Synthes, Stryker Corporation, NuVasive, Inc., Globus Medical, Inc., Zimmer, Inc., Alphatec Spine, Inc., Orthofix International N.V., Biomet, Inc., and over 200 smaller competitors and physician-owned companies.

#### Neuromodulation

Our Neuromodulation business develops, manufactures, and markets medical devices for the treatment of pain, movement disorders, psychological disorders, and urological and gastroenterological disorders.

The following are the principal products offered by our Neuromodulation business:

*Neurostimulators for Chronic Pain.* Spinal cord stimulation involves the delivery of mild electrical signals to the epidural space. We have the largest portfolio of neurostimulation systems in the industry, including rechargeable and non-rechargeable devices and a large selection of leads used to treat chronic back and leg pain. Our portfolio of products includes the RestoreSensor (EU), RestoreULTRA and RestoreADVANCED (rechargeable), and PrimeADVANCED (non-rechargeable) neurostimulation systems.

*Implantable Drug Delivery Systems.* The SynchroMed II Programmable Infusion System delivers small quantities of drug directly into the intrathecal space in the spine. These devices are used to treat chronic, intractable pain and severe spasticity associated with cerebral palsy, multiple sclerosis, spinal cord and traumatic brain injuries, and stroke.

Deep Brain Stimulation (DBS) Systems. DBS uses a surgically implanted medical device, similar to a cardiac pacemaker, to deliver carefully controlled electrical stimulation to precisely targeted areas in the brain. It works by electrically stimulating specific structures that control movement and muscle function. DBS is used to treat the symptoms of movement disorders such as Parkinson s disease, epilepsy, essential tremor, and dystonia, as well as psychiatric disorders such as obsessive-compulsive disorder. The recently approved Activa SC device is the latest addition to our family of Activa Neurostimulators for DBS, which now includes Activa SC (single-channel), Activa PC (dual channel primary cell), and Activa RC (dual channel rechargeable).

*Urology & Gastroenterology Devices.* Sacral nerve stimulation offers long-term control of urinary control and bowel control symptoms through modulation of the nerve activity by focusing on the nerves that control the pelvic floor and lower urinary tract. Our therapeutic portfolio for urology and gastroenterology includes: the InterStim Therapy System, which treats the symptoms of overactive bladder, urinary retention, and chronic fecal incontinence, which was approved in the U.S. in the fourth quarter of fiscal year 2011; the Prostiva RF Therapy System for the treatment of benign prostatic hyperplasia, or enlarged prostate; and the Enterra Therapy System for the treatment of chronic gastroparesis.

The charts below set forth net sales of our Neuromodulation products as a percentage of our total net sales for each of the last three fiscal years:

#### **Customers and Competitors**

The primary medical specialists who use our pain management and movement disorder products are neurosurgeons, neurologists, pain management specialists, anesthesiologists, physiatrists, and orthopedic spine surgeons. Our primary competitors in this business are Boston Scientific Corporation and St. Jude Medical, Inc.

The primary medical specialists who use our gastroenterology and urology products are urologists, urogynecologists, gastroenterologists, and colorectal surgeons. Our primary competitors in this business are Boston Scientific Corporation, Urologix, Inc., and American Medical Systems, Inc.

#### **Diabetes**

Our Diabetes business develops, manufactures, and markets advanced, integrated diabetes management solutions that include insulin pump therapy, continuous glucose monitoring systems, and therapy management software.

The following are the principal products offered by our Diabetes business:

Integrated Diabetes Management Solutions. We have the only integrated insulin pump and continuous glucose monitoring (CGM) system. Outside the U.S., we offer our Paradigm Veo System, an integrated system that includes a Low Glucose Suspend feature that automatically suspends insulin delivery when glucose levels become too low. In the U.S., we offer the Paradigm Revel System, which incorporates new CGM features including predictive alerts that can give early warning to people with diabetes so they can take action to prevent dangerous high or low glucose events.

**Professional CGM.** Medtronic offers physicians a Professional CGM product called the iPro CGM and iPro2 Professional CGM in the international market only. Physicians send patients home wearing the iPro recorder to capture glucose data, which is later uploaded in a physician s office to reveal glucose patterns and potential problems, including hyperglycemic and hypoglycemic episodes, which can lead to more informed treatment decisions.

CareLink Therapy Management Software. We offer web-based therapy management software solutions, including CareLink Personal software for patients and CareLink Pro software, to help patients and their health care providers control their diabetes.

**Blood Glucose Meters.** Outside the U.S., we have an alliance with a division of Bayer HealthCare LLC, a member of the Bayer Group, to distribute and co-market blood glucose meters for Medtronic patients. This agreement was expanded to include U.S. patients starting in May 2011.

The charts below set forth net sales of our Diabetes products as a percentage of our total net sales for each of the last three fiscal years:

#### Table of Contents

#### **Customers and Competitors**

The primary medical specialists who use and/or prescribe our diabetes products are endocrinologists, diabetologists, and internists. Our primary competitors for diabetes products are Abbott Laboratories, DexCom, Inc., Insulet Corporation, Johnson & Johnson, and Roche Ltd.

#### **Surgical Technologies**

Our Surgical Technologies business develops, manufactures, and markets products and therapies to treat diseases and conditions of the ear, nose, and throat (ENT) and certain neurological disorders. In addition, the business develops, manufactures, and markets image-guided surgery and intra-operative imaging systems that facilitate surgical planning during precision cranial, spinal, sinus, and orthopedic surgeries.

The following are the principal products offered by our Surgical Technologies business:

*ENT.* The following products treat ENT diseases and conditions: PEAK PlasmaBlade TnA (Tonsil and Adenoid) Tissue Dissection Device, NIM Nerve Monitoring Systems, Fusion ENT Navigation System, Hydrodebrider Endoscopic Sinus Irrigation System, Meniett Device for Meniere s Disease, Pillar Procedure for Snoring and Sleep Apnea, and Repose System for Obstructive Sleep Apnea.

*Neurological Technologies.* The following products treat certain neurological disorders and conditions: Midas Rex Spine Shaver, the Midas Rex MR7 Pneumatic Platform, the Midas Rex Legend EHS High Speed Surgical Drill, the Strata Family of Adjustable Valves for the treatment of Hydrocephalus, Duet External Drainage & Monitoring System, the IPC System, and the Subdural Evacuating Port System.

Navigation. The following products are used in cranial, spinal, sinus, and orthopedic surgeries: the StealthStation S7 Navigation and i7 Integrated Navigation Systems, the O-Arm 2D/3D Surgical Imaging System, and the PoleStar Surgical MRI System.

The charts below set forth net sales of our Surgical Technologies products as a percentage of our total net sales for each of the last three fiscal years:

#### **Customers and Competitors**

The primary customers for products relating to our ENT diseases and conditions are ENT surgeons and the hospitals and clinics where they perform surgery. Competitors in this part of our Surgical Technologies business include Gyrus ACMI (a group company of Olympus Corporation), Stryker Corporation, and Johnson & Johnson.

The primary customers for our neurosurgical products are neurosurgeons, spinal surgeons, and the hospitals and clinics where they perform surgery. Competitors include Johnson & Johnson, Stryker Corporation, and Integra LifeSciences Holdings Corporation.

The primary customers for our image-guided surgery and intra-operative imaging systems are hospitals and clinics. Competitors include BrainLAB, Inc., Stryker Corporation, GE Healthcare, Siemens Medical Solutions USA, Inc., and Philips Medical Systems.

# **Research and Development**

The markets in which we participate are subject to rapid technological advances. Constant improvement of products and introduction of new products is necessary to maintain market leadership. Our research and development efforts are directed toward maintaining or achieving technological leadership in each of the markets we serve in order to help ensure that patients using our devices and therapies receive the most advanced and effective treatment possible. We are committed to developing technological enhancements and new indications for existing products, as well as less invasive and new technologies to address unmet patient needs and to help reduce patient care costs and length of hospital stays. We have not engaged in significant customer or government-sponsored research.

During fiscal years 2011, 2010, and 2009, we spent \$1.508 billion (9.5 percent of net sales), \$1.460 billion (9.2 percent of net sales), and \$1.355 billion (9.3 percent of net sales) on research and development, respectively. Our research and development activities include improving existing products and therapies, expanding their indications and applications for use, and developing new products. While we continue to make substantial investments for the expansion of our existing product lines and for the search of new innovative products, we have also focused heavily on carefully planned clinical trials, which lead to market expansion and enable further penetration of our life changing therapies.

# **Acquisitions and Investments**

Our strategy to provide a broad range of therapies to restore patients to fuller, healthier lives requires a wide variety of technologies, products, and capabilities. The rapid pace of technological development in the medical industry and the specialized expertise required in different areas of medicine make it difficult for one company alone to develop a broad portfolio of technological solutions. In addition to internally generated growth through our research and development efforts, historically we have relied, and expect to continue to rely, upon acquisitions, investments, and alliances to provide access to new technologies both in areas served by our existing businesses as well as in new areas and markets.

We expect to make future investments or acquisitions where we believe that we can stimulate the development of, or acquire new technologies and products to further our strategic objectives and strengthen our existing businesses. Mergers and acquisitions of medical technology companies are inherently risky and no assurance can be given that any of our previous or future acquisitions will be successful or will not materially adversely affect our consolidated results of operations, financial condition, and/or cash flows.

On February 25, 2011, we acquired Jolife, a privately-held company. Jolife develops, manufactures, and markets the LUCAS Chest Compression System together with complementary technologies. Total consideration for the transaction was \$53 million.

