

MEDTRONIC INC  
Form 10-K  
June 23, 2009  
Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

- ☒ **Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.**  
**For the fiscal year ended April 24, 2009.**
- ☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**  
**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**  
**Commission File No. 1-7707**

**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)

Telephone Number, including area code: (763) 514-4000

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

Title of each class	Name of each exchange on which registered
Common stock, par value \$0.10 per share	New York Stock Exchange, Inc.
Preferred stock purchase rights	New York Stock Exchange, Inc.
Securities registered pursuant to section 12(g) of the Act:	
None	

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

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

## Edgar Filing: MEDTRONIC INC - Form 10-K

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 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 ☐ No ☐

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. ☐

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 ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐

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

Aggregate market value of voting stock of Medtronic, Inc. held by nonaffiliates of the registrant as of October 24, 2008, based on the closing price of \$37.81, as reported on the New York Stock Exchange: approximately \$42.4 billion. Shares of Common Stock outstanding on June 18, 2009: 1,112,348,250

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's 2009 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 2009 Annual Meeting are incorporated by reference into Part III hereto.

---

### TABLE OF CONTENTS

Item	Description	Page
<b><u>PART I</u></b>		
<u>1.</u>	<u>Business</u>	1
<u>1A.</u>	<u>Risk Factors</u>	30
<u>1B.</u>	<u>Unresolved Staff Comments</u>	35
<u>2.</u>	<u>Properties</u>	35
<u>3.</u>	<u>Legal Proceedings</u>	36
<u>4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	37
<b><u>PART II</u></b>		
<u>5.</u>	<u>Market for Medtronic's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities</u>	37
<u>6.</u>	<u>Selected Financial Data</u>	38
<u>7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operation</u>	38
<u>7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	38
<u>8.</u>	<u>Financial Statements and Supplementary Data</u>	38

## Edgar Filing: MEDTRONIC INC - Form 10-K

<u>9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	38
<u>9A.</u>	<u>Controls and Procedures</u>	38
<u>9B.</u>	<u>Other Information</u>	39

### **PART III**

<u>10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	39
<u>11.</u>	<u>Executive Compensation</u>	39
<u>12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters</u>	39
<u>13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	39
<u>14.</u>	<u>Principal Accounting Fees and Services</u>	40

### **PART IV**

<u>15.</u>	<u>Exhibits, Financial Statement Schedules</u>	40
------------	--	----

---

#### 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 27, 2009 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 29, 2009 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 ([www.medtronic.com](http://www.medtronic.com) under the Investors caption) 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 Board Members 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 [www.medtronic.com](http://www.medtronic.com) under the Investors caption.

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 <http://www.sec.gov>. The Company files annual reports, quarterly reports, proxy statements and other documents with the SEC under the Securities Exchange Act of 1934 (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.

---

#### Table of Contents

### **PART I**

#### **Item 1. Business**

##### **Overview**

## Edgar Filing: MEDTRONIC INC - Form 10-K

Medtronic is the global leader in medical technology alleviating pain, restoring health, and extending life for millions of people around the world. We are committed to offering market-leading therapies to restore patients to fuller, healthier lives. With beginnings in the treatment of heart disease, we have expanded well beyond our historical core business and today provide a wide range of products and therapies that help solve many challenging, life-limiting medical conditions. We hold market-leading positions in almost all of the major markets in which we operate.

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. Beginning with the development of the heart pacemaker in the 1950s, we have assembled a broad and diverse portfolio of progressive technology expertise both through internal development of core technologies as well as acquisitions. We remain committed to a mission written by our founder more than 40 years ago that directs us to contribute to human welfare by application of biomedical engineering in the research, design, manufacture and sale of products that alleviate pain, restore health and extend life.

With approximately 41,000 dedicated employees worldwide (including full-time equivalent employees) personally invested in supporting our mission, our success in leading global advances in medical technology is the result of several key strengths:

Broad and deep technological knowledge of microelectronics, implantable devices and techniques, power sources, coatings, materials, programmable devices and related areas, as well as a tradition of technological pioneering and breakthrough products that not only yield better medical outcomes, but more cost-effective therapies.

Strong intellectual property portfolio that underlies our key products.

High product quality standards, backed with stringent systems to help ensure consistent performance that meet or surpass customers' expectations.

Strong and appropriate professional collaboration with customers, extensive medical educational programs, and thorough clinical research.

Full commitment to superior patient and customer service.

Extensive experience with the regulatory process and sound working relationships with regulators and reimbursement agencies, including leadership roles in helping shape regulatory policy in the major markets in which we operate.

A proven financial record of sustained revenue and earnings growth and continual introduction of new products.

1

---

### Table of Contents

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

Cardiac Rhythm Disease Management

Spinal

CardioVascular

Neuromodulation

Diabetes

Surgical Technologies

Physio-Control

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 24, 2009 (fiscal year 2009).

With innovation and market leadership, we have pioneered advances in medical technology in all of our businesses and enjoyed steady growth. Over the last five years, our net sales on a compound annual growth basis have increased more than 9 percent, from \$9.087 billion in fiscal year 2004 to \$14.599 billion in fiscal year 2009. We attribute this growth to our commitment to develop or acquire new products to treat an expanding array of medical conditions.

## Edgar Filing: MEDTRONIC INC - Form 10-K

We will accomplish this commitment by operating as ONE Medtronic, 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

Strong focus on improving operating margins

Delivering EPS growth and disciplined capital allocation

Aligning the organization for market-leading and consistent execution

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

### Cardiac Rhythm Disease Management (CRDM)

CRDM is the world's leading supplier of medical devices for cardiac rhythm disease management. We pioneered the modern medical device industry by developing the first wearable external cardiac pacemaker in 1957, and manufactured the first reliable long-term implantable pacing system in 1960. Since then, we have been the world's leading producer of cardiac rhythm technology, and from these beginnings, a \$10 billion industry has emerged. Today, our products and technologies treat and monitor a wide variety of heart rhythm diseases and conditions.

2

---

#### Table of Contents

##### *Conditions Treated*

Natural electrical impulses stimulate the atria and ventricles, the heart's chambers, to rhythmically contract and relax with each heartbeat. Irregularities in the heart's normal electrical signals can result in debilitating and life-threatening conditions, including sudden cardiac arrest, one of the leading causes of death. Physicians rely on our CRDM products to monitor and correct these irregularities and restore the heart to its normal rhythm. Our CRDM products are designed to treat and monitor a broad range of heart conditions, including those described below.

**Bradycardia** abnormally slow or unsteady 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.

**Tachyarrhythmia** heart rates that are dangerously fast or irregular. In the lower chambers of the heart, called ventricles, this is called ventricular tachycardia or fibrillation and can lead to sudden cardiac arrest. In the upper chambers, called the atria, this is called atrial arrhythmia which can affect blood flow to the body and increase the risk of stroke.

**Heart Failure** impaired heart function resulting in the inability to pump enough blood to meet the body's needs, characterized by difficulty breathing, chronic fatigue and fluid retention.

**Sudden Cardiac Arrest** condition when the heart's ventricles suddenly develop a rapid, irregular rhythm (ventricular fibrillation) and the quivering ventricles cannot pump blood to the body, which, without immediate treatment, will almost always lead to death.

**Atrial Fibrillation** condition when the atria quiver instead of pumping blood effectively. Blood in the atria may pool and clot. If a clot breaks loose and advances to the brain, a stroke can result.

**Syncope** a sudden loss of consciousness, which occurs when the blood pressure drops and not enough oxygen reaches the brain. Causes vary and include heart-related conditions, exhaustion, stress, overheating, illness and certain medications.

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:

We offer the broadest array of products in the industry for the diagnosis and treatment of heart rhythm disorders and heart failure. Because many patients exhibit multiple heart rhythm problems, we have developed implantable devices that specifically address complex combinations of arrhythmias. In addition to implantable devices, we also provide leads, ablation products, electrophysiology catheters, and information systems for the management of patients with our devices. Our CRDM devices are currently implanted in more than 2.5 million patients worldwide.

***Implantable Cardiac Pacemakers (Pacemakers).*** Bradycardia is a common condition, with hundreds of thousands of patients diagnosed each year, and millions of people worldwide suffering from its effects. The only known treatment for this condition is a cardiac pacemaker, a battery-powered device implanted in the chest that delivers electrical impulses to stimulate the heart to beat at an appropriate rate. Pacemaker technology has extended the lives of millions of patients with heart rhythm conditions, and each year nearly one million pacemakers are implanted in patients worldwide. Medtronic's Adapta family of fully automatic pacemakers, which includes the Adapta, Versa, and Sensia models, incorporates an array of automatic features to help physicians improve pacing therapy and streamline the patient follow-up process, potentially minimizing the amount of time spent in a physician's office. An example is Atrial Capture Management, which is intended to automatically adjust impulses for optimal stimulation of the heart's upper right chamber. Adapta offers a pacing mode called Managed Ventricular Pacing (MVP), which enables the device to be programmed to minimize unnecessary pacing pulses to the right ventricle. The Adapta family leads our portfolio of pacemakers, which also includes the EnRhythm and EnPulse families.

---

Table of Contents

In November 2008, we received CE Mark approval for the EnRhythm MRI SureScan pacing system, the first-ever MRI-Conditional pacemaker system. The EnRhythm MRI SureScan pacing system consists of the dual-chamber EnRhythm MRI SureScan pacemaker and CapSureFix MRI SureScan pacing leads.

***Implantable Cardioverter-Defibrillators (ICDs).*** Approximately seven million people worldwide have tachyarrhythmia. Tachyarrhythmia is a potentially fatal condition that can lead to sudden cardiac arrest, the sudden and complete cessation of heart activity. Sudden cardiac arrest is one of the leading causes of death in the U.S. responsible for more than 300,000 deaths annually, with most due to ventricular fibrillation. ICDs are stopwatch-sized devices that continually monitor the heart and deliver appropriate therapy when an abnormal heart rhythm is detected.

Our family of dual and single chamber ICDs offer exclusive features including Anti-tachyarrhythmia Pacing (ATP) During Charging, OptiVol Fluid Status Monitoring (OptiVol), our pacing mode MVP, and Conexus Wireless Telemetry with SmartRadio. ATP During Charging is a feature that automatically uses pacing pulses to stop fast, dangerous heartbeats, while concurrently preparing to deliver a shock, if needed, with no delay.

OptiVol automatically monitors fluid status in the thoracic cavity, the chest area encompassing the lungs and heart. The accumulation of thoracic fluid is a primary indicator of worsening heart failure and will often result in patient hospitalization. The OptiVol diagnostic feature allows physicians earlier access to warning signs of deteriorating heart failure, which can then be used for early treatment of the patient's heart failure.

In May 2008, we announced U.S. Food and Drug Administration (FDA) approval of the first wave of cardiac rhythm disease management therapies under the new Vision 3D portfolio, which is comprised of a full line of ICDs, pacemakers and implantable cardiac resynchronization therapy devices to address the needs of patients with arrhythmias, heart failure and those at risk of sudden cardiac arrest. In addition to other Medtronic proprietary features, Vision 3D introduces automaticity with Complete Capture Management which continuously and automatically adjusts to changing patient needs. Complete automaticity provides physicians flexibility during in-office device checks and may also reduce battery drain.

***Implantable Cardiac Resynchronization Therapy (CRTs).*** Heart failure is a large and growing health problem. It is typically a late manifestation of one or more other cardiovascular diseases, including coronary artery disease, hypertension, cardiomyopathy, and valvular disease. Chronic heart failure occurs when the heart is unable to pump enough blood to sustain adequate circulation in the body's tissues. Approximately 22 million patients suffer from heart failure globally. Approximately 5.7 million Americans suffer from heart failure and more than 670,000 new cases are estimated to develop each year.

Since 1997, we have supported more than 20 randomized, controlled clinical studies evaluating device therapy in more than 8,000 heart failure and post-myocardial infarction patients. This research has resulted in several medical firsts, among them the first FDA approved resynchronization device for the treatment of heart failure, which was based on results from the groundbreaking MIRACLE trial; the first study of the risk of sudden cardiac death in a heart failure patient population with SCD-HeFT; and the landmark CARE-HF trial, which demonstrated that patients with moderate and severe heart failure who received a Medtronic CRT device experienced a significant reduction in risk in mortality and morbidity, and that long-term treatment with a CRT-pacing (CRT-P) device or CRT-D device is a cost-effective way to improve survival in patients with heart failure.

Medtronic continues to offer the industry's broadest selection of devices and features for the growing number of patients with heart failure who are also considered at high risk of sudden cardiac arrest. With the launch of our Vision 3D portfolio of products in May 2008, we introduced the Consulta CRT-D device which includes existing Medtronic proprietary features like MVP, ATP During Charging, and OptiVol along with Complete Capture Management. Complete Capture Management provides confidence in patients' safety by continuously and automatically adjusting to changing patient needs. Complete automaticity provides physicians flexibility during in-office device checks and may

also reduce battery drain.

## Table of Contents

Along with our existing Concerto CRT-D device, which is commercially available throughout the world, Consulta CRT-D also utilizes our proprietary Conexus wireless telemetry, enabling communication remotely between the implanted device and programmers at the time of implant, during follow-up in a clinician's office, or remotely using a patient home monitor. These CRT-D devices also offer Left Ventricular Capture Management (LVCN), a feature intended to automatically sense and adjust impulses for stimulation of the heart's left ventricle, and sequential biventricular pacing, or V-to-V (ventricle to ventricle) timing, a feature that allows physicians to separately adjust the timing of electrical therapy delivered to the heart failure patient's two ventricles, which can optimize the beating of the heart and enhance the flow of blood throughout the body.

In June 2008, we announced the FDA approval of the Attain StarFix OTW (over-the-wire) lead. As the first-ever active fixation left-heart lead for CRT, the Attain StarFix lead has demonstrated a zero percent chronic dislodgement rate. The Attain StarFix lead provides physicians with a new solution for achieving successful placement and stability of the left-heart lead in heart failure patients receiving a CRT device. A patient's vein size or configuration can make it difficult to secure a left-heart lead in the optimal location. Therefore, stable fixation of the left-heart lead is critical to a successful CRT implantation. Dislodgement of the left heart lead may require additional surgeries, which could increase the risk of infection.

In May 2009, we launched the Attain family of products in the U.S., including Attain Ability and Attain Command. Attain Ability is the first commercially available 4 French bipolar left-heart lead. It is also the first Medtronic left-heart lead with 3 pacing vectors for chronic electronic repositioning around extracardiac stimulation. Attain Ability is designed for reliability with new inner insulation to help protect from breaches. Attain Command is the first catheter family to feature a hydrophilic coating for deep seating.

**Atrial Fibrillation (AF).** AF is an irregular quivering or rapid heart rhythm in the upper chambers (atria) of the heart. AF is the most common cardiac rhythm condition, found in approximately two million Americans and seven million people worldwide. Treatment of AF can be difficult as episodes may show no symptoms and therefore go unnoticed by patients. AF is associated with a five-fold increase in a patient's risk of stroke and an increased risk of heart failure with its attendant risk of sudden cardiac arrest.

In October 2008, we formed an AF solutions business whose goal is to be the physician partner of choice for AF ablation by bringing breakthrough AF therapies to the patients and physicians that are simpler, safer, effective, and offer more predictable procedure times than current treatment methods. Medtronic will offer physicians a choice of ablation therapies and tools to best meet the needs of their AF patients, as well as the needs of their practices. To that end, in November 2008, we announced our successful acquisition of CryoCath Technologies Inc. (CryoCath), a publicly traded Canadian medical technology company that has developed cryotherapy products to treat cardiac arrhythmias. CryoCath's flagship product, Arctic Front, is a minimally invasive cryo-balloon catheter designed specifically to treat paroxysmal Atrial Fibrillation or Pulmonary Vein Isolation. Marketed in Europe and the subject of a pivotal study in the U.S. and Canada, Arctic Front has been used to treat nearly 5,000 patients. Additionally, in February 2009, we acquired Ablation Frontiers, Inc. (Ablation Frontiers), a privately held company. In 2006, Ablation Frontiers received CE Mark to begin marketing its portfolio of ablation catheters and its unique radio frequency (RF) energy system in Europe. Ablation Frontiers is conducting a clinical trial under a FDA approved investigational device exemption (IDE) in order to gain U.S. approval to market its products for the treatment of permanent and persistent AF.

In February 2009, we announced the commercial availability of our Reveal XT Insertable Cardiac Monitor in the U.S. Launched in Europe in July 2007, the Reveal XT monitors AF patients 24-hours a day, every day for up to three years. There are a variety of ways to treat AF, but prior to the launch of Reveal XT, physicians had no means of gathering detailed data over an extended period on the progression of AF and the effect of treatment. Reveal XT gives new insight into patients' heart rhythms, which may help physicians to evaluate stroke risk and determine appropriate treatment options for their patients. The Reveal XT will be marketed as part of our AF Solutions business.

## Table of Contents

**Diagnostics and Monitoring.** Approximately 1.5 million people worldwide suffer from unexplained syncope. In almost 10 percent of patients, syncope has a cardiac cause; in 50 percent of patients, a non-cardiac cause; and in 40 percent of patients, the cause of syncope is unknown. It is a leading cause of emergency room visits. Syncope is difficult to diagnose as syncopal episodes are often too infrequent and unpredictable for detection with conventional monitoring techniques. Our Reveal DX, which launched in Europe in July 2007 and the U.S. in December 2007, is a device that is placed under the skin and continuously monitors the heart's electrical activity before, during, and after a syncopal event. With the information obtained from the Reveal DX, the physician can understand if the cause of syncope is cardiac related,

## Edgar Filing: MEDTRONIC INC - Form 10-K

which may help to appropriately manage the patient's arrhythmia. In July 2008, we announced that Reveal DX received Japanese regulatory approval and was designated by the Japanese government as a high-priority medical device. Reveal DX is the first insertable cardiac monitor to be introduced in Japan.

**Patient Management Tools.** We have three different patient management tools, CareLink, Paceart, and CardioSight Service. The Medtronic CareLink Network, monitor, and software (CareLink) help physicians and patients better manage chronic cardiovascular disease which is being treated by implantable device therapy. CareLink enables patients to transmit data from their pacemaker, ICD, or CRT using a portable monitor that is connected to a standard telephone line. Within minutes, the patient's physician and nurses can view the data on a secure Internet website. The information, which is comparable to that provided during an in-clinic device follow-up visit, provides the physician with a view of how the device and patient's heart are operating. The system provides an efficient, safe and convenient way for specialty physicians to remotely monitor the condition of their patients and, if needed, make adjustments to medication or prescribe additional therapy. It also saves patients time by potentially eliminating some in-office visits. For patients implanted with devices featuring Conexus Wireless Telemetry, clinicians can schedule routine follow-ups to occur automatically while the patient sleeps, and program the device to send a CareAlert notification to physicians wirelessly and automatically, providing the potential for treatment decisions before the condition worsens. Today, the Medtronic CareLink Network is being utilized in more than 3,000 clinics and hospitals, and more than 360,000 patients are being monitored. In June 2007, CareLink was launched in Europe, and is now currently available in the U.S., Canada, and Western Europe, and is being piloted in other parts of the world including Japan and Australia.

In September 2008, we announced both FDA and CE Mark approval for our Lead Integrity Alert (LIA) software. LIA was designed to provide patients with certain Medtronic defibrillators and defibrillator leads with more advance notice via an audible sound of a potential lead fracture that could result in an unnecessary shock. In November 2008, the journal *Circulation* published results from a study of about 16,000 patients that showed our LIA significantly improves early identification of potential implantable ICD lead fractures. LIA offers added protection for ICD patients through more frequent audible alarms and is the first continuous ICD monitoring technology that triggers real-time device changes to reduce unnecessary shocks that could result from potential lead fractures.

For more than 20 years, the Paceart System has led in the development of information solutions for device clinic management, including activities such as automating patient scheduling, correspondence and reporting. Paceart supports a common workflow by organizing and archiving data for cardiac devices from all major device manufacturers, serving as the central hub for patients' device data. In addition to automatically downloading data from the Medtronic CareLink Network, Paceart can automatically receive data from the Medtronic 2090 Programmer, using SessionSync technology. Paceart acts as the gateway for managing clinics' device data, receiving registration and scheduling data from, and sending patient and device data to more than 15 of the leading electronic health record and practice management systems. Paceart can interface with any HL7-compatible system and is actively sharing data with such industry leaders as athenahealth, EPIC, GEMMS, and NextGen Healthcare, among others. Today, more than 1,100 clinics are using the Paceart System to streamline clinicians' daily activities and better serve 1.5 million patients.

The third patient management tool we offer is the Medtronic CardioSight Service, which is an in-clinic data access tool available to physicians treating heart failure patients who have one of several Medtronic CRT-D or ICD devices. CardioSight provides clinically valuable, device-derived information to help specialty physicians discern the status of the heart failure patient's symptoms. The CardioSight Reader gives insight into a patient's condition without using a device programmer. Within minutes of downloading device information using the reader, a Heart Failure Management Report or Cardiac Compass Trends Report is available to the clinic and can be added to the patient chart before the physician consults with the patient.

---

### Table of Contents

#### ***Customers and Competitors***

The primary medical specialists who use our implanted cardiac rhythm devices include electrophysiologists, implanting cardiologists, heart failure specialists, and cardiovascular surgeons. We hold the leading market position among implantable cardiac rhythm device manufacturers. Our primary competitors in the CRDM business are Boston Scientific Corporation, St. Jude Medical, Inc., Biotronik, Inc., and Sorin Group.

#### **Spinal**

Our Spinal business is a leading supplier for innovative medical devices and implants used in the treatment of the spine. Today we offer a wide range of products and therapies to treat a variety of conditions of the spine.

#### ***Conditions Treated***



## Edgar Filing: MEDTRONIC INC - Form 10-K

Our Spinal business offers products for treatment of many spinal conditions, including those listed below.

**Herniated Disc** A disc herniation occurs when the inner core of the intervertebral disc bulges out through the outer layer of ligaments that surround the disc. This tear in the outer layer of ligaments causes pain in the back at the point of herniation. If the protruding disc presses on a spinal nerve, the pain may spread to the area of the body that is served by that nerve. The terms ruptured, slipped, and bulging are also commonly used to describe this condition.

**Degenerative Disc Disease** As part of the natural aging process, intervertebral discs lose their flexibility and shock absorbing characteristics. The ligaments that surround the discs become brittle and easier to tear. At the same time, the inner core of the disc starts to dry out and shrink. Over time, these changes can cause the discs to lose their normal structure and/or function.

**Spinal Deformity** When viewed from behind, the human spine appears straight and symmetrical. When viewed from the side, however, the spine is curved. Some curvature in the neck, upper trunk, and lower trunk is normal. These curves help the upper body maintain proper balance and alignment over the pelvis. The term deformity is used to describe any variation in this natural shape. One form of spinal deformity, scoliosis, involves a lateral, or side-to-side, curvature of the spine. The vertebrae rotate along with the spine as a consequence of a scoliotic curve. Depending on the severity of the curve, a scoliotic spine may create asymmetries in the shoulders, thoracic spine, and pelvis, leading to an imbalance of the trunk and significant disfigurement.

**Spinal Tumors** Tumors or cancers of the spine and spinal cord are relatively rare. Three types of tumors affect the spine and spinal cord: primary benign tumors, primary malignant tumors, and metastatic tumors. The term primary is used to designate a tumor originating from actual spine cells. Secondary spinal tumors, or cancers, which are more commonly called metastases, spread from other organs in the body.

**Trauma/Fracture** Trauma to the spine refers to injury that has occurred to bony elements, soft tissues, and/or neurological structures. Stability to the spinal column can be compromised when bony elements are injured or there is disruption to soft tissues such as ligaments. Instability causes the back to become unable to successfully carry normal loads, which can lead to permanent deformity, severe pain, and, in some cases, catastrophic neurological injuries. Most often the instability comes from a fracture in one of the bony parts of the vertebra. Osteoporosis, a condition characterized by loss of bone mass and structural deterioration of bone tissue, can lead to bone fragility and an increased susceptibility to fracture.

**Stenosis** A condition caused by a gradual narrowing of the spinal canal, stenosis results from degeneration of both the facet joints and the intervertebral discs. Bone spurs, called osteophytes, which develop because of the excessive load on the intervertebral disc, grow into the spinal canal. The facet joints also enlarge as they become arthritic, which contributes to a decrease in the space available for the nerve roots.

7

---

### Table of Contents

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:

Our Spinal products include thoracolumbar, cervical and interbody devices that are employed utilizing the most modern surgical techniques, including the latest Minimal Access Spinal Technologies (MAST) along with bone growth substitutes, and devices for vertebral compression fractures and spinal stenosis.

**Spinal Instrumentation.** Each year approximately 25 million Americans experience back pain that is severe enough to visit a healthcare professional. Of the approximately 25 million Americans, 14 million endure a significant impairment of activity. We are committed to providing spinal surgeons with the most advanced options for treating low back pain and other spinal conditions.

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. Spinal fusions, which are currently one of the most common types of spine surgery, join two or more vertebrae to eliminate pain caused by movement of the unstable vertebrae. 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 biologic products, which include bone growth substitutes, dowels and wedges.

**Minimal Access Spinal Technologies (MAST).** We have developed a series of MAST products that facilitate safe, reproducible access to the spine with minimal disruption of vital muscles and complementary structures. These techniques involve the use of advanced navigation and instrumentation to allow surgeons to operate with smaller incisions and less tissue damage than traditional surgeries, thus reducing pain and

blood loss and improving recovery periods.

Our expanding portfolio of minimally invasive spinal technologies includes the CD HORIZON SEXTANT II System, a next-generation METRx System, to treat herniated discs and allow minimally invasive access for fusion procedures and the MAST QUADRANT Retractor System a retractor that allows access to complex degenerative pathology. These products are also part of our complete minimally invasive solution for Direct Lateral Interbody Fusions (DLIF). Our NIM-ECLIPSE Spinal System adds advanced neuromonitoring capabilities, an intuitive display, and an easy-to-use interface to this suite of products.

**Biologics.** Our INFUSE Bone Graft, used in lumbar spinal fusion, contains a recombinant human bone morphogenetic protein, or rhBMP-2, that induces the body to grow its own bone, eliminating the need for a painful second surgery to harvest bone from elsewhere in the body. In Europe, INFUSE Bone Graft is marketed as InductOs Bone Graft for spinal fusion. We also offer INFUSE Bone Graft for the treatment of certain types of acute, open fractures of the tibial shaft, a long bone in the lower leg, as well as certain oral maxillofacial indications.