On January 13, 2011, we acquired Ardian, a privately-held company. We had previously invested in Ardian and held an 11.3 percent ownership position. Ardian develops catheter-based therapies to treat uncontrolled hypertension and related conditions. Total consideration for the transaction was \$1.020 billion which includes the estimated fair value of revenue-based contingent consideration of \$212 million. The terms of the transaction included an up-front cash payment of \$717 million, excluding our pro-rata share in Ardian, plus potential future commercial milestone payments equal to the annual revenue growth beginning in fiscal year 2012 through the end of our fiscal year 2015. We recorded a gain of \$85 million on our previously held investment.

On November 16, 2010, we acquired Osteotech. Osteotech develops innovative biologic products for regenerative medicine. We paid shareholders \$6.50 per share in cash for each share of Osteotech common stock that they owned. Total consideration for the transaction was \$123 million.

On September 14, 2010, we acquired a developer of vascular suturing products used in connection with cardiovascular and vascular procedures that require a puncture or incision to the artery. Total consideration for the transaction was approximately \$21 million, which includes the estimated fair value of additional milestone-based contingent consideration of \$6 million.

On August 12, 2010, we acquired ATS Medical. ATS Medical is a leading developer, manufacturer, and marketer of products and services focused on cardiac surgery, including heart valves and surgical cryoablation technology. Under the terms of the agreement, ATS Medical shareholders received \$4.00 per share in cash for each share of ATS Medical common stock that they owned. Total consideration for the transaction was \$394 million which includes \$30 million of ATS Medical debt and acquired contingent consideration of \$10 million.

#### Table of Contents

On June 2, 2010, we acquired substantially all of the assets of Axon Surgical (Axon), a privately-held company. Prior to the acquisition, we distributed a large portion of Axon s products. We believe this acquisition will allow us to bring to market the next generation of surgeon-directed and professionally supported spinal neuromonitoring technology and expand the availability of this technology. Total consideration for the transaction, net of cash acquired, was \$62 million, which includes the settlement of existing Axon debt.

In April 2010, we acquired Invatec. Under the terms of the agreement, the transaction included an initial up-front payment of \$350 million, which includes the assumption and settlement of existing Invatec debt. The agreement also includes potential additional payments of up to \$150 million contingent upon achievement of certain milestones. Invatec is a developer of innovative medical technologies for the interventional treatment of cardiovascular disease.

#### **Patents and Licenses**

We rely on a combination of patents, trademarks, copyrights, trade secrets, and nondisclosure and non-competition agreements to establish and protect our proprietary technology. We have filed and obtained numerous patents in the U.S. and abroad, and regularly file patent applications worldwide in our continuing effort to establish and protect our proprietary technology. In addition, we have entered into exclusive and non-exclusive licenses relating to a wide array of third-party technologies. We have also obtained certain trademarks and tradenames for our products to distinguish our genuine products from our competitors products, and we maintain certain details about our processes, products, and strategies as trade secrets. Our efforts to protect our intellectual property and avoid disputes over proprietary rights have included ongoing review of third-party patents and patent applications. See Item 1A. Risk Factors in this Annual Report on Form 10-K and Note 16 to the consolidated financial statements set forth in Exhibit 13 hereto and included in our 2011 Annual Report for additional information.

#### **Markets and Distribution Methods**

We sell most of our medical devices through direct sales representatives in the U.S. and a combination of direct sales representatives and independent distributors in markets outside the U.S. The three largest markets for our medical devices are the U.S., Western Europe, and Japan. Emerging markets are an area of increasing focus and opportunity as we believe they remain underpenetrated.

Our marketing and sales strategy is focused on rapid, cost-effective delivery of high-quality products to a diverse group of customers worldwide including physicians, hospitals, other medical institutions, and group purchasing organizations. To achieve this objective, we organize our marketing and sales teams around physician specialties. This focus enables us to develop highly knowledgeable and dedicated sales representatives who are able to foster strong relationships with physicians and other customers and enhance our ability to cross-sell complementary products. We believe that we maintain excellent working relationships with physicians and others in the medical industry that enable us to gain a detailed understanding of therapeutic and diagnostic developments, trends, and emerging opportunities and respond quickly to the changing needs of physicians and patients. We attempt to enhance our presence in the medical community through active participation in medical meetings and by conducting comprehensive training and educational activities. We believe that these activities contribute to physician expertise.

In keeping with the increased emphasis on cost-effectiveness in health care delivery, the current trend among hospitals and other customers of medical device manufacturers is to consolidate into larger purchasing groups to enhance purchasing power. As a result, transactions with customers have become increasingly significant and more complex. This enhanced purchasing power may also lead to pressure on pricing and increased use of preferred vendors. We are not dependent on any single customer for more than 10 percent of our total net sales.

# **Competition and Industry**

We compete in both the therapeutic and diagnostic medical markets in more than 120 countries throughout the world. These markets are characterized by rapid change resulting from technological advances and scientific discoveries. In the product lines in which we compete, we face a mixture of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. In addition, we face competition from providers of alternative medical therapies such as pharmaceutical companies.

Major shifts in industry market share have occurred in connection with product problems, physician advisories, and safety alerts, reflecting the importance of product quality in the medical device industry. In the current environment of managed care, economically motivated buyers, consolidation among health care providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price. In order to continue to compete effectively, we must continue to create or acquire advanced technology, incorporate this technology into proprietary products, obtain regulatory approvals in a timely manner, and manufacture and successfully market these products.

#### **Worldwide Operations**

For financial reporting purposes, net sales and long-lived assets attributable to significant geographic areas are presented in Note 18 to the consolidated financial statements set forth in Exhibit 13 hereto and will be included in our 2011 Annual Report.

#### Impact of Business Outside of the U.S.

Our operations in countries outside the U.S. are accompanied by certain financial and other risks. Relationships with customers and effective terms of sale vary by country, often with longer-term receivables than are typical in the U.S. Inventory management is an important business concern due to the potential for obsolescence and long lead times from sole source providers. Foreign currency exchange rate fluctuations can affect revenues, net of expenses, and cash flows from operations outside the U.S. We use operational and economic hedges, as well as currency exchange rate derivative contracts to manage and the impact of currency exchange rate changes on earnings and cash flow. See the Market Risk section of Management's Discussion and Analysis of Financial Condition and Results of Operations and Note 9 to the consolidated financial statements set forth in Exhibit 13 hereto, which will be included in our 2011 Annual Report. In addition, the repatriation of certain earnings of our foreign subsidiaries may result in substantial U.S. tax cost.

#### Production and Availability of Raw Materials

We manufacture most of our products at 37 manufacturing facilities located in various countries throughout the world. The largest of these manufacturing facilities are located in Arizona, California, Canada, Florida, Germany, Indiana, Ireland, Italy, Massachusetts, Mexico, Minnesota, New Jersey, Puerto Rico, Singapore, Switzerland, Texas, and Washington. We purchase many of the components and raw materials used in manufacturing these products from numerous suppliers in various countries. For reasons of quality assurance, sole source availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. We work closely with our suppliers to help ensure continuity of supply while maintaining high quality and reliability. Due to the FDA s requirements regarding manufacturing of our products, we may not be able to quickly establish additional or replacement sources for certain components or materials. Generally, we have been able to obtain adequate supplies of such raw materials and components. However, the reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our operations.

#### Table of Contents

# **Working Capital Practices**

Our goal is to carry sufficient levels of inventory to ensure adequate supply of raw materials from suppliers and meet the product delivery needs of our customers. We also provide payment terms to customers in the normal course of business and rights to return product under warranty to meet the operational demands of our customers.

#### **Employees**

On April 29, 2011, we employed approximately 45,000 employees (including full-time equivalent employees). Our employees are vital to our success. We believe we have been successful in attracting and retaining qualified personnel in a highly competitive labor market due to our competitive compensation and benefits, and our rewarding work environment.

#### Seasonality

Worldwide sales, including U.S. sales, do not reflect any significant degree of seasonality.

#### **Government Regulation and Other Considerations**

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices.

Authorization to commercially distribute a new medical device in the U.S. is generally received in one of two ways. The first, known as pre-market notification or the 510(k) process, requires us to demonstrate that our new medical device is substantially equivalent to a legally marketed medical device. In this process, we must submit data that supports our equivalence claim. If human clinical data is required, it must be gathered in compliance with FDA investigational device exemption regulations. We must receive an order from the FDA finding substantial equivalence to another legally marketed medical device before we can commercially distribute the new medical device. Modifications to cleared medical devices can be made without using the 510(k) process if the changes do not significantly affect safety or effectiveness. A very small number of our devices are exempt from pre-market review.

The second, more rigorous process, known as pre-market approval (PMA), requires us to independently demonstrate that the new medical device is safe and effective. We do this by collecting data regarding design, materials, bench and animal testing, and human clinical data for the medical device. The FDA will authorize commercial distribution if it determines there is reasonable assurance that the medical device is safe and effective. This determination is based on the benefit outweighing the risk for the population intended to be treated with the device. This process is much more detailed, time-consuming, and expensive than the 510(k) process. A third, seldom used, process for approval exists for products intended for orphan populations, which is less than 4,000 patients per year in the U.S. This exemption is similar to the PMA process; however, a full showing of product effectiveness from large clinical trials is not required. The threshold for approving these products is probable benefit and safety.

#### **Table of Contents**

Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers—required reports of adverse experiences and other information to identify potential problems with marketed medical devices. We are also subject to periodic inspection by the FDA for compliance with the FDA—s quality system regulations among other FDA requirements, such as restrictions on advertising and promotion. The quality system regulations govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, and servicing of all finished medical devices intended for human use. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health, order a recall, repair, replacement, or refund payment of such devices, detain or seize adulterated or misbranded medical devices, or ban such medical devices. The FDA may also impose operating restrictions, enjoin and/or restrain certain conduct resulting in violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the U.S. Department of Justice (DOJ).

The FDA, in cooperation with U.S. Customs and Border Protection (CBP), administers controls over the import of medical devices into the U.S. The CBP imposes its own regulatory requirements on the import of our products, including inspection and possible sanctions for noncompliance. Medtronic is also subject to foreign trade controls administered by several U.S. government agencies, including the Bureau of Industry and Security within the Commerce Department and the Office of Foreign Assets Control within the Treasury Department.

The FDA also administers certain controls over the export of medical devices from the U.S. International sales of our medical devices that have not received FDA approval are subject to FDA export requirements. Many foreign countries to which we export medical devices also subject such medical devices to their own regulatory requirements. Frequently, we obtain regulatory approval for medical devices in foreign countries first because their regulatory approval is faster than that of the FDA. However, as a general matter, foreign regulatory requirements are becoming increasingly common and more stringent.

In the European Union, a single regulatory approval process exists, and conformity with the legal requirements is represented by the CE Mark. To obtain a CE Mark, defined products must meet minimum standards of performance, safety, and quality (i.e., the essential requirements), and then, according to their classification, comply with one or more of a selection of conformity assessment routes. A notified body assesses the quality management systems of the manufacturer and the product conformity to the essential and other requirements within the medical device directive. Medtronic is subject to inspection by notified bodies for compliance. The competent authorities of the European Union countries, generally in the form of their ministries or departments of health, oversee the clinical research for medical devices and are responsible for market surveillance of products once they are placed on the market. We are required to report device failures and injuries potentially related to product use to these authorities in a timely manner. Various penalties exist for non-compliance with the laws transcribing the medical device directives.

To be sold in Japan, most medical devices must undergo thorough safety examinations and demonstrate medical efficacy before they are granted approval, or shonin. The Japanese government, through the Ministry of Health, Labour, and Welfare (MHLW), regulates medical devices under the Pharmaceutical Affairs Law (PAL). Oversight for medical devices is conducted with participation by the Pharmaceutical and Medical Devices Agency (PMDA), a quasi-government organization performing many of the review functions for MHLW. Penalties for a company s noncompliance with PAL could be severe, including revocation or suspension of a company s business license and criminal sanctions. MHLW and PMDA also assess the quality management systems of the manufacturer and the product conformity to the requirements of the PAL. Medtronic is subject to inspection for compliance by these agencies.

The process of obtaining approval to distribute medical products is costly and time-consuming in virtually all of the major markets where we sell medical devices. We cannot assure that any new medical devices we develop will be approved in a timely or cost-effective manner or approved at all.

Federal and state laws protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by health care providers. In particular, in April 2003, the U.S. Department of Health and Human Services (HHS) published patient privacy rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA privacy rule) and, in April 2005, published security rules for protected health information. The HIPAA privacy and security rules govern the use, disclosure, and security of protected health information by Covered Entities, which are health care providers that submit electronic claims, health plans, and health care clearinghouses. In 2009, Congress passed the HITECH Act, which modified certain provisions of the HIPAA privacy and security rules for Covered Entities and their Business Associates (which is anyone that performs a service on behalf of a Covered Entity involving the use or disclosure of protected health information and is not a member of the Covered Entity s workforce). These included directing HHS to publish more specific security standards, and increasing breach notification requirements, as well as tightening certain aspects of the privacy rules. HHS has proposed, but not finalized, these new rules. In addition, the HITECH Act provided that Business Associates will now be subject to the same security requirements as Covered Entities, and that with regard to both the security and privacy rule. Business Associates will be subject to direct enforcement by HHS, including civil and criminal liability, just as Covered Entities are. In the past, HIPAA has generally affected us indirectly. Medtronic is generally not a Covered Entity, except for a few units such as our Diabetes business and our health insurance plans. Medtronic only operates as a Business Associate to Covered Entities in a limited number of instances. In those cases, the patient data that we receive and analyze may include protected health information. We are committed to maintaining the security and privacy of patients health information and believe that we meet the expectations of the HIPAA rules. Some modifications to our systems and policies may be necessary, but the framework is already in place. However, the potential for enforcement action against us is now greater, as HHS can take action directly against Business Associates. Thus, while we believe we are and will be in substantial compliance with HIPAA standards, there is no guarantee that the government will not disagree. Enforcement actions can be costly and interrupt regular operations of our business. Nonetheless, these requirements affect a limited subset of our business. We believe the ongoing costs and impacts of assuring compliance with the HIPAA privacy and security rules are not material to our business. We are also impacted by the privacy requirements of countries outside the U.S. Privacy standards in Europe and Asia are becoming increasingly strict. We will continue our efforts to comply with those requirements and to adapt our business processes to the standards.

Government and private sector initiatives to limit the growth of health care costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments, and managed-care arrangements, are continuing in many countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical devices and therapies. Government programs, including Medicare and Medicaid, private health care insurance, and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments, tying reimbursement to outcomes, and other mechanisms designed to constrain utilization and contain costs. Hospitals, which purchase implants, are also seeking to reduce costs through a variety of mechanisms, including, for example, gainsharing, where a hospital agrees with physicians to share any realized cost savings resulting from the physicians collective change in practice patterns such as standardization of devices where medically appropriate. This has created an increasing level of price sensitivity among customers for our products. Some third-party payors must also approve coverage for new or innovative devices or therapies before they will reimburse health care providers who use the medical devices or therapies. Even though a new medical device may have been cleared for commercial distribution, we may find limited demand for the device until reimbursement approval has been obtained from governmental and private third-party payors. In addition, some private third-party payors require that certain procedures or that the use of certain products be authorized in advance as a condition of reimbursement. As a result of our manufacturing efficiencies and cost controls, we believe we are well-positioned to respond to changes resulting from the worldwide trend toward cost-containment; however, uncertainty remains as to the nature of any future legislation, making it difficult for us to predict the potential impact of cost-containment trends on future operating results.

The delivery of our devices is subject to regulation by HHS and comparable state and foreign agencies responsible for reimbursement and regulation of health care items and services. U.S. laws and regulations are imposed primarily in connection with the Medicare and Medicaid programs, as well as the government s interest in regulating the quality and cost of health care. Foreign governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services.

#### **Table of Contents**

Federal health care laws apply when we or customers submit claims for items or services that are reimbursed under Medicare, Medicaid, or other federally-funded health care programs. The principal federal laws include: (1) the False Claims Act which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program; (2) the Anti-Kickback Statute which prohibits offers to pay or receive remuneration of any kind for the purpose of inducing or rewarding referrals of items or services reimbursable by a Federal health care program; (3) the Stark law which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician s immediate family) has a financial relationship with that provider; and (4) health care fraud statutes that prohibit false statements and improper claims to any third-party payor. There are often similar state false claims, anti-kickback, and anti-self referral and insurance laws that apply to state-funded Medicaid and other health care programs and private third-party payors. In addition, the U.S. Foreign Corrupt Practices Act can be used to prosecute companies in the U.S. for arrangements with physicians, or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the law of that country.

The laws applicable to us are subject to change, and subject to evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, Medtronic and its officers and employees could be subject to severe criminal and civil penalties including substantial penalties, fines, and damages and exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

We operate in an industry characterized by extensive patent litigation. Patent litigation can result in significant damage awards and injunctions that could prevent the manufacture and sale of affected products or result in significant royalty payments in order to continue selling the products. At any given time, we are involved as both a plaintiff and a defendant in a number of patent infringement actions. While it is not possible to predict the outcome of patent litigation incident to our business, we believe the costs associated with this type of litigation could have a material adverse impact on our consolidated results of operations, financial position, or cash flows. See Note 16 to the consolidated financial statements set forth in Exhibit 13 hereto as well as our 2011 Annual Report for additional information.

We operate in an industry susceptible to significant product liability claims. These claims may be brought by individuals seeking relief on their own behalf or purporting to represent a class. In addition, product liability claims may be asserted against us in the future based on events we are not aware of at the present time.

We are also subject to various environmental laws and regulations both within and outside the U.S. Like other medical device companies, our operations involve the use of substances regulated under environmental laws, primarily manufacturing and sterilization processes. To the best of our knowledge at this time, we do not expect that compliance with environmental protection laws will have a material impact on our consolidated results of operations, financial position, or cash flows.

We have elected to self-insure most of our insurable risks, including medical and dental costs, physical loss to property, business interruptions, workers—compensation, comprehensive general, director and officer, and product liability. Decisions to self-insure are based on comparisons between the price, availability, and value of insurance coverage. We continue to monitor the insurance marketplace to evaluate the value to the Company of obtaining insurance coverage in the future. Based on historical loss trends, we believe that our self-insurance program accruals will be adequate to cover future losses. Historical trends, however, may not be indicative of future losses. These losses could have a material adverse impact on our consolidated results of operations, financial position, or cash flows.

# **Executive Officers of Medtronic**

Set forth below are the names and ages of current Section 16(b) executive officers of Medtronic, Inc., as well as information regarding their positions with Medtronic, their periods of service in these capacities, and their business experiences. There are no family relationships among any of the officers named, nor is there any arrangement or understanding pursuant to which any person was selected as an officer.