In April 2007, we began to market INFUSE Bone Graft for certain oral maxillofacial and dental regenerative bone grafting procedures. It is estimated that more than 350,000 bone grafting procedures of this type are performed in the U.S. each year. Medtronic has also submitted a PMA with the FDA for a posterolateral spinal indication for Amplify rhBMP-2 Matrix.

---

## Table of Contents

**Aging Spine.** During the third quarter of fiscal year 2008, we acquired Kyphon Inc. (Kyphon), a public company, and it became our wholly owned subsidiary. Kyphon develops and markets medical devices designed to restore and preserve spinal function in aging patients using minimally invasive technology. Kyphon's primary products are balloon kyphoplasty devices for the treatment of vertebral compression fractures caused by osteoporosis, trauma or cancer, and interspinous process devices (IPD) for treating the symptoms of lumbar spinal stenosis (LSS).

In the U.S., Kyphon's X-STOP IPD device provides us with the first FDA-approved minimally invasive device for the treatment of mild to moderate LSS patients. In Europe, both the X-STOP and the next generation Aperius PercLID device are available for the treatment of LSS. This degenerative condition can cause compression of the spinal cord and nerves in the lower back, leading to back and leg pain or numbness that can affect mobility. An estimated 875,000 Americans are diagnosed with LSS each year, and more than two million Americans currently suffer from this disease. In October 2008, we announced the U.S. launch of the X-STOP PEEK IPD System, the first IPD device approved by the FDA that offers a PEEK-Bone interface for treating the symptoms of LSS. PEEK, or polyetheretherketone polymer, is a biomaterial widely accepted for spinal applications.

### ***Customers and Competitors***

The primary medical specialists who use our Spinal products are spinal surgeons, orthopedic surgeons, neurosurgeons, and interventional radiologists. Our competitors in the Spinal business include Johnson & Johnson, Synthes-Stratec, Inc., Stryker Corporation, Zimmer, Inc., NuVasive Inc., and over 200 small and physician owned companies.

### **CardioVascular**

Our CardioVascular business offers a comprehensive line of minimally invasive products and therapies to treat coronary artery disease, abdominal and thoracic aortic aneurysms, peripheral vascular disease, and heart valve disorders.

#### ***Conditions Treated***

Our CardioVascular business offers minimally invasive products for the treatment of the following conditions.

**Coronary artery disease** deposits of cholesterol and other fatty materials (plaque) on the walls of the heart's arteries, causing narrowing or blockage of the vessel and reducing the blood supply to the heart. Blockage in a coronary artery can prevent the heart from receiving sufficient oxygen, which can impair heart function, potentially resulting in a heart attack.

**Peripheral vascular disease** narrowing or blockage of arteries outside the heart, impeding blood supply to the brain, legs, and other vital organs.

**Abdominal and Thoracic aortic aneurysm (AAA/TAA)** an aneurysm is a dangerous bulge or weakening of the body's main artery that can rupture with fatal consequences if left untreated.

Heart valve disorders – diseased or damaged heart valves can restrict blood flow or leak, which limits the heart's ability to pump blood, causing the heart to work harder to meet the needs of the circulatory system.

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

---

Table of Contents

Our CardioVascular products include coronary and peripheral stents and related delivery systems, endovascular stent graft systems, distal embolic protection systems, perfusion systems which oxygenate and circulate a patient's blood during arrested heart revascularization surgery, positioning and stabilization systems for beating heart revascularization surgery, products for the repair and replacement of heart valves, surgical ablation products, and a broad line of balloon angioplasty catheters, guide catheters, guidewires, diagnostic catheters and accessories.

***Percutaneous Coronary Intervention (PCI).*** If a blockage in a coronary artery prevents the heart from receiving sufficient oxygen, the heart cannot function properly and a heart attack may result. Coronary artery disease is commonly treated with balloon angioplasty, a procedure in which a special balloon is threaded through the coronary arteries to the site of the blockage, where it is inflated, pressing the obstructive plaque against the wall of the vessel to improve blood flow.

Following balloon angioplasty, physicians often place coronary stents at the blockage site to prop open diseased arteries to maintain blood flow to the heart. Stents are cylindrical, wire-mesh devices small enough to be inserted into coronary arteries. Our Driver and Micro-Driver bare metal stent systems are composed of an advanced cobalt-based alloy, which surpasses the limitations of stainless steel by creating very strong, ultra-thin struts that offer excellent flexibility and vessel support. In February 2009, Driver Sprint received CE Mark approval and is currently being introduced in international markets. Driver Sprint features advanced balloon technology that builds on our existing Driver platform.

Drug-eluting stents (DES) are designed to inhibit the re-narrowing or re-clogging of arteries, known as restenosis, that can occur after PCI. In February 2008 we announced FDA approval and the initiation of the U.S. launch of the Endeavor DES (Endeavor) drug-eluting coronary stent system. Endeavor combines our advanced Driver cobalt alloy stent, zotarolimus (a sirolimus analogue), and a biomimetic polymer coating that controls the release of the drug into the vessel wall. Endeavor received Shonin approval in March 2009 and was launched in Japan in May 2009.

In May 2002, we entered into an agreement with Abbott Laboratories (Abbott) granting us co-exclusive use of Abbott's proprietary immunosuppressant drug zotarolimus, as well as the phosphorylcholine coating Abbott has licensed from Biocompatibles International PLC for use in conjunction with zotarolimus. The term of the agreement covers the life of the patents necessary to use the drug alone or in conjunction with the coating. Clinical and preclinical studies have shown that this proprietary biocompatible polymer, which mimics the outer membrane of a red blood cell, is safe and thrombo-resistant.

In November 2007, we received CE Mark approval for the Sprinter Legend Semicompliant Rapid Exchange Balloon Dilatation Catheter for use in coronary angioplasty procedures. The Sprinter Legend provides the latest innovations in balloon technology, including the unique 1.25 mm ZeroFold balloon, and is designed to address the most technically difficult lesions in coronary angioplasty procedures.

In November 2008, we launched our portfolio of angioplasty products in the U.S. on the rapid exchange (RX) delivery system, including the Endeavor, the Driver and MicroDriver bare-metal stents, and the Sprinter Legend and NC (non-compliant) Sprinter balloon catheter systems. Used in angioplasty procedures to treat coronary artery disease, RX is a short-, single-wire delivery system that can be used by one operator.

Worldwide, Medtronic has approximately 16,000 Endeavor patients enrolled in its multiple clinical trials, and the growing volume of positive data and number of patients with long-term follow-up continues to reinforce the stent's favorable safety and efficacy profile. Ultimately, the ENDEAVOR clinical program will enroll more than 22,500 patients followed to five years; approximately 16,630 of these patients will receive an Endeavor stent.

Endeavor Resolute DES (Endeavor Resolute) is a next-generation DES featuring BioLinx, the first polymer designed specifically for use on a DES. The BioLinx polymer is designed to extend the duration of drug exposure in the vessel - an elution profile of potential relevance to patients that physicians consider to be at high risk of needing a repeat procedure - without trading off polymer biocompatibility. In October 2007 we announced the CE Mark approval and the international launch of Endeavor Resolute. Endeavor Resolute is now commercially available in more than 100 countries across Europe, Asia, the Middle East and Africa - making Medtronic the first company to offer two internally developed DES options for the treatment of coronary artery disease.

Table of Contents

The Endeavor Resolute clinical program will enroll more than 6,000 patients worldwide across a series of single-arm and randomized controlled trials.

**Peripheral Stents.** According to the Peripheral Arterial Disease Coalition, Peripheral Arterial Disease (PAD) of the lower extremities affects approximately eight million people in the United States, although many patients are unaware of their condition or the seriousness of it. PAD patients have a two- to six-fold increase in cardiovascular mortality and a significantly increased risk of amputation, disability and diminished quality of life, the PAD Coalition reports.

In 2008 we commenced enrollment in two PAD studies to evaluate the treatment of iliac artery lesions with our stents. The Complete SE stent is currently being evaluated in an IDE-approved clinical trial for use in the treatment of iliac artery lesions in subjects with symptomatic and asymptomatic PAD. The Complete SE Iliac Registry is a non-randomized, prospective study designed to enroll 60 subjects. The primary study endpoints are major adverse events (MAEs) at 30 days and nine months. With 12 U.S. sites participating, enrollment is complete. Additionally, the balloon-expandable Assurant Cobalt stent is currently being evaluated in an IDE-approved clinical trial as a treatment for iliac artery lesions in subjects with symptomatic PAD. Initiated in October 2008, this study is a non-randomized, prospective, single-arm trial with an enrollment target of 123 subjects at 20 U.S. sites. The primary endpoint of the study is MAEs at nine months.

In January 2009, we announced the first enrollment in the FDA-approved clinical trial of our self-expanding (SE) Complete SE stent for the treatment of PAD in the superficial femoral artery (SFA). The SFA study is a prospective, multicenter, single-arm trial planned to enroll 178 subjects at up to 30 sites globally. Enrolling patients with symptomatic PAD in the SFA, the study has primary endpoints of MAEs and patency of the stent at 12 months.

**Endovascular Stent Grafts.** Our CardioVascular product line also includes a range of endovascular stent grafts including the market-leading Talent and Endurant Stent Grafts for minimally invasive AAA repair and the Talent Thoracic and Valiant Thoracic Stent Grafts for TAA repair. Present in an estimated 20 million people worldwide and 1.3 million people in the U.S., an AAA is a dangerous bulge or weakening of the body's main artery that can rupture with fatal consequences if left untreated. This is compared to over 1.25 million people worldwide and 150,000 people in the U.S. with a TAA. Medtronic now has more than 10 years of clinical experience with its endograft implants, by far the most clinical experience in the endovascular industry. More than 160,000 patients have been treated worldwide with Medtronic stent grafts for AAA or TAA.

In June 2008, we initiated the U.S. launch of the Talent Abdominal Stent Graft System (Talent AAA). Talent AAA is a leading stent graft with more than 45,000 worldwide implants to date. The stent graft is specifically indicated for endovascular repair (EVAR) of abdominal aortic and aorto-iliac aneurysms. It expands the indication for EVAR with a proximal aortic neck length requirement of 10 mm or greater and a proximal aortic neck angulation of 60 degrees or less. Talent AAA is available in diameters of up to 36 mm, as well as flared and tapered iliac limbs of 8 mm to 24 mm. This indication enables physicians to treat a broader range of patients than with other abdominal stent graft systems available in the U.S. In November 2008, we announced the U.S. market launch of the Talent AAA on the Xcelarent Hydro Delivery System. Now available globally, the Xcelarent Hydro Delivery System features a hydrophilic coating which attracts and holds water at the device surface to reduce friction and ease implantation.

In June 2008, we announced the FDA approval and commercial launch of our Talent Thoracic Stent Graft with the CoilTrac Delivery System in the U.S. The Talent Thoracic Stent Graft (Talent TAA) received Shonin approval in April and will launch in Japan in May, 2009. Talent TAA expands the indication for thoracic stent grafting by as much as 25 percent due to the introduction of smaller and larger diameter stent grafts. In October 2008, we announced the U.S. market launch of the Talent TAA on the Xcelarent Delivery System, which makes minimally-invasive treatment of thoracic aortic aneurysms easier to perform.

In July 2008, we announced the international market launch of the Endurant Abdominal Stent Graft System (Endurant) and the first implants of this next-generation medical device in the U.S. clinical trial. Endurant's precise deployment, flexibility, and low delivery profile are designed for patients whose aortas are highly angulated or whose aneurysms have short necks. Patients with these complex anatomies would previously have had no choice but watchful waiting or open surgical repair, in which the abdomen is opened and major organs temporarily moved in order to access the aorta. The U.S. clinical trial of Endurant is designed to evaluate the device's safety and effectiveness in the endovascular treatment of abdominal aortic aneurysms. As the pivotal trial for Endurant, it will be used to seek FDA approval of the device. The study will enroll 150 patients at up to 30 U.S. sites. Enrollment in the study is now complete.

Table of Contents

**Coronary Artery Bypass Surgery.** When physicians determine that they cannot effectively treat a blockage in a coronary artery using balloon angioplasty or a stent, they often turn to cardiac surgery to address the problem. The most common surgical procedure used to treat blockage in a coronary artery is a Coronary Artery Bypass Graft (CABG). In a CABG procedure, surgeons re-route the blood flow around the blockage by attaching a graft, usually from an artery or vein from another part of the patient's body, as an alternative pathway to the heart. There are two primary techniques, arrested heart surgery and beating heart surgery.

**Arrested Heart Surgery.** In a conventional coronary artery bypass 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.** As an alternative to conventional arrested heart coronary artery bypass surgery, physicians are performing CABG on the beating heart to avoid the complexity and potential risks of arresting the heart. To assist physicians performing beating heart surgery, we offer positioning and stabilization technologies. These technologies include our Starfish 2 and Urchin heart positioners, which use suction technology to gently lift and position the beating heart to expose arteries on any of its surfaces. These heart positioners are designed to work in concert with our Octopus tissue stabilizer, which holds a small area of the cardiac surface tissue nearly stationary while the surgeon is suturing the bypass grafts to the arteries. In June 2006, we introduced the Octopus Evolution tissue stabilizer, the latest in a 10-year series of innovative cardiac surgery instruments. It is currently estimated that beating heart surgeries make up approximately 20 percent of the estimated 270,000 coronary artery bypass surgeries that are performed in the U.S. each year.