*Omar Ishrak*, age 55, has been Chairman and Chief Executive Officer of Medtronic since June 2011. Prior to joining Medtronic, Mr. Ishrak served as President and Chief Executive Officer of GE Healthcare Systems, a division of GE Healthcare, from 2009 to 2011. He was President and Chief Executive Officer of GE Healthcare Clinical Systems from 2005 to 2008 and President and Chief Executive Officer of GE Healthcare Ultrasound and BMD from 1995 to 2004.

*Jean-Luc Butel*, age 54, has been Executive Vice President and Group President, International since August 2009. Prior to that, he was Senior Vice President and President, International from May 2008 to August 2009, Senior Vice President and President, Asia Pacific from August 2003 to May 2008 and President of Independence Technology, a Johnson & Johnson company, from 1999 to 2003. From 1991 to 1999, he worked for Becton, Dickinson and Company, initially as General Manager of its Microbiology business in Japan and then as President of Nippon Becton Dickinson. His last assignment at Becton, Dickinson and Company was President, Worldwide Consumer Healthcare.

*Michael J. Coyle*, age 48, has been Executive Vice President and Group President, Cardiac and Vascular Group since December 2009. Prior to that, he served as President of the Cardiac Rhythm Management division at St. Jude Medical, Inc. (St. Jude) from 2001 to 2007, and prior positions included serving St. Jude as President of the company s Daig Catheter division and numerous leadership positions at Eli Lilly & Company. Mr. Coyle is a member of the board of directors of Volcano Corporation.

*H. James Dallas*, age 52, has been Senior Vice President, Quality and Operations since April 2008. Prior to that he was Senior Vice President and Chief Information Officer of Medtronic from April 2006 to April 2008. He was Vice President and Chief Information Officer of Georgia Pacific Corporation from December 2002 to December 2005; General Manager of the Transportation Division and President of the Lumber Division of Georgia Pacific Corporation from October 2001 to December 2002; and Vice President, Building Products Distribution Sales and Logistics, Georgia Pacific Corporation from October 2000 to October 2001.

Gary L. Ellis, age 54, has been Senior Vice President and Chief Financial Officer since May 2005. Prior to that, he was Vice President, Corporate Controller and Treasurer since October 1999 and Vice President and Corporate Controller from August 1994 to October 1999. Mr. Ellis joined Medtronic in 1989 as Assistant Corporate Controller and was promoted to Vice President of Finance for Medtronic Europe in 1992, until being named as Corporate Controller in 1994. Mr. Ellis is a member of the board of directors of The Toro Company and past chairman of the American Heart Association.

*D. Cameron Findlay*, age 51, has been Senior Vice President, General Counsel and Corporate Secretary since August 2009. Prior to that, Mr. Findlay was Executive Vice President and General Counsel of Aon Corporation from August 2003 to June 2009. Prior to joining Aon, Mr. Findlay served as the U.S. Deputy Secretary of Labor. Before joining the Labor Department in June 2001, Mr. Findlay was a partner at the law firm now known as Sidley Austin LLP. Before that, he served in the White House as an aide to U.S. President George H.W. Bush.

*Richard Kuntz, M.D.*, age 54, has been Senior Vice President and Chief Scientific, Clinical and Regulatory Officer since August 2009. Prior to that, he was Senior Vice President and President, Neuromodulation from October 2005 to August 2009, and prior to that he was an interventional cardiologist and Chief of the Division of Clinical Biometrics at Brigham and Women s Hospital, Associate Professor of Medicine and Chief Scientific Officer of the Harvard Clinical Research Institute. Mr. Kuntz is a member of the board of directors of Tengion, Inc.

Christopher J. O Connell, age 44, has been Executive Vice President and Group President, Restorative Therapies Group, since August 2009. Prior to that, he was Senior Vice President and President, Diabetes from October 2006 to August 2009, President of Medtronic s Emergency Response Systems division from May 2005 to October 2006, and Vice President of Sales and Marketing of Medtronic s Cardiac Rhythm Disease Management division from November 2001 to May 2005. Mr. O Connell has served in various management positions since joining the Company in 1994.

Caroline Stockdale, age 47, has been Senior Vice President of Human Resources since April 2010. Prior to that she served as Vice President of Revenue Cycle Operations at Accretive Health from January 2009 to May 2010. From 2005 to 2009, she served as Executive Vice President of Global Human Resources at Warner Music Group; from 2002 to 2005, she was Senior Vice President, Human Resources, at American Express Financial Advisors (Ameriprise) and from 1997 to 2002, she was Executive Vice President and Global HR Leader at GE Capital.

#### Item 1A. Risk Factors

Investing in Medtronic involves a variety of risks and uncertainties, known and unknown, including, among others, those discussed below.

The medical device industry is highly competitive and we may be unable to compete effectively.

We compete in both the therapeutic and diagnostic medical markets in more than 120 countries throughout the world. These markets are characterized by rapid change resulting from technological advances and scientific discoveries. In the product lines in which we compete, we face a mixture of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of niche products. Development by other companies of new or improved products, processes, or technologies may make our products or proposed products less competitive. In addition, we face competition from providers of alternative medical therapies such as pharmaceutical companies. Competitive factors include:

product reliability,
product performance,
product technology,
product quality,
breadth of product lines,
product services,
customer support,
price, and

reimbursement approval from health care insurance providers.

Major shifts in industry market share have occurred in connection with product problems, physician advisories, and safety alerts, reflecting the importance of product quality and quality systems in the medical device industry. In the current environment of managed care, consolidation among health care providers, increased competition, and declining reimbursement rates, we have been increasingly required to compete on the basis of price. In order to continue to compete effectively, we must continue to create, invest in, or acquire advanced technology, incorporate this technology into our proprietary products, obtain regulatory approvals in a timely manner, and manufacture and successfully market our products. Given these factors, we cannot guarantee that we will be able to continue our level of success in the industry.

Reduction or interruption in supply and an inability to develop alternative sources for supply may adversely affect our manufacturing operations and related product sales.

We manufacture most of our products at 37 manufacturing facilities located throughout the world. We purchase many of the components and raw materials used in manufacturing these products from numerous suppliers in various countries. Generally we have been able to obtain adequate supplies of such raw materials and components. However, for reasons of quality assurance, cost effectiveness, or availability, we procure certain components and raw materials from a sole supplier. We work closely with our suppliers to try to ensure continuity of supply while maintaining high quality and reliability. However, we cannot guarantee that these efforts will be successful. In addition, due to the stringent regulations and requirements of the FDA regarding the manufacture of our products, we may not be able to quickly establish additional or replacement sources for certain components or materials. A reduction or interruption in supply, and an inability to develop alternative sources for such supply, could adversely affect our ability to manufacture our products in a timely or cost-effective manner and to make our related product sales.

Our industry is experiencing greater scrutiny and regulation by governmental authorities, which may lead to greater regulation in the future.

Our medical devices and our business activities are subject to rigorous regulation, including by the FDA, DOJ, and numerous other federal, state, and foreign governmental authorities. These authorities and members of Congress have been increasing their scrutiny of our

industry. For example, we have received inquiries from members of Congress and other government agencies regarding a variety of matters. In addition, certain states have recently passed or are considering legislation restricting our interactions with health care providers and requiring disclosure of certain payments to them. We anticipate that governmental authorities will continue to scrutinize our industry closely, and that additional regulation may increase compliance and legal costs, exposure to litigation, and other adverse effects to our operations.

We are subject to many laws and governmental regulations and any adverse regulatory action may materially adversely affect our financial condition and business operations.

Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices. We cannot guarantee that we will be able to obtain marketing clearance for our new products or enhancements or modifications to existing products. If such approval is obtained, it may:

take a significant amount of time,

require the expenditure of substantial resources,

involve stringent clinical and pre-clinical testing, as well as increased post-market surveillance,

involve modifications, repairs, or replacements of our products, and

result in limitations on the proposed uses of our products.

Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. We are also subject to periodic inspections by the FDA to determine compliance with the FDA is requirements, including primarily the quality system regulations and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA is Form-483, warning letters, or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations, including medical device companies, by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, refuse to grant pending pre-market approval applications or require certificates of foreign governments for exports, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also impose operating restrictions on a company-wide basis, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the DOJ. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products.

Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to more rigorous regulation by foreign governmental authorities in the future. Penalties for a company s non-compliance with foreign governmental regulation could be severe, including revocation or suspension of a company s business license and criminal sanctions. Any domestic or foreign governmental law or regulation imposed in the future may have a material adverse effect on us.

We are also subject to various environmental laws and regulations both within and outside the U.S. Our operations involve the use of substances regulated under environmental laws, primarily those used in manufacturing and sterilization processes. We cannot guarantee that compliance with environmental protection laws and regulations will not have a material impact on our consolidated earnings, financial condition, and/or cash flows.

Our failure to comply with rules relating to reimbursement and regulation of health care goods and services may subject us to penalties and adversely impact our reputation and business operations.

Our devices and therapies are subject to regulation regarding quality and cost by the HHS, including the Centers for Medicare & Medicaid Services (CMS) as well as comparable state and foreign agencies responsible for reimbursement and regulation of health care goods and services. U.S. federal government health care laws apply when we submit a claim on behalf of a U.S. federal health care program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U.S. federal government-funded health care program, such as Medicare or Medicaid. The principal U.S. federal laws implicated include those that prohibit the filing of false or improper claims for federal payment, known as the false claims laws; those that prohibit unlawful inducements for the referral of business reimbursable under federally-funded health care programs, known as the anti-kickback laws; and that which prohibits health care service providers seeking reimbursement for providing certain services to a patient who was referred by a physician who has certain types of direct or indirect financial relationships with the service provider, known as the Stark law.

The laws applicable to us are subject to evolving interpretations. If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we and our officers and employees could be subject to severe criminal and civil penalties, including, for example, exclusion from participation as a supplier of product to beneficiaries covered by CMS. If we are excluded from participation based on such an interpretation it could adversely affect our reputation and business operations.

Quality problems with our processes, goods, and services could harm our reputation for producing high-quality products and erode our competitive advantage, sales, and market share.

Quality is extremely important to us and our customers due to the serious and costly consequences of product failure. Our quality certifications are critical to the marketing success of our goods and services. If we fail to meet these standards, our reputation could be damaged, we could lose customers, and our revenue and results of operations could decline. Aside from specific customer standards, our success depends generally on our ability to manufacture to exact tolerances precision-engineered components, subassemblies, and finished devices from multiple materials. If our components fail to meet these standards or fail to adapt to evolving standards, our reputation as a manufacturer of high-quality components will be harmed, our competitive advantage could be damaged, and we could lose customers and market share.

We are substantially dependent on patent and other proprietary rights and failing to protect such rights or to be successful in litigation related to such rights may result in our payment of significant monetary damages and/or royalty payments, negatively impact our ability to sell current or future products, or prohibit us from enforcing our patent and other proprietary rights against others.

We operate in an industry characterized by extensive patent litigation. Patent litigation can result in significant damage awards and injunctions that could prevent our manufacture and sale of affected products or require us to pay significant royalties in order to continue to manufacture or sell affected products. At any given time, we are generally involved as both a plaintiff and a defendant in a number of patent infringement actions, the outcomes of which may not be known for prolonged periods of time. While it is not possible to predict the outcome of patent litigation, we believe the results associated with any such litigation could result in our payment of significant monetary damages and/or royalty payments, negatively impact our ability to sell current or future products, or prohibit us from enforcing our patent and proprietary rights against others, which would generally have a material adverse impact on our consolidated earnings, financial condition, and/or cash flows.

We rely on a combination of patents, trade secrets, and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and we will continue to do so. While we intend to defend against any threats to our intellectual property, these patents, trade secrets, or other agreements may not adequately protect our intellectual property. Further, pending patent applications owned by us may not result in patents being issued to us, patents issued to or licensed by us in the past or in the future may be challenged or circumvented by competitors and such patents may not be found to be valid or sufficiently broad to protect our technology or to provide us with any competitive advantage. Third parties could obtain patents that may require us to negotiate licenses to conduct our business, and the required licenses may not be available on reasonable terms or at all. We also rely on nondisclosure and non-competition agreements with certain employees, consultants, and other parties to protect, in part, trade secrets and other proprietary rights. We cannot be certain that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop substantially equivalent proprietary information, or that third parties will not otherwise gain access to our trade secrets or proprietary knowledge.

# Product liability claims could adversely impact our financial condition and our earnings and impair our reputation.

Our business exposes us to potential product liability risks that are inherent in the design, manufacture, and marketing of medical devices. In addition, many of the medical devices we manufacture and sell are designed to be implanted in the human body for long periods of time or indefinitely. Component failures, manufacturing defects, design flaws, or inadequate disclosure of product-related risks or product-related information with respect to our products could result in an unsafe condition or injury to, or death of, a patient. The occurrence of such a problem could result in product liability claims or a recall of, or safety alert relating to, one or more of our products which could ultimately result, in certain cases, in the removal from the body of such products and claims regarding costs associated therewith. We have elected to self-insure with respect to product liability risks. Product liability claims or product recalls in the future, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation and on our ability to attract and retain customers for our products.

# Health care policy changes, including U.S. health care reform legislation signed in 2010, may have a material adverse effect on us.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control these costs and, more generally, to reform the U.S. health care system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of some or all of these proposals could have a material adverse effect on our financial position and results of operations.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010. The legislation imposes significant new taxes on medical device makers in the form of a 2.3% excise tax on all U.S. medical device sales beginning in 2013. Under the legislation, the total cost to the medical device industry is expected to be approximately \$20 billion over ten years. This significant increase in the tax burden on our industry could have a material, negative impact on our results of operations and our cash flows. Other elements of this legislation, such as comparative effectiveness research, an independent payment advisory board, payment system reforms, including shared savings pilots, and other provisions, could meaningfully change the way health care is developed and delivered, and may materially impact numerous aspects of our business.

#### Our self-insurance program may not be adequate to cover future losses.

We have elected to self-insure most of our insurable risks. We made this decision based on conditions in the insurance marketplace that have led to increasingly higher levels of self-insurance retentions, increasing numbers of coverage limitations, and dramatically higher insurance premium rates. We continue to monitor the insurance marketplace to evaluate the value to us of obtaining insurance coverage in the future. While based on historical loss trends we believe that our self-insurance program accruals will be adequate to cover future losses, we cannot guarantee that this will remain true. Historical trends may not be indicative of future losses. These losses could have a material adverse impact on our consolidated earnings, financial condition, and/or cash flows.

If we experience decreasing prices for our goods and services and we are unable to reduce our expenses, our results of operations will suffer.

We may experience decreasing prices for our goods and services due to pricing pressure experienced by our customers from managed care organizations and other third-party payors, increased market power of our customers as the medical device industry consolidates, and increased competition among medical engineering and manufacturing services providers. If the prices for our goods and services decrease and we are unable to reduce our expenses, our results of operations will be adversely affected.

We are subject to a variety of risks due to our international operations that could adversely affect those operations or our profitability and operating results.

Our operations in countries outside the U.S., which accounted for 43 percent of our net sales for the year ended April 29, 2011, are accompanied by certain financial and other risks. We intend to continue to pursue growth opportunities in sales outside the U.S., especially in emerging markets, which could expose us to greater risks associated with international sales and operations. Our profitability and international operations are, and will continue to be, subject to a number of risks and potential costs, including:

changes in foreign medical reimbursement programs and policies,

changes in foreign legal and regulatory requirements,

local product preferences and product requirements,

longer-term receivables than are typical in the U.S.,

fluctuations in foreign currency exchange rates,

less intellectual property protection in some foreign countries than exists in the U.S.,

trade protection measures and import and export licensing requirements,

work force instability,

political and economic instability, and

the potential payment of U.S. income taxes on certain earnings of our foreign subsidiaries upon repatriation.

In particular, the Obama Administration has announced potential legislative proposals to tax profits of U.S. companies earned abroad. While it is impossible for us to predict whether these and other proposals will be implemented, or how they will ultimately impact us, they may materially impact our results of operations if, for example, our profits earned abroad are subject to U.S. income tax, or we are otherwise disallowed deductions as a result of these profits.

In addition, a significant amount of trade receivables are with national health care systems in many countries (including, but not limited to Greece, Ireland, Portugal, and Spain). Repayment of these receivables is dependent upon the financial stability of the economies of those countries. In light of the current economic state of many foreign countries, we continue to monitor their creditworthiness. Failure to receive payment of all or a significant portion of these receivables could adversely affect our results of operations.

Finally, changes in foreign currency exchange rates may reduce the reported value of our foreign currency revenues, net of expenses, and cash flows. We cannot predict changes in currency exchange rates, the impact of exchange rate changes, nor the degree to which we will be able to manage the impact of currency exchange rate changes.

# Consolidation in the health care industry could have an adverse effect on our revenues and results of operations.

Many health care industry companies, including health care systems, are consolidating to create new companies with greater market power. As the health care industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate price concessions or reductions for medical devices that incorporate components produced by us. If we are forced to reduce our prices because of consolidation in the health care industry, our revenues would decrease and our consolidated earnings, financial condition, and/or cash flows would suffer.

Our business is indirectly subject to health care industry cost-containment measures that could result in reduced sales of medical devices containing our components.

Most of our customers, and the health care providers to whom our customers supply medical devices, rely on third-party payors, including government programs and private health insurance plans, to reimburse some or all of the cost of the procedures in which medical devices that incorporate components we manufacture or assemble are used. The continuing efforts of governmental authorities, insurance companies, and other payors of health care costs to contain or reduce these costs could lead to patients being unable to obtain approval for payment from these third-party payors. If third-party payor payment approval cannot be obtained by patients, sales of finished medical devices that include our components may decline significantly and our customers may reduce or eliminate purchases of our components. The cost-containment measures that health care providers are instituting, both in the U.S. and internationally, could harm our ability to operate profitably. For example, managed care organizations have successfully negotiated volume discounts for pharmaceuticals. While this type of discount pricing does not currently exist for medical devices, if managed care or other organizations were able to affect discount pricing for devices, it could result in lower prices to our customers from their customers and, in turn, reduce the amounts we can charge our customers for our medical devices.

Our research and development efforts rely upon investments and investment collaborations, and we cannot guarantee that any previous or future investments or investment collaborations will be successful.

Our strategy to provide a broad range of therapies to restore patients to fuller, healthier lives requires a wide variety of technologies, products, and capabilities. The rapid pace of technological development in the medical industry and the specialized expertise required in different areas of medicine make it difficult for one company alone to develop a broad portfolio of technological solutions. In addition to internally generated growth through our research and development efforts, historically we have relied, and expect to continue to rely, upon investments and investment collaborations to provide us access to new technologies both in areas served by our existing businesses as well as in new areas.

We expect to make future investments where we believe that we can stimulate the development of, or acquire, new technologies and products to further our strategic objectives and strengthen our existing businesses. Investments and investment collaborations in and with medical technology companies are inherently risky, and we cannot guarantee that any of our previous or future investments or investment collaborations will be successful or will not materially adversely affect our consolidated earnings, financial condition, and/or cash flows.