**Surgical Ablation.** Our Cardioblate surgical ablation systems (CSAS), which includes the Cardioblate LP Surgical Ablation System and Cardioblate Navigator Tissue Dissector, allow cardiac surgeons to create ablation lines during cardiac surgery. In November 2006, we announced FDA approval to initiate the Feasibility of the Lone Atrial Fibrillation Clinical Trial to evaluate the use of the CSAS thoroscopically in paroxysmal atrial fibrillation (AF) patients.

**Surgical 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. The valve market continues to shift from mechanical to tissue valves, which is beneficial to us due to our broad selection of tissue valve products. Our Mosaic bioprosthetic heart valve is a reduced-profile valve engineered from porcine tissue incorporating a proven flexible stent. The low profile and flexibility of the stent offer benefits to the surgeon when implanting the valve. Other tissue product offerings include the Freestyle stentless and Hancock II stented valves. Our mechanical heart valve offerings include the Medtronic Hall, the ADVANTAGE and the ADVANTAGE Supra bileaflet valves. Our valve repair products include the Duran Flexible and CG Future Band and CG Composite Annuloplasty Systems. In May 2008, we announced the U.S. launch of the Profile 3D Annuloplasty Ring used by heart surgeons to repair rather than replace a failing mitral valve. To promote natural function, the Profile 3D ring design is based on the geometry of the saddle-shaped human mitral annulus. Data suggest that nature conserves the saddle-shaped annulus for a mechanical benefit. Specifically, leaflet stress can be related to saddle height, which could affect long-term durability of the repair.

**Transcatheter Heart Valves.** Transcatheter valve 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, thus eliminating the need to open the chest. Traditionally, open heart surgery has been required to correct the problem and it is not unusual for a patient to undergo multiple, open-heart surgeries during their lifetime.

---

Table of Contents

In October 2006, our Melody Transcatheter Pulmonary Valve and Ensemble Transcatheter Delivery System (Melody TCV) received European CE Mark making it the first transcatheter valve in the world to receive such an approval. The system is the first of its kind to treat patients with congenital structural heart disease requiring pulmonary heart valve replacement. According to the American Heart Association, congenital heart defects are the No. 1 birth defect worldwide. In the U.S. alone, more than 36,000 babies are born each year with a congenital heart defect. Approximately 22 percent of these babies have defects disrupting the blood flow from the right ventricle to the pulmonary artery. In November 2008, the first U.S. clinical trial data on the Melody TCV were presented at the American Heart Association Meeting. The results involved 66 patients and showed a high acute procedural success rate of 98 percent. At six-months follow up, maintenance of excellent valve competence was demonstrated as was a corresponding, clinically-significant, reduction of more than 18 percent in right ventricular volume.

In February 2009, we acquired Ventor Technologies, Ltd. (Ventor) and in April 2009, we acquired CoreValve, Inc. (CoreValve), both privately held companies. CoreValve and Ventor have developed transcatheter, aortic valve replacement technologies. CoreValve's ReValving System, which received CE Mark approval in 2007, utilizes a transfemoral approach and is comprised of a porcine pericardial tissue valve, mounted on a self-expanding frame and implanted via a low profile (18F) delivery catheter. Ventor has developed a transapical product, the Ventor Embracer, which is under clinical investigation in Europe. Ventor is also developing a next generation percutaneous transfemoral technology. These complementary technologies offer compelling clinical benefit to distinctly different subsets of patients with aortic stenosis

who are at high or prohibitive risk for surgery.

### ***Customers and Competitors***

The primary medical specialists who use our catheter-based products for treating coronary artery disease are interventional cardiologists, while products treating peripheral vascular disease and aortic aneurysms may be used by interventional radiologists, vascular surgeons, cardiac surgeons and interventional cardiologists. Our primary competitors in the coronary and peripheral vascular business are Boston Scientific Corporation, Johnson & Johnson, and Abbott Laboratories. Our primary competitors in the endovascular business are Cook, Inc. and W. L. Gore & Associates, Inc. The principal medical specialists who use our cardiac surgery products are cardiac surgeons. Our primary competitors in the structural heart disease business are Edwards LifeSciences Corporation, Boston Scientific Corporation, Johnson & Johnson, St. Jude Medical, Inc., Terumo Medical Corporation, and Sorin S.p.A.

### **Neuromodulation**

Our Neuromodulation business develops, manufactures, and markets devices for the treatment of neurological, urological, and gastroenterological disorders. We pioneered the use of site-specific neurostimulation and targeted drug delivery to modulate nervous system function. Through collaborative efforts with our customers we have developed a unique portfolio of therapeutic technologies for the treatment of debilitating chronic diseases that represent large, unmet medical needs.

### ***Conditions Treated***

Our Neuromodulation business offers products for the treatment or diagnosis of the conditions described below.

Pain Management including neurostimulation and implantable drug delivery systems for chronic pain.

Movement Disorders including deep brain stimulation for Parkinson's disease, essential tremor, dystonia and intrathecal baclofen (ITB) therapy for spasticity.

Urological and gastroenterological disorders including neurostimulation for overactive bladder and urinary and fecal incontinence, radio frequency ablation for benign prostatic hyperplasia (BPH or enlarged prostate), and neurostimulation for gastroparesis.

Psychological Disorders including deep brain stimulation for obsessive compulsive disorder (OCD).

13

---

### **Table of Contents**

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:

Neuromodulation products consist of therapeutic devices, including implantable spinal cord stimulation systems used to treat intractable chronic pain; deep brain stimulation systems to treat movement disorders like Parkinson's disease, as well as OCD; implantable intrathecal drug delivery systems for intractable spasticity and intractable chronic pain; sacral nerve stimulation systems to treat overactive bladder and urinary incontinence; a product for the treatment of BPH, or enlarged prostate; and a gastric stimulator for gastroparesis.

***Neurostimulators for Chronic Pain.*** We offer the largest portfolio of neurostimulation systems, including rechargeable and non-rechargeable devices, along with the largest selection of leads. In February 2008, we announced the worldwide launch of the RestoreULTRA neurostimulation systems for the treatment of chronic pain. Chronic pain affects an estimated 75 million people in the U.S. alone. This rechargeable neurostimulator, the most advanced device in our market-leading family of RESTORE devices, is the smallest and thinnest 16-electrode rechargeable neurostimulator available from Medtronic. Furthermore, for the first time with any neurostimulator, the patient programmer includes an innovative new feature called TARGETmyStim. This feature allows patients to make appropriate and immediate adjustments in their stimulation in order to best address normal fluctuations in pain, including changing pain patterns. By using the remote control programmer, patients can fine-tune their stimulation to specific sites up and down the spinal cord and increase/decrease the intensity of the electrical impulses. These adjustments allow the patient to customize their pain therapy in a way that was previously only possible with a physician programmer during an office visit.

## Edgar Filing: MEDTRONIC INC - Form 10-K

Our portfolio of neurostimulators also includes RestoreADVANCED (rechargeable) and PrimeADVANCED (non-rechargeable) neurostimulation systems. All of the neurostimulation systems are implanted under the skin and have up to two leads with eight electrodes each that deliver electrical pulses to the spinal cord. Based on individual patient need, the positioning of the electrodes can be customized to deliver stimulation directly to the target area on the spinal cord, and in doing so, block pain signals from reaching the brain.

A continuing major initiative in fiscal year 2009 was the establishment of higher levels of evidence for our therapies' efficacy and cost-effectiveness. In November 2008, the scientific journal *Neurosurgery* published 24-month data from a study known as PROCESS showing that spinal cord stimulation provides sustained, significant improvement in otherwise intractable, chronic leg pain, quality of life and functional capacity out to 24 months of therapy.

**Implantable Drug Delivery Systems.** Our portfolio of intrathecal drug delivery systems consist of the only programmable, implantable drug pump available in the U.S. and a catheter that deliver small quantities of drug directly into the intrathecal space in the spine. These devices are used to treat chronic, intractable pain and severe spasticity of cerebral or spinal origin.

Medtronic ITB Therapy is indicated for the management of severe spasticity of cerebral and spinal origin, including stroke, cerebral palsy, brain injury, spinal cord injury, and multiple sclerosis. It uses our SynchroMed II Implantable Infusion System, which consists of a programmable, implanted drug pump connected to a thin tube, or catheter, to deliver precise amounts of a muscle relaxant manufactured by Novartis Corporation under the trade name Lioresal® Intrathecal (baclofen injection) directly to the intrathecal space—the fluid-filled area surrounding the spinal cord, the drug's site of action. By targeting the spinal cord, ITB therapy reduces spasticity with smaller amounts of medication than would be required if taken orally. Intrathecal infusion, which bypasses the body's blood-brain barrier, also minimizes systemic side-effects.

14

---

### Table of Contents

**Deep Brain Stimulation (DBS) Systems.** Deep brain stimulation is approved for treating the symptoms of movement disorders like Parkinson's disease or psychological disorders like treatment resistant OCD. DBS therapy uses an implantable medical device akin to a cardiac pacemaker to deliver carefully controlled electrical pulses to precisely targeted areas of the brain. Continuous stimulation of these areas blocks the signals that cause the disabling motor symptoms. In the case of OCD, DBS is believed to influence the circuit of the brain involved in moods.

In December 2008, data from a prospective, randomized, double-blind pivotal study designed to evaluate the use of Medtronic DBS for epilepsy was presented at the American Epilepsy Society Annual Meeting. The study, known as SANTE (Stimulation of the Anterior Nucleus of the Thalamus in Epilepsy), included 110 patients at 17 U.S. centers and showed DBS significantly reduced seizure frequency among patients with medically refractory epilepsy with partial-onset seizures, a form of the neurological condition that does not respond well to antiepileptic drugs. According to the Epilepsy Foundation, epilepsy and seizures affect more than three million Americans of all ages, at an estimated annual cost of \$12.5 billion in direct and indirect costs. Despite trying a range of treatment options, about one-third of people with epilepsy cannot adequately control their seizures or tolerate other available therapies. The unpredictability of seizures affects daily activities and disrupts school days, work responsibilities and social functioning. Based on the results of this study, we plan to submit a PMA application to the FDA seeking approval for Medtronic DBS Therapy for epilepsy in early fiscal year 2010.

In February 2009, we announced the FDA approval for a humanitarian device exemption (HDE) for our Reclaim DBS therapy for chronic, severe OCD. Reclaim DBS is the first medical device to receive U.S. FDA approval for the treatment of OCD and is also the first psychiatric indication to be approved for DBS. While OCD is estimated to affect one in 50 adults in the U.S., it is anticipated that DBS therapy will be appropriate for a small subset of the patient population, below the threshold of 4,000 patients per year allowed under an HDE. Medtronic plans to make Reclaim DBS therapy for OCD available in the U.S. by mid-2009 under the HDE.

**Urology and Gastroenterology Devices.** Our therapeutic products for urology and gastroenterology include the InterStim Therapy for the treatment of overactive bladder and urinary incontinence; Prostiva RF Therapy, which uses low-level radio frequency energy to treat BPH, or enlarged prostate; and Enterra Therapy for the treatment of gastroparesis.

In October 2008, we submitted our PMA application with the FDA for InterStim Therapy for the treatment of fecal incontinence. InterStim Therapy is a reversible treatment for patients with fecal incontinence after conservative treatments have failed. This therapy has been available in markets outside of the U.S. since 2000 where it has been used by more than 6,000 patients. Fecal incontinence is the inability to control your bowels and is a debilitating condition that is often underreported and stigmatized. According to the National Institutes of Health, more than 5.5 million Americans have fecal incontinence.

### ***Customers and Competitors***

## Edgar Filing: MEDTRONIC INC - Form 10-K

The primary medical specialists who use our Pain Management and Movement Disorders products are neurosurgeons, neurologists, pain management specialists, psychiatrists, and orthopedic spine surgeons. The primary medical specialists who use our urology and gastroenterology products are urologists, urogynecologists, and gastroenterologists. Our primary competitors for pain management and movement disorders are Boston Scientific Corporation and St. Jude Medical, Inc. Our primary competitors for urology and gastroenterology products are Boston Scientific Corporation, Urologix, Inc., and American Medical Systems, Inc.

15

---

### Table of Contents

#### **Diabetes**

Our Diabetes business develops advanced diabetes management solutions. We are the world leader in integrated diabetes management systems, insulin pump therapy, continuous glucose monitoring systems and therapy management software, and are committed to providing improved tools and technologies to help people with diabetes live longer, healthier lives.

#### ***Conditions Treated***

Our Diabetes business offers solutions for the treatment of diabetes the inability to control glucose (blood sugar) levels resulting from the body's failure to produce or properly use insulin.

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

Our Diabetes products help patients control their glucose levels. Diabetes afflicts roughly 250 million people worldwide, and almost 24 million people in the U.S. Currently, our products serve the insulin-dependent population, approximately six million people in the U.S. The key to managing diabetes is to maintain tight control of glucose levels. If not well-managed, diabetes can lead to blindness, kidney failure, amputation, impotence and heart failure. More than \$174 billion is spent annually on diabetes and its complications, including \$116 billion in direct medical costs.