#### The continuing development of many of our products depends upon us maintaining strong relationships with physicians.

If we fail to maintain our working relationships with physicians, many of our products may not be developed and marketed in line with the needs and expectations of the professionals who use and support our products, which could cause a decline in our earnings and profitability. The research, development, marketing, and sales of many of our new and improved products is dependent upon our maintaining working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing, and sale of our products. Physicians assist us as researchers, marketing and product consultants, inventors, and public speakers. If we are unable to maintain our strong relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could have a material adverse effect on our consolidated earnings, financial condition, and/or cash flows.

Negative conditions in the global credit market may impair our commercial paper program, our auction rate securities, and our other fixed income securities, which may cause us losses and liquidity issues.

We have investments in marketable debt securities that are classified and accounted for as available-for-sale. Our debt securities include U.S. and foreign government and agency securities, corporate debt securities, certificates of deposit, and mortgage-backed and other asset-backed securities, including auction rate securities. Market conditions over the past several years have included periods of significant economic uncertainty and at times general market distress, especially in the banking and financial services sector. During these periods of economic uncertainty, we may experience reduced liquidity across the fixed-income investment market, including the securities that we invest in. In the event we need to sell these securities, we may not be able to do so in a timely manner or for a value that is equal to the underlying principal. In addition, we may be required to adjust the carrying value of the securities and record an impairment charge. If we determine that the fair value of such securities is temporarily impaired, we would record a temporary impairment as a component of accumulated other comprehensive loss within shareholders—equity. If it is determined that the fair value of these securities is other-than-temporarily impaired, we would record a loss in our consolidated statements of earnings, which could materially adversely impact our results of operations and financial condition.

#### Table of Contents

Negative market conditions may also impair our ability to access the capital markets through the issuance of commercial paper or debt securities, or may impact our ability to sell such securities at a reasonable price and may negatively impact our ability to borrow from financial institutions.

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

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

As part of our strategy to develop and identify new products and technologies, we have made several acquisitions in recent years and may make additional acquisitions in the future. Our integration of the operations of acquired businesses requires significant efforts, including the coordination of information technologies, research and development, sales and marketing, operations, manufacturing, and finance. These efforts result in additional expenses and involve significant amounts of management s time that cannot then be dedicated to other projects. Our failure to manage and coordinate the growth of the combined company successfully could also have an adverse impact on our business. In addition, we cannot be certain that the businesses we acquire will become profitable or remain so. If our acquisitions are not successful, we may record unexpected impairment charges. Factors that will affect the success of our acquisitions include:

the presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies,

adverse developments arising out of investigations by governmental entities of the business practices of acquired companies,

any decrease in customer loyalty and product orders caused by dissatisfaction with the combined companies product lines and sales and marketing practices, including price increases,

our ability to retain key employees, and

the ability of the combined company to achieve synergies among its constituent companies, such as increasing sales of the combined company s products, achieving cost savings, and effectively combining technologies to develop new products.

The medical device industry is the subject of numerous governmental investigations into marketing and other business practices. These investigations could result in the commencement of civil and/or criminal proceedings, substantial fines, penalties, and/or administrative remedies, divert the attention of our management, and have an adverse effect on our financial condition and results of operations.

We are subject to rigorous regulation by the FDA and numerous other federal, state, and foreign governmental authorities. These authorities have been increasing their scrutiny of our industry. We have received subpoenas and other requests for information from state and federal governmental agencies, including, among others, the U.S. Department of Justice and the Office of Inspector General of HHS. These investigations have related primarily to financial arrangements with health care providers, regulatory compliance, and product promotional practices. Similar requests were made of our major competitors.

We are fully cooperating with these investigations and are responding to these requests. However, we cannot predict when these investigations will be resolved, the outcome of these investigations, or their impact on us. An adverse outcome in one or more of these investigations could include the commencement of civil and/or criminal proceedings, substantial fines, penalties, and/or administrative remedies, including exclusion from government reimbursement programs, entry into Corporate Integrity Agreements (CIAs) with governmental agencies and amendments to existing CIAs. In addition, resolution of any of these matters could involve the imposition of additional and costly compliance obligations. Finally, if these 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 administrative burdens, including cost, on us. These potential consequences, as well as any adverse outcome from these investigations or other investigations initiated by the government at any time, could have a material adverse effect on our financial condition and results of operations.

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

We are subject to income taxes as well as non-income based taxes, in both the U.S. and various foreign jurisdictions. We are subject to ongoing tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision. However, there can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes of these audits could have a material impact on our consolidated earnings and financial condition. Additionally, changes in tax laws or tax rulings could materially impact our effective tax rate.

#### **Item 1B. Unresolved Staff Comments**

None.

# **Item 2. Properties**

Our principal offices are owned by us and located in the Minneapolis, Minnesota metropolitan area. Manufacturing or research facilities are located in Arizona, California, Colorado, Connecticut, Florida, Indiana, Massachusetts, Michigan, Minnesota, Tennessee, Texas, Washington, Puerto Rico, China, France, Ireland, Mexico, The Netherlands, Singapore, and Switzerland. Our total manufacturing and research space is approximately 3.9 million square feet, of which approximately 63 percent is owned by us and the balance is leased.

We also maintain sales and administrative offices in the U.S. at approximately 92 locations in 41 states or jurisdictions and outside the U.S. at approximately 106 locations in over 42 countries. Most of these locations are leased. We are using substantially all of our currently available productive space to develop, manufacture, and market our products. Our facilities are in good operating condition, suitable for their respective uses and adequate for current needs.

#### **Item 3. Legal Proceedings**

A discussion of the Company s policies with respect to legal proceedings is discussed in our legal proceedings and other loss contingencies footnote as described in Note 16 to the consolidated financial statements set forth in Exhibit 13 hereto and included in our 2011 Annual Report.

#### Item 4. Removed and Reserved

#### **PART II**

# Item 5. Market for Medtronic s Common Equity, Related Shareholder Matters, and Issuer Purchases of Equity Securities

The information in the section entitled Price Range of Medtronic Common Stock is incorporated herein by reference set forth in Exhibit 13 hereto and will be included in our 2011 Annual Report. The Company s common stock is listed on the New York Stock Exchange under the symbol MDT.

In June 2007, 2009, and 2011, the Company s Board of Directors authorized the repurchase of 50 million, 60 million, and 75 million shares of the Company s stock. As authorized by the Board of Directors our program expires when its total number of authorized shares has been

#### Table of Contents

Medtronic did not repurchase any shares during the fourth quarter of fiscal year 2011.

On June 27, 2011, there were approximately 49,950 shareholders of record of the Company s common stock. Cash dividends declared and paid totaled 22.50 cents per share for each quarter of fiscal year 2011 and 20.50 cents per share for each quarter of fiscal year 2010. Stock price comparison follows:

Fiscal Qtr.	1st	Qtr.	2	nd Qtr.	3rd Qtr.	4th Qtr.
2011 High	\$	44.13	\$	37.90	\$ 38.51	\$ 41.86
2011 Low		36.03		31.21	33.53	36.67
2010 High		35.83		39.06	46.03	45.81
2010 Low		29.96		35.58	35.99	41.67

#### **Stock Performance Graph**

The following graph compares the cumulative total shareholder return on Medtronic  $\,$ s common stock with the cumulative total shareholder return on the Standard & Poor  $\,$ s (S&P) 500 Composite Index and the S&P 500 Health Care Equipment Index for the last five fiscal years. The graph assumes that \$100 was invested at market close on April 28, 2006 in Medtronic  $\,$ s common stock, the S&P 500 Index, and the S&P 500 Health Care Equipment Index and that all dividends were reinvested.

Company/Index	April 2006	April 2007	April 2008	April 2009	April 2010	April 2011
Medtronic, Inc.	\$ 100.00	\$ 107.90	\$ 100.45	\$ 61.32	\$ 92.49	\$ 90.58
S&P 500 Index	100.00	116.14	110.81	70.51	98.65	115.64
S&P 500 Health Care Equipment Index	100.00	115.52	114.95	78.31	103.46	115.05

# Item 6. Selected Financial Data

The information for fiscal years 2007 through 2011 in the section entitled Selected Financial Data is incorporated herein by reference to Exhibit 13 hereto and will be included in our 2011 Annual Report.

# Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

The information in the section entitled Management's Discussion and Analysis of Financial Condition and Results of Operations is incorporated herein by reference to Exhibit 13 hereto and will be included in our 2011 Annual Report.

# Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The information in the sections entitled Management's Discussion and Analysis of Financial Condition and Results of Operations and Market Risk, as well as Notes 5 and 9 to the consolidated financial statements is incorporated herein by reference to Exhibit 13 hereto and will be included in our 2011 Annual Report.

# **Item 8. Financial Statements and Supplementary Data**

The Consolidated Financial Statements and Notes thereto, together with the report of independent registered public accounting firm, are incorporated herein by reference to Exhibit 13 hereto and will be included in our 2011 Annual Report.

# Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

#### Item 9A. Controls and Procedures

#### **Disclosure Controls and Procedures**

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) and changes in the Company s internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this annual report, our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) are effective.

#### Management s Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company (as defined in Exchange Act Rule 13a-15(f)). Management conducted an evaluation of the effectiveness of internal control over financial reporting based on the framework in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management concluded that the Company's internal control over financial reporting was effective as of April 29, 2011. Our internal control over financial reporting as of April 29, 2011, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm who has also audited our consolidated financial statements, as stated in their report in the section entitled Report of Independent Registered Public Accounting Firm, which expresses an unqualified opinion on the effectiveness of the Company's internal control over financial reporting as of April 29, 2011, which is incorporated by reference to Exhibit 13 hereto and will be included in our 2011 Annual Report.