***Integrated Diabetes Management Systems.*** The MiniMed Paradigm REAL-Time System (Paradigm REAL-Time System) is the first and only integrated insulin pump and continuous glucose monitoring system. The Paradigm REAL-Time System is made up of two components, a REAL-Time Continuous Glucose Monitor (CGM), and a Paradigm insulin pump. The system receives glucose readings every five minutes from a glucose sensor worn on the body. This REAL-Time glucose information is displayed on the insulin pump, allowing patients to take immediate action to improve their glucose control after taking a confirmatory fingerstick. The Paradigm REAL-Time System is indicated for any patient seven years of age or older.

Integrating an insulin pump with REAL-Time CGM is a major step toward the development of a closed-loop insulin delivery system that may one day mimic some functions of the human pancreas. We are testing future systems that employ advanced scientific algorithms to proactively recommend insulin dosages to patients. Through this process, we anticipate developing an external, closed-loop system designed to simplify and improve patient diabetes management.

***External Insulin Pumps.*** Our insulin pumps are primarily used by patients with type 1 diabetes, which occurs when the pancreas stops producing insulin. In order to survive, people with type 1 diabetes must administer insulin on a daily basis. Our therapies are also helpful in managing insulin-dependent type 2 diabetes, which results from the body's inability to produce enough insulin or properly use the insulin.

Our MiniMed Paradigm insulin pumps are currently the leading choice in insulin pump therapy in the U.S. About the size of a cell phone, and worn in a pocket or on your belt like a phone or MP3 player, insulin pumps calculate complex diabetes math and recommend precise insulin dosages to help patients manage their disease without daily insulin injections. Because insulin pump therapy delivers precise micro-doses of insulin to the body, it helps diabetes patients control their glucose, offering both short- and long-term health benefits. MiniMed Paradigm insulin pumps are indicated for all patients requiring insulin.

16

---

### Table of Contents

***Continuous Glucose Monitors (CGM).*** Medtronic's Personal CGM is patient owned and automatically displays the patient's latest glucose level every five minutes, indicates when glucose is changing rapidly, graphically shows glucose variability and sounds alerts based on predicted



## Edgar Filing: MEDTRONIC INC - Form 10-K

glucose levels, rate-of-change and/or glucose thresholds. Personal CGM is intended to help diabetes patients avoid dangerous high and low glucose levels and learn to maintain tighter glucose control 24 hours a day. Medtronic offers two Personal CGM product categories. Our Guardian REAL-Time System is a stand-alone Personal CGM device that monitors glucose levels for patients to better manage their diabetes. The MiniMed Paradigm REAL-Time System combines Personal CGM with insulin pump therapy to make the world's only integrated diabetes management system. Both systems are supported by the Medtronic CareLink Therapy Management Software.

Medtronic also offers physicians a Professional CGM product, the iPro CGM. Physicians send patients home wearing a tiny iPro recorder, which silently collects glucose data blinded to the patient. The data is uploaded in a physician's office to reveal glucose patterns and potential problems that often go undetected with today's standard glucose measurements like finger stick meters and A1c tests. The new iPro is smaller, simpler to use, lighter weight and less time consuming than previous Medtronic Professional CGM devices. There is no display or user interface for the patient and improved ergonomics give patients added freedom when wearing the device. Physician services associated with the iPro are reimbursed by Medicare in all 50 states, and have broad private insurance reimbursement.

**CareLink Therapy Management Software.** We also offer therapy management software solutions to help patients and their healthcare providers optimize their diabetes control and quality of life. These Web-based platforms consist of CareLink Personal software for patients and CareLink Pro software for healthcare providers. It allows patients to quickly and easily upload data from their diabetes management devices to a secure online database. Because the platform is totally integrated, healthcare providers can quickly and easily download patient data remotely in advance of the office visit. Both the patient and healthcare provider can save time to focus on optimizing therapy.

**Blood Glucose Meters.** Medtronic has an alliance with LifeScan, Inc., a Johnson & Johnson company, to distribute and co-market blood glucose meters developed by LifeScan for Medtronic patients in the U.S. Concurrently, we announced 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 outside the U.S. These meters wirelessly transmit blood glucose test results directly to our MiniMed Paradigm insulin pumps and GuardianREAL-Time Systems. Wireless communications make data entry easier and more convenient for patients.

### ***Customers and Competitors***

The primary medical specialists who use and/or prescribe our diabetes products are endocrinologists, diabetologists, and internists. Our most significant 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 segment manufactures and markets image guided surgery and intra-operative imaging systems that facilitate surgical planning during precision cranial, spinal, sinus and orthopedic surgeries. As a market leader in ENT and neurosurgery, we are changing the way surgery is performed with innovative, minimally invasive products and techniques that benefit both patients and surgeons.

---

### **Table of Contents**

#### ***Conditions Treated***

Our Surgical Technologies products are used in the treatment of the conditions described below.

ENT diseases and disorders, such as chronic sinusitis, chronic otitis media, hearing loss, Ménière's disease, thyroid diseases, and tumors of the head and neck.

Neurological diseases and disorders, including both pediatric and normal pressure hydrocephalus, traumatic brain injury, and spinal conditions.

A broad range of cranial, spinal, sinus, and orthopedic maladies through the use of computer-assisted navigation and imaging during surgery.

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

## Edgar Filing: MEDTRONIC INC - Form 10-K

Our primary Surgical Technologies products include powered tissue-removal systems, high-speed powered surgical drill systems to facilitate surgical access in the spine and cranium, fluid-control products including shunts for pediatric and normal pressure hydrocephalus and systems for the treatment of traumatic brain injury, a full line of cranial fixation devices that include both titanium and resorbable plates and screws, nerve monitoring systems, image-guided surgery systems, intra-operative imaging systems, a Ménière's disease therapy device, and a portfolio of products to treat benign snoring and obstructive sleep apnea.

**Chronic Rhinosinusitis (sinus infections).** For the surgical treatment of chronic sinus infections, we offer powered and manual instruments with a variety of blade configurations for removing soft tissue and bone. Our bioresorbable nasal packing and dressings, such as MeroGel Dressing and the recently introduced MeroPak CMC gel, aid in wound-healing and help reduce postoperative complications following these procedures. We also offer image-guided surgery and intra-operative imaging systems to improve safety and efficacy when surgeons operate near critical structures such as the brain and eyes. The FUSION EM system provides a robust, expandable system that may be used for virtually any ENT image guidance procedure.

**Chronic Otitis Media (ear infections).** For the treatment of chronic otitis media, we provide a wide range of middle ear ventilation tubes to facilitate middle ear ventilation and prevent fluid accumulation. We also offer powered instruments and drills, such as the M4 and Integrated Power Console System, to remove enlarged adenoid tissue, enable surgical access and remove diseased bone. Untreated chronic otitis media is the most common cause of hearing loss in children, which can impair learning and speech development. It can also spread to other areas of the head and neck and lead to serious complications.

**Hearing Loss.** To correct conductive hearing loss, we offer various types of implantable middle ear prostheses that replace missing bone(s) in the ear necessary to conduct sound. These products are malleable/trimmable and may be shaped by the surgeon to fit each particular patient's anatomy.

**Thyroid Disease.** For surgery related to thyroid disease, we offer the NIM-Response 3.0 Nerve Integrity Monitor, NIM-Neuro 3.0 Nerve Integrity Monitor, and NIM EMG Tubes. These products assist surgeons in identifying and continuously monitoring the recurrent laryngeal or vagus nerves during complicated, high-risk thyroid surgery. Since the actual nerve damage during surgery is much higher than perceived, using our nerve monitoring products in these procedures is a benefit to both the patient and the surgeon, reducing the risk of patient injury and enabling more precise, complete dissection.

---

### Table of Contents

**Ménière's Disease.** To alleviate debilitating vertigo associated with the inner ear condition known as Ménière's disease, we offer the portable, minimally invasive Meniett Low-Pressure Pulse Generator. Severe vertigo, which can cause nausea and vomiting, is considered by patients to be the most problematic and debilitating symptom of Ménière's disease, often affecting their ability to work or participate in daily activities. Using Meniett therapy, patients can self-administer their treatment at home or work for a few minutes each day by delivering low-pressure air pulses through a tube connected to an earpiece placed in the outer ear.

**Surgical Access and Cranial Fixation.** To facilitate surgical access in cranial, spinal and orthopedic procedures, we offer the Legend electric and pneumatic high-speed powered surgical drill systems. The Stylus system, our high-speed electric drill line, provides significant power in a small, ergonomic design. We recently introduced a procedure specific microdebrider for use in certain spine procedures. We also offer titanium and resorbable polymer plates and screw systems designed to provide for rigid fixation of the skull. In addition to plates and screws, our Durepair dura substitute is indicated for use as both an on-lay and suturable graft for repair of the dura skin layer.

**Hydrocephalus.** The Strata valve is an adjustable shunt system for the treatment of hydrocephalus, a condition characterized by an abnormal accumulation of cerebral spinal fluid in the brain. There are two primary forms of hydrocephalus; congenital or pediatric hydrocephalus, and normal pressure hydrocephalus, which afflicts the elderly. The Strata valve allows surgeons to non-invasively adjust the valve's performance level settings with an external magnetic adjustment device. This enables the surgeon to change the valve's performance characteristics over time without subjecting the patient to additional surgery. The shunt line also includes a wide assortment of nonadjustable valves.

**Brain Injury.** We also provide a large selection of external drainage and monitoring systems such as the Becker and Exacta and the newly introduced DUET systems as well as catheters that are used for the treatment of traumatic brain injury. These systems are designed to remove fluid from the brain in a controlled fashion to alleviate the build-up of intracranial pressure, which can be life threatening.

**Sleep Apnea.** Obstructive sleep apnea (OSA) is a disorder characterized by interruptions and cessations in breathing during sleep, which can occur up to hundreds of times a night. During fiscal year 2009, we greatly expanded our portfolio of treatments for sleep-disordered breathing. In July 2008, we acquired Restore Medical, Inc. (Restore Medical), a publicly traded company. Restore Medical's Pillar Palatal

Implant System (Pillar System) is an innovative, minimally invasive, implantable medical device used to treat the soft palate component of sleep breathing disorders, including mild to moderate OSA and snoring. Additionally, in December 2008, we announced the acquisition of InluENT Medical's Repose product line for the treatment of OSA. The Repose surgical devices advance the base of the tongue and the hyoid bone to prevent obstructions of the airway during sleep.

**Navigation.** We are one of the leaders in the field of computer-assisted surgery (CAS) and have installed approximately 2,500 StealthStation Treatment Guidance Systems in hospitals worldwide. In recent years, the pace of innovation in CAS has quickened considerably. We have developed and delivered new and updated hardware and software solutions to assist with varied surgeries including total joint replacements, minimally invasive spinal surgery, cranial tumor resection, biopsies, functional neurosurgery, and functional endoscopic sinus surgery. In June 2007, we acquired the O-Arm Imaging System (O-Arm), an intraoperative crossover technology enabling two-dimensional, multi-plane two-dimensional, and three-dimensional volumetric imaging. We continue to expand into new procedures leveraging navigation and imaging in existing cranial, spinal and ENT markets. Seamless integration of O-Arm with navigation is driving market adoption of navigation in minimally invasive spine procedures. New technologies such as electromagnetic (EM) navigation, advanced visualization tools and enhanced user interface design will enable new applications and drive adoption in existing and new markets.

#### ***Customers and Competitors***

Our primary customers for products relating to our ENT diseases and disorders are ENT surgeons and the hospitals and clinics where they perform surgery. The most significant competitors in this part of our Surgical Technologies business are Olympus Corporation and Stryker Corporation.

---

#### **Table of Contents**

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

Our primary customers for our computer assisted surgery products are hospitals and clinics. The primary competitors of our computer assisted surgery products are BrainLAB, Inc. and Stryker Corporation.

#### **Physio-Control**

We develop, manufacture, market and service external defibrillators, including manual defibrillator/monitors used by hospitals and emergency response personnel and automated external defibrillators (AEDs) used in commercial and public settings. In addition to the portfolio of external defibrillation and emergency response systems, we offer related data management solutions and support services.

#### ***Conditions Treated***

Our Physio-Control products are used in the treatment of the condition described below.

Sudden Cardiac Arrest (SCA) is a condition in which the heartbeat stops suddenly and unexpectedly. SCA is caused by life-threatening arrhythmias or abnormalities in the heart's electrical system.

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

**External Defibrillators.** Many victims of SCA could be saved if they had quicker access to AEDs. In the U.S., the survival rate for victims of sudden cardiac arrest is only about 5 percent because the average response time to an emergency call for help is six to twelve minutes. Chances of survival are reduced significantly if the victim is not treated within five minutes. In August 2004, results from the largest-ever clinical trial studying the outcomes of public access to defibrillation were published in the New England Journal of Medicine. The data indicated that the use of portable AEDs by trained volunteers can significantly improve the probability of saving lives that otherwise might have been lost to sudden cardiac arrest. Hospitals, emergency medical services (EMS) and targeted responders rely on LIFEPAK products in the most urgent cardiac emergencies. Our LIFEPAK series of external defibrillators are designed to adapt to the physical needs of the patient and surrounding emergency conditions enabling fast, smooth transitions from the care from EMS to the treatment at the hospital. Physio-Control offers a broad range of life-saving tools for multiple user needs and our products have been incorporated in environments ranging from hospitals to emergency medical units to public places such as airports, sports arenas, schools, and workplaces. Today there are more than 700,000 LIFEPAK devices distributed worldwide.