#### **Changes in Internal Control over Financial Reporting**

There have been no changes in the Company s internal control over financial reporting during the Company s most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

# **Item 9B. Other Information**

None.

# **PART III**

# Item 10. Directors, Executive Officers, and Corporate Governance

The sections entitled Proposal 1 Election of Directors Directors and Nominees, Governance of Medtronic Committees of the Board and Meetings, Governance of Medtronic Audit Committee, Governance of Medtronic Audit Committee Independence and Financial Experts, Governance of Medtronic Corporate Governance Committee, and Share Ownership Information Section 16(a) Beneficial Ownership Reporting Compliance in our Proxy Statement for our 2011 Annual Shareholders Meeting are incorporated herein by reference. See also Executive Officers of Medtronic on page 16 herein.

We have adopted a written Code of Ethics that applies to our Chief Executive Officer, Chief Financial Officer, Corporate Treasurer, Corporate Controller, and other senior financial officers performing similar functions who are identified from time to time by the Chief Executive Officer. We have also adopted a written Code of Business Conduct and Ethics for Members of the Board of Directors. The Code of Ethics for Senior Financial Officers, which is part of our broader Code of Conduct applicable to all employees, and the Code of Business Conduct and Ethics for Board members are posted on our website, www.medtronic.com under the Investors caption and then under the Corporate Governance subcaption. Any amendments to, or waivers for executive officers or directors of, these ethics codes will be disclosed on our website promptly following the date of such amendment or waiver.

# **Item 11. Executive Compensation**

The sections entitled Governance of Medtronic Director Compensation, Governance of Medtronic Compensation Committee Compensation Committee Interlocks and Insider Participation, Compensation Discussion and Analysis, and Executive Compensation in our Proxy Statement for our 2011 Annual Shareholders Meeting are incorporated herein by reference. The section entitled Compensation Discussion and Analysis Compensation Committee Report in our Proxy Statement for our 2011 Annual Shareholders Meeting is furnished herein by reference.

# Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters

The sections entitled Share Ownership Information Significant Shareholders, Share Ownership Information Beneficial Ownership and Management, and Executive Compensation Equity Compensation Plan Information in our Proxy Statement for our 2011 Annual Shareholders Meeting are incorporated herein by reference.

# Item 13. Certain Relationships and Related Transactions, and Director Independence

The sections entitled Proposal 1 Election of Directors Related Transactions and Other Matters and Proposal 1 Election of Directors Director Independence in our Proxy Statement for our 2011 Annual Shareholders Meeting are incorporated herein by reference.

#### **Item 14. Principal Accounting Fees and Services**

The sections entitled Governance of Medtronic Audit Committee Audit Committee Pre-Approval Policies and Audit and Non-Audit Fees in our Proxy Statement for our 2011 Annual Shareholders Meeting are incorporated herein by reference.

#### **PART IV**

# Item 15. Exhibits, Financial Statement Schedules

#### (a) 1. Financial Statements

The following report and consolidated financial statements are incorporated herein by reference in Item 8.

The sections entitled Report of Independent Registered Public Accounting Firm and Consolidated Statements of Earnings years ended April 29, 2011, April 30, 2010, and April 24, 2009 are set forth in Exhibit 13 hereto and will be included in our 2011 Annual Report.

The section entitled Consolidated Balance Sheets April 29, 2011 and April 30, 2010 is set forth in Exhibit 13 hereto and will be included in our 2011 Annual Report.

The section entitled Consolidated Statements of Shareholders Equity years ended April 29, 2011, April 30, 2010, and April 24, 2009 is set forth in Exhibit 13 hereto and will be included in our 2011 Annual Report.

The section entitled Consolidated Statements of Cash Flows years ended April 29, 2011, April 30, 2010, and April 24, 2009 is set forth in Exhibit 13 hereto and will be included in our 2011 Annual Report.

The section entitled Notes to Consolidated Financial Statements is set forth in Exhibit 13 hereto and will be included in our 2011 Annual Report.

#### 2. Financial Statement Schedules

Schedule II. Valuation and Qualifying Accounts years ended April 29, 2011, April 30, 2010, and April 24, 2009 (set forth on page 31 of this report).

All other schedules are omitted because they are not applicable or the required information is shown in the financial statements or Notes thereto.

#### 3. Exhibits

- Agreement and Plan of Merger Among Medtronic, Inc., Jets Acquisition Corporation and Kyphon Inc. (Dated as of July 26, 2007) (Exhibit 2.1).(u)
- 3.1 Medtronic, Inc. Restated Articles of Incorporation, as amended (Exhibit 3.1).(v)
- 3.2 Medtronic, Inc. Bylaws, as amended to date (Exhibit 3.2).(b)
- 4.1 Indenture, dated as of September 11, 2001, between Medtronic, Inc. and Wells Fargo Bank Minnesota, National Association. (Exhibit 4.2).(d)
- 4.2 Form of Indenture between Medtronic, Inc. and Wells Fargo Bank, National Association (Exhibit 4.1).(f) Indenture dated as of September 15, 2005 between Medtronic, Inc. and Wells Fargo Bank, N. A., as Trustee,
- 4.3 with respect to the 4.375% Senior Notes due 2010 and 4.750% Senior Notes due 2015 (including the Forms of Notes thereof) (Exhibit 4.1).(g)
- 4.4 Form of 4.375% Senior Notes, Series B due September 15, 2010 (Exhibit 4.2).(g)
- 4.5 Form of 4.750% Senior Notes, Series B due September 15, 2015 (Exhibit 4.3).(g)
- 4.6 Indenture by and between Medtronic, Inc. and Wells Fargo Bank, N.A., as trustee dated as of April 18, 2006 (including the Form of Convertible Senior Notes thereof) (Exhibit 4.1).(h)
- 4.7 Form of Indenture between Medtronic, Inc. and Wells Fargo Bank, National Association (Exhibit 4.1).(aa)
- First Supplemental Indenture Dated March 12, 2009 between Medtronic, Inc. and Wells Fargo Bank,
- National Association (including the Forms of Notes thereof) (Exhibit 4.1).(bb)

- 4.9 Second Supplemental Indenture Dated March 16, 2010 between Medtronic, Inc. and Wells Fargo Bank, National Association (including the Forms of Notes thereof) (Exhibit 4.1).(ff)
- 4.10 Third Supplemental Indenture Dated March 15, 2011 between Medtronic, Inc. and Wells Fargo Bank, National Association (including the Forms of Notes thereof) (Exhibit 4.1).(gg)
- \*10.1 1994 Stock Award Plan (amended and restated as of January 1, 2008) (Exhibit 10.1).(t)
- \*10.2 Medtronic Incentive Plan (amended and restated effective January 1, 2008) (Exhibit 10.2).(t)
- \*10.3 Medtronic, Inc. Executive Incentive Plan (Appendix C).(1)
- \*10.4 Form of Employment Agreement for Medtronic executive officers (Exhibit 10.5).(a)
- \*10.5 Medtronic, Inc. Capital Accumulation Plan Deferral Program (as restated generally effective January 1, 2008)(Exhibit 10.5).(w)
- \*10.6 Stock Option Replacement Program (Exhibit 10.8).(a)
- \*10.7 Medtronic, Inc. 1998 Outside Director Stock Compensation Plan (as amended and restated effective as of January 1, 2008) (Exhibit 10.3).(t)
- \*10.8 Amendment effective October 2001, regarding change in control provisions in the Management Incentive Plan (Exhibit 10.10).(j)
- 10.9 Indemnification Trust Agreement (Exhibit 10.11).(b)
  Asset Purchase and Settlement Agreement dated as of April 21, 2005 among Medtronic, Inc., Medtronic
- 10.10 Sofamor Danek, Inc., SDGI Holdings, Inc., Gary K. Michelson, M.D. and Karlin Technology, Inc. (Exhibit 10.13).(o)
- \*10.11 Form of Restricted Stock Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.3).(e)
- \*10.12 Form of Non-Qualified Stock Option Agreement under 2003 Long-Term Incentive Plan (four year vesting) (Exhibit 10.1).(e)
- \*10.13 Form of Non-Qualified Stock Option Agreement under 2003 Long-Term Incentive Plan (immediate vesting) (Exhibit 10.2).(e)
- \*10.14 Form of Initial Option Agreement under the Medtronic, Inc. 1998 Outside Director Stock Compensation Plan (Exhibit 10.17).(o)
- \*10.15 Form of Annual Option Agreement under the Medtronic, Inc. 1998 Outside Director Stock Compensation Plan (Exhibit 10.18).(o)
- \*10.16 Form of Replacement Option Agreement under the Medtronic, Inc. 1998 Outside Director Stock Compensation Plan (Exhibit 10.19).(o)
- \*10.17 Form of Restricted Stock Units Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.20).(o)
- \*10.18 Form of Performance Share Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.21).(o)
- \*10.19 Medtronic, Inc. Supplemental Executive Retirement Plan (as restated generally effective January 1, 2008) (Exhibit 10.1).(s)
- Purchase Agreement by and among Medtronic, Inc. and the Initial Purchasers named therein dated as of April 12, 2006 (Exhibit 10.1).(h)
- Registration Rights Agreement between Medtronic, Inc. and Banc of America Securities LLC and Morgan Stanley & Co. Incorporated dated as of April 18, 2006 (Exhibit 4.2).(h)
- \*10.22 2003 Long-Term Incentive Plan (as amended and restated effective January 1, 2008) (Exhibit 10.4).(t)
- \*10.23 Form of Non-Qualified Stock Option Agreement under 2003 Long-Term Incentive Plan effective June 22, 2006 (Exhibit 10.23).(q)

- \*10.24 Form of Restricted Stock Award Agreement under 2003 Long-Term Incentive Plan effective June 22, 2006 (Exhibit 10.24).(q)
- \*10.25 Form of Restricted Stock Unit Award Agreement under 2003 Long-Term Incentive Plan effective June 22, 2006 (Exhibit 10.25).(q)
- \*10.26 Form of Performance Award Agreement under 2003 Long-Term Incentive Plan effective June 22, 2006 (Exhibit 10.26).(q)
- 10.27† Form of Confirmations of Convertible Note Hedge related to Convertible Senior Debentures issued on April 12, 2006, including Schedule thereto (Exhibit 10.27).(q)
- 10.28† Form of Warrants issued on April 12, 2006, including Schedule thereto (Exhibit 10.28).(q)
- 10.29† Form of Amendment to Confirmation issued on April 13, 2006 to Form of Warrants issued on April 12, 2006, including Schedule thereto (Exhibit 10.29).(q)
- 10.30 Amendment No. 1 dated September 5, 2006, to Indemnification Trust Agreement (Exhibit 10.1).(r)
- \*10.31 Form of Restricted Stock Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.3).(s)
- \*10.32 Form of Restricted Stock Unit Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.4).(s)
- \*10.33 Medtronic, Inc. Israeli Amendment to the 2003 Long-Term Incentive Plan (Exhibit 10.5).(t)
- \*10.34 Medtronic, Inc. Kyphon Inc. 2002 Stock Plan (Amended and Restated July 26, 2007, as further amended on October 18, 2007) (Exhibit 10.6).(t)
- \*10.35 Addendum: Medtronic, Inc. Kyphon Inc. 2002 Stock Plan (dated December 13, 2007) (Exhibit 10.7).(t)
- \*10.36 Letter Agreement dated April 29, 2008 between Michael DeMane and Medtronic, Inc. (Exhibit 10.37).(w)
- \*10.37 Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.2).(ee)
- \*10.38 Form of Non-Qualified Stock Option Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.39).(w)
- \*10.39 Form of Restricted Stock Unit Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.40).(w)
- \*10.40 Form of Restricted Stock Unit Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.41).(w)
- \*10.41 Form of Restricted Stock Unit Award Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.2).(x)
- \*10.42 Form of Restricted Stock Award Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.3).(x)
- \*10.43 Form of Restricted Stock Award Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.4).(x)
- \*10.44 Form of Restricted Stock Unit Award Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.5).(x)
- \*10.45 Form of Non-Qualified Stock Option Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.6).(x)
- \*10.46 Terms of Non-Employee Director Compensation under the Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.7).(x)
- \*10.47 Form of Non-Employee Director Initial Option Agreement under the Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.1).(y)
- \*10.48 Form of Non-Employee Director Annual Option Agreement under the Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.2).(y)

- \*10.49 Form of Non-Employee director Deferred Unit Award Agreement under the Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.3).(y)
- \*10.50 Form of Change of Control Employment Agreement for Medtronic Executive Officers (Exhibit 10.38).(w)
- \*10.51 Amendment to Change of Control Agreement for Medtronic Executive Officers (Exhibit 10.1).(z)
- \*10.52 Amendment No. 2 dated April 27, 2009, to Indemnification Trust Agreement (Exhibit 10.53). (cc)
- \*10.53 Form of Amended and Restated Change of Control Employment Agreement for Medtronic Executive Officers (Exhibit 10.1).(dd)
- \*10.54 Form of Change of Control Employment Agreement for Medtronic Executive Officers (Exhibit 10.1).(ee)
- \*10.55 Medtronic, Inc. 2005 Employee Stock Purchase Plan (Exhibit 10.3).(ee)
- \*10.56 Bonus Agreement by and between Medtronic, Inc. and Christopher J. O'Connell dated December 23, 2009 (Exhibit 10.56).(hh)
- \*10.57 Amendment dated December 18, 2008 to the Medtronic, Inc. Capital Accumulation Plan Deferral Program and Supplemental Executive Retirement Plan (Exhibit 10.57).(ii)
- \*10.58 Separation Agreement by and between Medtronic, Inc. and William A. Hawkins dated December 28, 2010 (Exhibit 10.1).(jj)
- \*10.59 Letter Agreement by and between Medtronic, Inc. and Omar Ishrak dated May 11, 2011 (Exhibit 10.1).(kk)
- 12.1 Computation of ratio of earnings to fixed charges
- 13 This exhibit contains the information referenced under Part II, Items 5, 6, 7, 7A and 8
- 21 List of Subsidiaries
- 23 Consent of Independent Registered Public Accounting Firm
- 24 Powers of Attorney
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 The following materials from Medtronic's Annual Report on Form 10-K for year ended April 29, 2011,
- formatted in Extensible Business Reporting Language (XBRL), (i) consolidated statements of earnings, (ii) consolidated balance sheets, (iii) consolidated statements of cash flows, (iv) consolidated statements of shareholders' equity, and (v) the notes to the consolidated financial statements.
- (a) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 27, 2001, filed with the Commission on July 26, 2001.
- (b) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 30, 2004, filed with the Commission on June 30, 2004.
- (c) Incorporated herein by reference to the cited exhibit in our registration statement on Form 8-A, including the exhibits thereto, filed with the Commission on November 3, 2000.

- (d) Incorporated herein by reference to the cited exhibit in our amended Current Report on Form 8-K/A, filed with the Commission on November 13, 2001.
- (e) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended January 28, 2005, filed with the Commission on March 7, 2005.
- (f) Incorporated herein by reference to the cited exhibit in our registration statement on Amendment No. 2 to Form S-4, filed with the Commission on January 10, 2005.
- (g) Incorporated herein by reference to the cited exhibit in our registration statement on Form S-4, filed with the Commission on December 6, 2005.
- (h) Incorporated herein by reference to the cited exhibit in our Current Report on Form 8-K, filed with the Commission on April 18, 2006.
- (i) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended January 26, 2007, filed with the Commission on March 6, 2007.
- (j) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 26, 2002, filed with the Commission on July 19, 2002.
- (k) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 25, 2003, filed with the Commission on July 14, 2003.
- (1) Incorporated herein by reference to the cited appendix to our 2003 Proxy Statement, filed with the Commission on July 28, 2003.
- (m) Incorporated herein by reference to the cited exhibit in our registration statement on Form S-8, filed with the Commission on November 21, 2005.
- (n) Incorporated herein by reference to the cited appendix to our 2005 Proxy Statement, filed with the Commission on July 21, 2005.
- (o) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 29, 2005, filed with the Commission on June 29, 2005.
- (p) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended October 28, 2005, filed with the Commission on December 6, 2005.
- (q) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 28, 2006, filed with the Commission on June 28, 2006.
- (r) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended October 27, 2006, filed with the Commission on December 5, 2006.
- (s) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended October 26, 2007, filed with the Commission on December 4, 2007.
- (t) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended January 25, 2008, filed with the Commission on March 4, 2008.
- (u) Incorporated herein by reference to the cited exhibit in our Current Report on Form 8-K, filed with the Commission on July 30, 2007.
- (v) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended July 27, 2007, filed with the Commission on September 5, 2007.
- (w) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 25, 2008, filed with the Commission on June 24, 2008.
- (x) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended July 25, 2008, filed with the Commission on September 3, 2008.
- (y) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended October 24, 2008, filed with the Commission on December 3, 2008.

#### **Table of Contents**

- (z) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended January 23, 2009, filed with the Commission on March 4, 2009.
- (aa) Incorporated herein by reference to the cited exhibit in our registration statement on Form S-3, filed with the Commission on March 9, 2009.
- (bb) Incorporated herein by reference to the cited exhibit in our Current Report on Form 8-K, filed with the Commission on March 12, 2009.
- (cc) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 24, 2009, filed with the Commission on June 23, 2009.
- Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended July 31, 2009, filed with the Commission on September 9, 2009.
- (ee) Incorporated herein by reference to the cited exhibit in our Quarterly Report on Form 10-Q for the quarter ended October 30, 2009, filed with the Commission on December 9, 2009.
- (ff) Incorporated herein by reference to the cited exhibit in our Current Report on Form 8-K, filed with the Commission on March 16, 2010.
- Incorporated herein by reference to the cited exhibit in our Current Report on Form 8-K, filed with the Commission on March 16, 2011.
- (hh) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 30, 2010, filed with the Commission on June 29, 2010.
- (ii) Incorporated herein by reference to the cited exhibit in our Annual Report on Form 10-K for the year ended April 30, 2010, filed with the Commission on June 29, 2010.
- (jj) Incorporated herein by reference to the cited exhibit in our Current Report on Form 8-K, filed with the Commission on December 30, 2010.
- (kk) Incorporated herein by reference to the cited exhibit in our Current Report on Form 8-K, filed with the Commission on May 11, 2011.

†Confidential treatment requested as to portions of the exhibit. Confidential portions omitted and filed separately with the Securities and Exchange Commission.

<sup>\*</sup>Exhibits that are management contracts or compensatory plans or arrangements.

# Table of Contents

# **SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDTRONIC, INC.

Dated: June 28, 2011

By: /s/ Omar Ishrak

Omar Ishrak