Table of Contents

On January 15, 2007, we announced our voluntary suspension of U.S. shipments of Physio-Control products manufactured at our facility in Redmond, Washington in order to address quality system issues. In the months following the suspension of U.S. shipments, we worked diligently with the FDA to address the quality system issues and resumed limited shipments to critical need customers. As a result of the work performed to date, in April 2008, we announced that we had reached an agreement on a consent decree with the FDA regarding quality system improvements for our external defibrillator products. The agreement was filed on April 25, 2008 in the U.S. District Court for the Western District of Washington and was approved by the court on May 9, 2008. The agreement addresses issues raised by the FDA during inspections regarding Physio-Control's quality system processes and outlines the actions Physio-Control must take in order to resume unrestricted distribution of our external defibrillators. We are continuing to work diligently on implementing the required actions necessary to resolve the quality issues addressed by the FDA.

In October 2008, we announced clearance by the FDA to market the LIFEPAK 20e defibrillator/monitor within the U.S. The 20e is an enhancement of the LIFEPAK 20 defibrillator/monitor, which has become the standard of care in many hospitals worldwide since its introduction in 2002. It offers all the capabilities of the LIFEPAK 20 device, along with a more powerful Lithium-ion battery that doubles ECG monitoring time and the run time of other parameters such as noninvasive pacing and pulse oximetry, a noninvasive way to monitor the oxygenation of a patient's hemoglobin. Additionally, a new on-screen fuel gauge displays the real-time status of available battery capacity so clinicians can monitor remaining use time. The 20e also was developed to be easily transported, helping hospitals meet the Joint Commission for Accreditation of Healthcare Organizations standard for having resuscitation services readily available in all facility areas.

In March 2009, we received 510(k) FDA market clearance for the LIFEPAK 15 Monitor/Defibrillator. The LIFEPAK 15 device builds on a 54-year Physio-Control legacy of providing innovative, reliable and durable equipment to emergency personnel so they can focus on the most important task at hand—saving lives. During the development of the LIFEPAK 15 monitor, Physio-Control partnered with emergency services personnel to create an all-new monitoring platform housing the fullest range of energy dosing, up to 360 joules, and the broadest range of monitoring options available. The LIFEPAK 15 device also builds on Physio-Control's legacy of industry firsts as it is the first monitor/defibrillator available to integrate noninvasive monitoring for carbon monoxide, the leading cause of poisoning death in industrialized countries. The 15 design focuses on several clinical and operational innovations, which include the largest, dual mode screen on the market providing maximum viewing capability from all angles, a one-touch button that flips the screen full-color to high-contrast SunVue mode for easy viewing in sunlight; and CPR Metronome, an audible prompt that actively guides users to a consistent compression rate without the need for extra external hardware. Additionally, the 15 provides ten times the speed and processing power of its predecessor, the LIFEPAK 12 defibrillator/monitor, and is powered by the latest lithium-ion and smart battery technology allowing nearly six hour run time. The 15, and its predecessor the LIFEPAK 12 monitor, are the only devices in the marketplace with ST-Segment Trending feature, which can continuously monitor 12-lead ECGs and alert emergency professionals to changes in a patient's heart rhythm during critical heart attack or other cardio-respiratory events. Minutes matter during cardiac events, so when the 15 is used in conjunction with the Web-based LIFENET System (available separately), customers can simultaneously transmit critical patient data from the field to multiple locations in the hospital, such as the cardiac cath lab and the emergency department. Physio-Control developed the LIFEPAK 15 device to be tougher and more durable than any other monitor/defibrillator on the market.

***Customers and Competitors***

The primary customers for our manual external defibrillators are EMS 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 facility. Our primary competitors in the AED business are Cardiac Science, Inc., Zoll Medical Corporation, Philips Medical Systems, Defibtech, LLC, and Welch Allyn Inc.

**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.

---

Table of Contents

During fiscal years 2009, 2008, and 2007, we spent \$1.355 billion (9.3 percent of net sales), \$1.275 billion (9.4 percent of net sales) and \$1.239 billion (10.1 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 devices.

**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.

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, or cash flows.

During April 2009, we acquired privately held CoreValve. Total consideration for the transaction was approximately \$700 million including payment of direct acquisition costs. CoreValve develops percutaneous, catheter-based transfemoral aortic valve replacement products.

During February 2009, we acquired privately held Ventor, a development stage company focused on transcatheter heart valve technologies for the treatment of aortic valve disease. This acquisition adds two technologies to our transcatheter valve portfolio: a minimally invasive, surgical transapical technology and a next generation percutaneous, transfemoral technology. Total consideration for the transaction, net of cash acquired, was approximately \$308 million.

During February 2009, we acquired privately held Ablation Frontiers. Under the terms of the agreement, the transaction included an initial up-front payment of \$225 million plus potential additional payments contingent upon achievement of certain clinical milestones. Total consideration for the transaction was approximately \$235 million including the assumption and settlement of existing Ablation Frontiers debt and payment of direct acquisition costs. Ablation Frontiers develops radiofrequency (RF) ablation solutions for treatment of atrial fibrillation. Ablation Frontiers' system of ablation catheters and RF generator is currently approved in certain markets outside the U.S.

During November 2008, we acquired substantially all of the outstanding stock of CryoCath. Under the terms of the agreement, CryoCath shareholders received \$8.75 Canadian dollars per share in cash for each share of CryoCath common stock that they owned. Total consideration for the transaction, net of cash acquired, was approximately \$352 million U.S. dollars including the purchase of outstanding CryoCath common stock, the assumption and settlement of existing CryoCath debt and payment of direct acquisition costs. CryoCath develops cryotherapy products to treat cardiac arrhythmias. CryoCath's Arctic Front product is a minimally invasive cryo-balloon catheter designed specifically to treat atrial fibrillation and is currently approved in certain markets outside the U.S.

During July 2008, we acquired all of the outstanding stock of Restore Medical. Restore Medical shareholders received \$1.60 per share in cash for each share of Restore Medical's common stock they owned. Total consideration for the transaction, net of cash acquired, was approximately \$29 million. Restore Medical's Pillar System will provide us with a minimally invasive, implantable medical device used to treat the soft palate component of sleep breathing disorders, including mild to moderate obstructive sleep apnea and snoring.

---

Table of Contents

**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 trade names for

## Edgar Filing: MEDTRONIC INC - Form 10-K

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 and Note 16 to the consolidated financial statements set forth in Exhibit 13 hereto 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 international markets. The three largest markets for our medical devices are the U.S., Western Europe, and Japan. Markets outside the U.S. are an area of increasing focus and opportunity as we believe they remain under penetrated.

In December 2008, we announced the completion of our equity investment in Shandong Weigao Group Medical Polymer Company Limited (Weigao). In connection with this transaction, we initiated with Weigao a joint venture to market in China our spinal products and Weigao's orthopedic products which include therapies for the hip, shoulder, spine and trauma. The joint venture entity commenced operations in September 2008, with an affiliate of Medtronic holding a 51 percent interest in the joint venture and Weigao holding the remaining 49 percent interest. These efforts enable us to further build on our product, distribution and marketing platforms, improving our strategic position to take advantage of existing and future opportunities in manufacturing and distribution in the spinal, orthopedic and trauma sectors in China.

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 healthcare 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, more complex, and tend to involve more long-term contracts than in the past. 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.

23

---

### Table of Contents

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 healthcare 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 2009 Annual Report.

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

## Edgar Filing: MEDTRONIC INC - Form 10-K

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, long lead times from sole source providers and currency exposure. Currency exchange rate fluctuations can affect net sales from, and profitability of, operations outside the U.S. We attempt to hedge these exposures to reduce the effects of foreign currency fluctuations on net earnings. 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 and will be included in our 2009 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 22 manufacturing facilities located in various countries throughout the world. The largest of these manufacturing facilities are located in Arizona, California, Florida, Indiana, Ireland, Massachusetts, Mexico, Minnesota, Puerto Rico, 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 manufacture 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.

24

---

### Table of Contents

### **Employees**

On April 24, 2009, we employed approximately 41,000 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. We believe our employee relations are excellent.

### **Seasonality**

Worldwide 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 release if it determines there is reasonable assurance that the medical device is safe and effective. This determination is based on benefit outweighing 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 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 these products is probable benefit and safety.

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 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 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 Department of Justice.

---

Table of Contents

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. 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 or simpler 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 has been created, and approval is represented by the CE Mark. To obtain a CE Mark in the European Union, defined products must meet minimum standards of performance, safety and quality (i.e., the essential requirements) and then comply with one or more of a selection of conformity 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 departments of health, oversee the clinical research for medical devices and are responsible for the products once they are in commercial distribution. 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 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 Pharmaceutical Affairs Law. 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 healthcare 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 healthcare providers that submit electronic claims, health plans and healthcare 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. 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 operating segment 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 compliance with all 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 new requirements affect only a small portion 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.

---

Table of Contents

Government and private sector initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments, and managed-care arrangements, are continuing in many countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical devices. Government programs, including Medicare and Medicaid, private healthcare insurance, and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments, and other mechanisms designed to constrain utilization and contain costs, 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 healthcare 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 healthcare 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 healthcare. Foreign governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services.

Federal healthcare laws apply when we or customers submit claims for items or services that are reimbursed under Medicare, Medicaid or other federally-funded healthcare 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 healthcare program; and (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) healthcare fraud statutes that prohibit false statements and improper claims with 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 healthcare programs and private third-party payors. In addition, the U.S. Federal 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 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 2009 Annual Report for additional information.

---

Table of Contents

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, disability coverage, 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 of insurance and the economic value of insurance coverage. Currently, external insurance is not considered to be an economically sound means of financing losses for the Company. We continue to monitor the insurance marketplace to evaluate the value to us 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 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.

**William A. Hawkins**, age 55, has been a Director of Medtronic since March 2007 and Chairman and Chief Executive Officer since August 2008. He served as President and Chief Executive Officer of Medtronic since from August 2007 to August 2008 and as President and Chief Operating Officer from May 2004 to August 2007. He served as Senior Vice President and President, Medtronic Vascular, from January 2002 to May 2004. He served as President and Chief Executive Officer of Novoste Corporation from 1998 to 2002. He is also a member of the board of visitors of the Engineering School of Duke University and the Guthrie Theatre board.

**Susan Alpert, Ph.D., M.D.**, age 63, has been Senior Vice President, Chief Regulatory Officer since May 2008. Prior to that, she was Senior Vice President, Chief Quality and Regulatory Officer from November 2005 to May 2008, and prior to that, Vice President, Chief Quality and Regulatory Officer from May 2004 to November 2005, and Vice President, Regulatory Affairs and Compliance from July 2003 to May 2004. Prior to that, she was Vice President of Regulatory Sciences at C.R. Bard, Inc. from October 2000 to July 2003. She held a variety of positions at the FDA from June 1987 to August 2000.

**Martha Goldberg Aronson**, age 41, has been Senior Vice President and Chief Talent Officer since March 2008. Prior to that, she was Vice President, Investor Relations from May 2006 to March 2008, Vice President of the Neurological, Gastroenterology/Urology, Obesity Management, ENT/Neurologic Technology and Diabetes businesses in Western Europe from May 2003 to May 2006 and Vice President and General Manager of Medtronic Gastroenterology/Urology from 2001 to May 2003. She joined Medtronic in April 1991, from Bain & Company, a global management consulting firm.

**Robert H. Blankemeyer**, age 62, has been Senior Vice President and President of Surgical Technologies since June 2008. Prior to that, he was President of the Ear, Nose & Throat and Neurologic Technologies business unit from April 2000 until its merger into Surgical Technologies in 2008. Prior to joining Medtronic, he was President of Storz Ophthalmics Inc., where he held several business leadership positions.

**Jean-Luc Butel**, age 52, has been Senior Vice President and President, International since May 2008. Prior to that, he was 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.

---

#### **Table of Contents**

**H. James Dallas**, age 50, 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.

## Edgar Filing: MEDTRONIC INC - Form 10-K

**Gary L. Ellis**, age 52, 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 Corporate Controller from August 1994. 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.

**Richard Kuntz, M.D.**, age 52, has been Senior Vice President and President, Neuromodulation since October 2005. 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.

**Steve La Neve**, age 50, has been Senior Vice President and President Spinal and Biologics since April 2008. Prior to that, he was President of Medtronic Japan from April 2004 to April 2008. He was Senior Vice President of Business Development and Supplier Integration and Executive Vice President of Relationship Management at Premier, Inc. from September 2000 to March 2004. He was Vice President and General Manager and Director of Sales and Marketing at Becton, Dickinson and Company from March 1990 to August 2000, and prior to that, he held other healthcare management roles with Hoffmann-La Roche and EM Diagnostic Systems.

**James P. Mackin**, age 42, has been Senior Vice President and President Cardiac Rhythm Disease Management (CRDM) since August 2007. Prior to that, he was Vice President, CRDM Commercial Operations from November 2006 to August 2007 and Vice President, Vascular, Western Europe, from July 2004 to November 2006. He was Vice President and General Manager of Medtronic Vascular's Endovascular business from October 2002 to July 2004. Prior to joining Medtronic, he served in a number of sales and executive positions at Genzyme Corporation from 1996 to 2004.

**Stephen H. Mahle**, age 63, has been Executive Vice President Healthcare Policy and Regulatory since April 2008. Prior to that he was Executive Vice President and Senior Healthcare Policy Advisor from August 2007 to April 2008, and prior to that was Executive Vice President and President, Cardiac Rhythm Disease Management since May 2004. He was Senior Vice President and President, Cardiac Rhythm Management, since January 1998. Prior to that, he was President, Brady Pacing, from 1995 to 1997 and Vice President and General Manager, Brady Pacing, from 1990 to 1995. Mr. Mahle has been with the Company for 36 years and served in various general management positions prior to 1990. Mr. Mahle serves on the board of directors of ATMI, Inc.

**Christopher J. O'Connell**, age 42, has been Senior Vice President and President, Diabetes, since October 2006. Prior to that, he was President of Medtronic's Emergency Response Systems division from May 2005 to October 2006, and prior to that, he was Vice President of Sales and Marketing of Medtronic's Cardiac Rhythm Disease Management division from November 2001 to May 2005 and Vice President/General Manager of the Patient Management Business from January 2000 to November 2001. Mr. O'Connell has served in various management positions since joining the Company in 1994.

**Stephen N. Oesterle, M.D.**, age 58, has been Senior Vice President, Medicine and Technology, since January 2002. Prior to that, he was Associate Professor of Medicine at Harvard Medical School and Director of Invasive Cardiology Services at Massachusetts General Hospital from 1998 to 2002, and was Associate Professor of Medicine at Stanford University and Director of Cardiac Catheterization and Coronary Intervention Laboratories at the Stanford University Medical Center from 1992 to 1998. Prior to that he held other academic positions and directed interventional cardiology programs at Georgetown University and in Los Angeles, CA.

29

---

### Table of Contents

**Catherine Szyman**, age 42, has been Senior Vice President, Strategy and Innovation since April 2008. Prior to that, she was Vice President and General Manager of Endovascular Innovations, part of the CardioVascular business unit, from October 2004 to April 2008. From 1991 to 2004, she held numerous management and leadership roles at Medtronic, including Vice President of Corporate Strategy and Vice President of Finance for the Vascular business.

**Scott R. Ward**, age 49, has been Senior Vice President and President, CardioVascular since May 2007. Prior to that he was Senior Vice President and President, Vascular from May 2004 to May 2007, Senior Vice President and President, Neurological and Diabetes Business, from February 2002 to May 2004, and was President, Neurological, from January 2000 to January 2002. He was Vice President and General Manager of Medtronic's Drug Delivery Business from 1995 to 2000. Prior to that, Mr. Ward led the Company's Neurological Ventures in the successful development of new therapies. Mr. Ward also held various research, regulatory and business development positions since joining Medtronic in 1981. He is also a board member of MAP Pharmaceuticals, Inc.

### **Item 1A. Risk Factors**

## Edgar Filing: MEDTRONIC INC - Form 10-K

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 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 healthcare 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 in the medical device industry. In the current environment of managed care, consolidation among healthcare 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.

30

---

### Table of Contents

***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 22 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 only from a sole supplier. While we work closely with our suppliers to try to ensure continuity of supply while maintaining high quality and reliability, 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 governmental regulation in the future.***

Our medical devices and our business activities are subject to rigorous regulation, including by the FDA 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 many payments to them. Also, while recent case law has clarified that the FDA's authority over medical devices preempts state tort laws,

## Edgar Filing: MEDTRONIC INC - Form 10-K

legislation has been introduced at the Federal level to allow state intervention. We anticipate that the government will continue to scrutinize our industry closely, and that additional regulation by governmental authorities may increase compliance 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, and if we do, such approval may:

- take a significant amount of time,
- require the expenditure of substantial resources,
- involve stringent clinical and pre-clinical testing,
- 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. 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, and 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, 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 Department of Justice. 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 noncompliance 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.

31

---

### Table of Contents

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, or cash flows.

***Our failure to comply with strictures relating to reimbursement and regulation of healthcare goods and services may subject us to penalties and adversely impact our reputation and business operations.***

Our devices 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 healthcare goods and services. Foreign governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare goods and services. U.S. federal government healthcare laws apply when we submit a claim on behalf of a U.S. federal healthcare program beneficiary, or when a customer submits a claim for an item or service that is reimbursed under a U.S. federal government funded healthcare 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, those that prohibit unlawful inducements for the referral of business reimbursable under federally-funded healthcare programs, known as the anti-kickback laws, and those that prohibit healthcare service providers seeking reimbursement for providing certain services to a patient who was referred by a physician that 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.***

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 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 be successful in patent or other litigation may result in our payment of significant money 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.***

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 incident to our business, we believe the results associated with any litigation could result in our payment of significant money 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, or cash flows.

---

## Table of Contents

We rely on a combination of patents, trade secrets and nondisclosure and non-competition agreements to protect our proprietary intellectual property, and will continue to do so. While we intend to defend against any threats to our intellectual property, there can be no assurance that these patents, trade secrets, or other agreements will adequately protect our intellectual property. There can also be no assurance that pending patent applications owned by us will result in patents issuing to us, that patents issued to or licensed by us in the past or in the future will not be challenged or circumvented by competitors or that such patents will be found to be valid or sufficiently broad to protect our technology or to provide us with any competitive advantage. Third parties could also obtain patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would 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. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, that others will not independently develop 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 which 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. Component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information with respect to these or other products we manufacture or sell 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.

***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, 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 the goods and services we offer 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 38 percent of our net sales for the year ended April 24, 2009, are accompanied by certain financial and other risks. We intend to continue to pursue growth opportunities in sales internationally, 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:

33

---

Table of Contents

changes in foreign medical reimbursement programs and policies,  
changes in foreign 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 protection of intellectual property in some countries outside of 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.

***Consolidation in the healthcare industry could have an adverse effect on our revenues and results of operations.***

Many healthcare industry companies, including medical device companies, are consolidating to create new companies with greater market power. As the healthcare 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 healthcare industry, our revenues would decrease and our consolidated earnings, financial condition, or cash flows would suffer.

***Healthcare policy changes, including pending proposals to reform the U.S. healthcare system, may have a material adverse effect on us.***

## Edgar Filing: MEDTRONIC INC - Form 10-K

Healthcare costs have risen significantly over the past decade. There have been and continue to be proposals by legislators, regulators, and third-party payors to keep these costs down. Certain proposals, if passed, would impose limitations on the prices we will be able to charge for our products, or the amounts of reimbursement available for our products from governmental agencies or third-party payors. These limitations could have a material adverse effect on our financial position and results of operations.

Recently, President Obama and members of Congress have proposed significant reforms to the U.S. healthcare system. Both the U.S. Senate and House of Representatives have conducted hearings about U.S. healthcare reform. In the Obama administration's fiscal year 2010 federal budget proposal, the administration emphasized maintaining patient choice, reducing inefficiencies and costs, increasing prevention programs, increasing coverage portability and universality, improving quality of care and maintaining fiscal sustainability. The Obama administration's fiscal year 2010 budget included proposals to limit Medicare payments, reduce drug spending and increase taxes. In addition, members of Congress have proposed a single-payer healthcare system, a government health insurance option to compete with private plans and other expanded public healthcare measures. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, an expansion in government's role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business, possibly materially.

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

Most of our customers, and the healthcare 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 government, insurance companies, and other payors of healthcare costs to contain or reduce these costs could lead to patients being unable to obtain approval for payment from these third-party payors. If that were to occur, 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 healthcare 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 may 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 alliances, and we cannot guarantee that any previous or future investments or alliances 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 alliances to provide us access to new technologies both in areas served by our existing businesses as well as in new areas.

---

### Table of Contents

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 alliances in and with medical technology companies are inherently risky, and we cannot guarantee that any of our previous or future investments or alliances will be successful or will not materially adversely affect our consolidated earnings, financial condition, or cash flows.

***The success of many of our products depends upon 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 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 our products and the marketing of our products. Physicians assist us as researchers, marketing and product consultants, inventors, and as 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 effect on our consolidated earnings, financial condition, 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 losses and cause us to face liquidity issues.*

We have investments in marketable debt securities which are classified and accounted for as available-for-sale. Our debt securities include government securities, commercial paper, corporate bonds, bank certificates of deposit, and mortgage backed and other asset backed securities, including auction rate securities. Recent market conditions indicate significant uncertainty on the part of investors on the economic outlook for the U.S. and for financial institutions that have potential exposure to the sub-prime housing market. This uncertainty has created reduced liquidity across the fixed income investment market, including the securities that we invest in. As a result, some of our investments have experienced reduced liquidity. 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 the securities is temporarily impaired, we would record a temporary impairment within other comprehensive income, a component of 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.

Additionally, if uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any rating downgrades on any investments in our portfolio, funds associated with these securities may not be liquid or available to fund current operations, and/or we may incur further temporary or other-than-temporary impairments in the carrying value of our investments, which could negatively affect our financial condition, cash flow and reported earnings. 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.

## 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, and Switzerland. Our total manufacturing and research space is approximately 3.0 million square feet, of which approximately 75 percent is owned by us and the balance is leased.

35

---

## Table of Contents

We also maintain sales and administrative offices in the U.S. at approximately 90 locations in 40 states or jurisdictions and outside the U.S. at approximately 130 locations in 38 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 the management's discussion and analysis and our legal proceedings and other loss contingencies are described in Note 16 and a portion of Note 13 of the consolidated financial statements. The description of our legal proceedings in Note 16 and a portion of Note 13 of the consolidated financial statements to this filing is incorporated herein by reference.

On October 24, 2005, the Company received a subpoena from the Office of the United States Attorney for the District of Massachusetts issued under the Health Insurance Portability & Accountability Act of 1996 requesting documents the Company may have, if any, relating to pacemakers and defibrillators and related components; monitoring equipment and services; a provision of benefits, if any, to persons in a position to recommend purchases of such devices; and the Company's training and compliance materials relating to the fraud and abuse and federal Anti-Kickback statutes. In September 2008, the United States Attorney's office for the District of Massachusetts informed Medtronic that it is no longer pursuing its investigation of Medtronic, related to the October 24, 2005 subpoena. On September 5, 2008, Medtronic received a subpoena from the Office of Inspector General for the Department of Health and Human Services in the District of Minnesota, requesting production of substantially the same materials covered in the 2005 Massachusetts subpoena. Medtronic is in the process of responding to the subpoena and will comply as required with the terms of the subpoena.

## Edgar Filing: MEDTRONIC INC - Form 10-K

Beginning on September 20, 2007, the Company has received letter requests from Senator Grassley of the U.S. Senate Finance Committee requesting information on a variety of subjects, including financial ties between the medical device industry and practicing physicians; the Company's decision to suspend distribution of its Sprint Fidelis family of defibrillation leads; financial ties between the Company and physicians who use INFUSE Bone Graft; the Cardiac Research Foundation and Columbia University; and certain communications regarding INFUSE Bone Graft and the Company's clinical research projects with the U.S. military and compensation paid to physicians working for the U.S. military. The Company has cooperated, and will continue to cooperate with, the Senator's requests.

On September 25, 2007, the Company received a letter from the SEC requesting information relating to any potential violations of the U.S. Foreign Corrupt Practices Act in connection with the sale of medical devices in an unspecified number of foreign countries, including Greece, Poland and Germany. Turkey, Italy and Malaysia have since been added to the inquiry. The letter notes that the Company is a significant participant in the medical device industry, and seeks any information concerning certain types of payments made directly or indirectly to government-employed doctors. A number of competitors have publicly disclosed receiving similar letters. On November 16, 2007, the Company received a letter from the Department of Justice requesting any information provided to the SEC. Since that time the SEC and Department of Justice have made additional requests for information from the Company. The Company is cooperating with the requests.

On or about October 31, 2007, the Company received a letter from the United States Attorney's Office for the Eastern District of Pennsylvania requesting documents relating to the Company's relationship with one of its customers and any payments or things of value provided by the Company to physicians, physician groups, hospitals, medical practices or other entities relating to the purchase of the Company's cardiac resynchronization therapy devices and cardiac stents. The Company will comply as required with the terms of the letter.

In late June 2008, the Company received a subpoena issued by the United States Attorney's Office for the District of Massachusetts pursuant to the Health Insurance Portability & Accountability Act of 1996, relating to the Company's marketing of biliary stents. The Company will comply as required with the terms of the subpoena.

36

---

### Table of Contents

On October 6, 2008, the Company received a subpoena from the United States Attorney's Office for the District of Massachusetts pursuant to the Health Insurance Portability & Accountability Act of 1996 requesting production of documents relating to Medtronic's INFUSE Bone Graft product. The Company will comply as required with the terms of the subpoena.

On December 18, 2008, the Company received a civil investigative demand from the Massachusetts Attorney General's Office, requesting production of documents related to Medtronic's INFUSE Bone Graft product. The Company is in the process of responding to the demand and will comply as required with the terms of the demand.

On February 9, 2009, the Company received letter notice that the United States Department of Justice in the Southern District of Texas is investigating marketing practices, reimbursement advice of the Company and appropriateness of therapy delivery relating to the Company's cardiac surgical ablation devices. The Company is in the process of responding to the requests of the government, and will comply as required with the investigation.

On April 13, 2009, the Company received an administrative health care subpoena from the United States Attorney's office for the Northern District of Indiana requesting documents relating to the Company's relationship with customers, as well as documents relating to certain employees. The Company will comply as required by the terms of the subpoena.

On May 21, 2009, the Company received a subpoena from the United States Attorney's Office for the District of Massachusetts pursuant to the Health Insurance Portability & Accountability Act of 1996 seeking documents related to a study published in the British volume of the Journal of Bone & Joint Surgery, and contracts, research grants, speaking and education programs, and payments for certain named physicians. The Company will comply, as required, with the terms of the subpoena.

On June 16, 2009, the Company received an administrative subpoena from the New Jersey Attorney General, Division of Consumer Affairs, requesting production of documents relating to the Company's clinical studies, its financial arrangements with certain physicians and health care providers, and clinical research done by certain physicians and health care providers. The Company will comply as required with the terms of the subpoena.

### **Item 4. Submission of Matters to a Vote of Security Holders**

Not applicable.

**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 Stock" is incorporated by reference herein set forth in Exhibit 13 hereto and will be included in our 2009 Annual Report. The Company's common stock is listed on the New York Stock Exchange under the symbol MDT.

In October 2005 and June 2007, the Company's Board of Directors authorized the repurchase of 40 million and 50 million shares of the Company's stock, respectively. In addition, in April 2006, the Board of Directors made a special authorization for the repurchase of up to 50 million shares in connection with the \$4.400 billion Senior Convertible Note offering. As authorized by the Board of Directors each program expires when its total number of authorized shares has been repurchased. On June 18, 2009, the Board of Directors authorized the repurchase of an additional 60 million shares of the Company's common stock.

The following table provides information about the shares repurchased by Medtronic during fourth quarter of fiscal year 2009:

Fiscal Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as a Part of Publicly Announced Program	Maximum Number of Shares that May Yet Be Purchased Under the Program
01/24/09 - 02/20/09		\$		18,838,084
02/21/09 - 03/27/09	358,500	27.91	358,500	18,479,584
03/28/09 - 04/24/09	644,000	31.07	644,000	17,835,584
Total	1,002,500	\$ 29.94	1,002,500	17,835,584

37

Table of Contents

On June 22, 2009, there were approximately 53,600 shareholders of record of the Company's common stock. Cash dividends declared and paid totaled 18.75 cents per share for each quarter of fiscal year 2009 and 12.50 cents per share for each quarter of fiscal year 2008. Stock price comparison follows:

Fiscal Qtr.	1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
2009 High	\$ 54.41	\$ 56.55	\$ 40.69	\$ 34.56
2009 Low	46.98	37.81	28.67	24.38
2008 High	54.05	57.86	51.21	50.44
2008 Low	50.57	47.00	45.25	46.19

**Item 6. Selected Financial Data**

The information for fiscal years 2005 through 2009 in the section entitled "Selected Financial Data" is incorporated herein by reference to Exhibit 13 hereto and will be included in our 2009 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 2009 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 Note 5 to the consolidated financial statements is incorporated herein by reference to Exhibit 13 hereto and will be included in our 2009 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 2009 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 (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 and are adequately designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified by the SEC's applicable rules and forms.

### 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. 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 24, 2009. Our internal control over financial reporting as of April 24, 2009, 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 is incorporated by reference to Exhibit 13 hereto and will be included in our 2009 Annual Report.

38

---

### Table of Contents

### Changes in Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the period covered by this Annual Report on Form 10-K 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 of our Proxy Statement for our 2009 Annual Shareholders Meeting are incorporated herein by reference. See also "Executive Officers of Medtronic" on page 28 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 Board members. 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](http://www.medtronic.com) under the Corporate Governance caption. 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, Compensation Discussion and Analysis Compensation Committee Report, and Executive Compensation in our Proxy Statement for our 2009 Annual Shareholders Meeting are incorporated herein by reference. The section entitled Compensation Committee Report in our Proxy Statement for our 2009 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 and Executive Compensation Equity Compensation Plan Information in our Proxy Statement for our 2009 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 2009 Annual Shareholders Meeting are incorporated herein by reference.

39

---

### Table of Contents

## Item 14. Principal Accounting Fees and Services

The sections entitled Governance of Medtronic Audit Committee Audit Committee Pre-Approval Policies and Report of the Audit Committee Audit and Non-Audit Fees in our Proxy Statement for our 2009 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 24, 2009, April 25, 2008, and April 27, 2007 are set forth in Exhibit 13 hereto and will be included in our 2009 Annual Report.

The section entitled Consolidated Balance Sheets April 24, 2009 and April 25, 2008 is set forth in Exhibit 13 hereto and will be included in our 2009 Annual Report.

The section entitled Consolidated Statements of Shareholders Equity years ended April 24, 2009, April 25, 2008, and April 27, 2007 is set forth in Exhibit 13 hereto and will be included in our 2009 Annual Report.

The section entitled Consolidated Statements of Cash Flows years ended April 24, 2009, April 25, 2008, and April 27, 2007 is set forth in Exhibit 13 hereto and will be included in our 2009 Annual Report.

The section entitled Notes to Consolidated Financial Statements is set forth in Exhibit 13 hereto and will be included in our 2009 Annual Report.

## 2. Financial Statement Schedules

Schedule II. Valuation and Qualifying Accounts years ended April 24, 2009, April 25, 2008, and April 27, 2007 (set forth on page 47 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

- 2.1 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 Rights Agreement, dated as of October 26, 2000, between Medtronic, Inc. and Wells Fargo Bank Minnesota, N.A., including as: Exhibit A thereto the form of Certificate of Designations, Preferences and Rights of Series A Junior Participating Preferred Shares of Medtronic, Inc.; Exhibit B the form of Preferred Stock Purchase Right Certificate; and Exhibit C the Summary of Rights to Purchase Preferred Shares (Exhibit 4).(c)
- 4.2 Indenture, dated as of September 11, 2001, between Medtronic, Inc. and Wells Fargo Bank Minnesota, National Association. (Exhibit 4.2).(d)
- 4.3 Credit Agreement (\$1,000,000,000 Five Year Revolving Credit Facility) dated as of January 20, 2005, among Medtronic, Inc. as Borrower, certain of its subsidiaries as Guarantors, Citicorp USA, Inc., as Administrative Agent and Bank of America, N.A. as Syndication Agent, and Citigroup Global Markets Inc. and Banc of America Securities LLC as Joint Lead Arrangers and Joint Book Managers (Exhibit 4.1).(e)

40

---

## Table of Contents

- 4.4 Form of Indenture between Medtronic, Inc. and Wells Fargo Bank, National Association (Exhibit 4.1).(f)
- 4.5 Indenture dated as of September 15, 2005 between Medtronic, Inc. and Wells Fargo Bank, N. A., as Trustee, 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)
- 4.6 Form of 4.375% Senior Notes, Series B due September 15, 2010 (Exhibit 4.2).(g)
- 4.7 Form of 4.750% Senior Notes, Series B due September 15, 2015 (Exhibit 4.3).(g)
- 4.8 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)
- 4.9 Credit Agreement dated as of December 20, 2006, among Medtronic, Inc., as Borrower, the Lenders party thereto, Bank of America N.A., as Issuing Bank, and Citicorp USA, Inc., as Administrative Agent, Issuing Bank and Swingline Lender (Exhibit 4.1).(i)
- 4.10 Form of Indenture between Medtronic, Inc. and Wells Fargo Bank, National Association (Exhibit 4.1).(aa)
- 4.11 First Supplemental Indenture Dated March 12, 2009 between Medtronic, Inc. and Wells Fargo Bank, National Association (Exhibit 4.1).(bb)
- \*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).(l)

## Edgar Filing: MEDTRONIC INC - Form 10-K

*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)
10.10	Asset Purchase and Settlement Agreement dated as of April 21, 2005 among Medtronic, Inc., Medtronic 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)

---

### Table of Contents

*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)
10.20	Purchase Agreement by and among Medtronic, Inc. and the Initial Purchasers named therein dated as of April 12, 2006 (Exhibit 10.1).(h)
10.21	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)

## Edgar Filing: MEDTRONIC INC - Form 10-K

*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	Amendment to Change of Control Agreement for Medtronic Executive Officers (Exhibit 10.1).(z)
*10.32	Form of Restricted Stock Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.3).(s)
*10.33	Form of Restricted Stock Unit Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.4).(s)
*10.34	Medtronic, Inc. Israeli Amendment to the 2003 Long-Term Incentive Plan (Exhibit 10.5).(t)
*10.35	Medtronic, Inc. Kyphon Inc. 2002 Stock Plan (Amended and Restated July 26, 2007, as further amended on October 18, 2007) (Exhibit 10.6).(t)
*10.36	Addendum: Medtronic, Inc. Kyphon Inc. 2002 Stock Plan (dated December 13, 2007) (Exhibit 10.7).(t)
*10.37	Letter Agreement dated April 29, 2008 between Michael DeMane and Medtronic, Inc. (Exhibit 10.37).(w)
*10.38	Medtronic, Inc. 2008 Stock Award and Incentive Plan
*10.39	Form of Non-Qualified Stock Option Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.39).(w)
*10.40	Form of Restricted Stock Unit Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.40).(w)

42

---

### Table of Contents

*10.41	Form of Restricted Stock Unit Award Agreement under 2003 Long-Term Incentive Plan (Exhibit 10.41).(w)
*10.42	Form of Restricted Stock Unit Award Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.2).(x)
*10.43	Form of Restricted Stock Award Agreement Under 2008 Stock Award and Incentive Plan (Exhibit 10.3).(x)
*10.44	Form of Restricted Stock Award Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.4).(x)
*10.45	Form of Restricted Stock Unit Award Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.5).(x)
*10.46	Form of Non-Qualified Stock Option Agreement under 2008 Stock Award and Incentive Plan (Exhibit 10.6).(x)
*10.47	Terms of Non-Employee Director Compensation under the Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.7).(x)
*10.48	Form of Non-Employee Director Initial Option Agreement under the Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.1).(y)
*10.49	Form of Non-Employee Director Annual Option Agreement under the Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.2).(y)
*10.50	Form of Non-Employee director Deferred Unit Award Agreement under the Medtronic, Inc. 2008 Stock Award and Incentive Plan (Exhibit 10.3).(y)
*10.51	Form of Change of Control Employment Agreement for Medtronic Executive Officers (Exhibit 10.38).(w)



## Edgar Filing: MEDTRONIC INC - Form 10-K

*10.52	Summary of Compensation Arrangements for Named Executive Officers and Directors
*10.53	Amendment No. 2 dated April 27, 2009, to Indemnification Trust Agreement
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

- (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.

43

---

### Table of Contents

- (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.
- (l) Incorporated herein by reference to the cited appendix to our 2003 Proxy Statement, filed with the Commission on July 28, 2003.
- (m)

## Edgar Filing: MEDTRONIC INC - Form 10-K

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.

44

---

### 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.
- \*Items that are management contracts or compensatory plans or arrangements required to be filed as an exhibit pursuant to Item 15(a)(3) of Form 10-K.

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

45

---

### Table of Contents

## SIGNATURES

## Edgar Filing: MEDTRONIC INC - Form 10-K

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 23, 2009

**By: /s/ William A. Hawkins  
William A. Hawkins  
Chairman and  
Chief Executive Officer**

Pursuant to the requirements of the Securities Exchange Act of 1934, the report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

### **MEDTRONIC, INC.**

Dated: June 23, 2009

**By: /s/ William A. Hawkins  
William A. Hawkins  
Chairman and  
Chief Executive Officer  
(Principal Executive Officer)**

Dated: June 23, 2009

**By: /s/ Gary L. Ellis  
Gary L. Ellis  
Senior Vice President and  
Chief Financial Officer  
(Principal Financial and  
Accounting Officer)**

### **Directors**

**Richard H. Anderson  
David L. Calhoun  
Victor J. Dzau, M.D.  
William A. Hawkins  
Shirley Ann Jackson, Ph.D  
James T. Lenehan  
Denise M. O'Leary  
Kendall J. Powell  
Robert C. Pozen  
Jean-Pierre Rosso  
Jack W. Schuler**

Keyna P. Skeffington, by signing her name hereto, does hereby sign this document on behalf of each of the above named directors of the registrant pursuant to powers of attorney duly executed by such persons.

Dated: June 23, 2009

**By: /s/ Keyna P. Skeffington  
Keyna P. Skeffington**

46

---

[Table of Contents](#)

## **MEDTRONIC, INC. AND SUBSIDIARIES SCHEDULE II VALUATION AND QUALIFYING ACCOUNTS**

**(dollars in millions)**

Edgar Filing: MEDTRONIC INC - Form 10-K

	Balance at Beginning of Fiscal Year	Charges to Earnings	Other Changes (Debit) Credit	Balance at End of Fiscal Year
Allowance for doubtful accounts:				
Year ended 4/24/09	\$ 99	\$ 39	\$ (61)(a)	\$ 61
			\$ (16)(b)	
Year ended 4/25/08	\$ 160	\$ 31	\$ (101)(a)	\$ 99
			\$ 9(b)	
Year ended 4/27/07	\$ 184	\$ 31	\$ (59)(a)	\$ 160
			\$ 4(b)	

(a) Uncollectible accounts written off, less recoveries.

(b) Reflects primarily the effects of foreign currency fluctuations.