GREATBATCH, INC. Form 10-K February 28, 2012 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 December 30, 2011

**Commission File Number 1-16137** 

# GREATBATCH, INC.

(Exact name of Registrant as specified in its charter)

**Delaware** (State of Incorporation)

16-1531026 (I.R.S. Employer Identification No.)

10000 Wehrle Drive

Clarence, New York 14031

(Address of principal executive offices)

(716) 759-5600

(Registrant s telephone number, including area code)

#### Edgar Filing: GREATBATCH, INC. - Form 10-K

#### Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class:

Common Stock, Par Value \$0.001 Per Share
Preferred Stock Purchase Rights

Securities Registered Pursuant to Section 12(g) of the Act: None

Name of Each Exchange on Which Registered:
New York Stock Exchange
New York Stock Exchange

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

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

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

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

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

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

Large accelerated filer " Accelerated filer x

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 Act). Yes " No x

The aggregate market value of common stock of Greatbatch, Inc. held by non-affiliates as of July 1, 2011 (last business day of most recently completed second fiscal quarter), based on the last sale price of \$27.23, as reported on the New York Stock Exchange: \$625.8 million. Solely for the purpose of this calculation, shares held by directors and officers and 10 percent shareholders of the Registrant have been excluded. Such exclusion should not be deemed a determination by or an admission by the Registrant that these individuals are, in fact, affiliates of the Registrant.

Shares of common stock outstanding on February 28, 2012: 23,431,594

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the following document are specifically incorporated by reference into the indicated parts of this report:

## Edgar Filing: GREATBATCH, INC. - Form 10-K

**Document** Part

Proxy Statement for the 2012 Annual Meeting of Stockholders

Part III, Item 10

Directors, Executive Officers and Corporate Governance

Part III, Item 11

**Executive Compensation** 

Part III, Item 12

Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Part III, Item 13

Certain Relationships and Related Transactions, and Director Independence

Part III, Item 14

Principal Accounting Fees and Services

### TABLE OF CONTENTS

ITEM NUMBER		PAGE NUMBER
	<u>PART I</u>	
1	<u>Business</u>	3
1A	Risk Factors	20
1B	<u>Unresolved Staff Comments</u>	28
2	<u>Properties</u>	29
3	<u>Legal Proceedings</u>	29
4	Mine Safety Disclosures	30
	PART II	
5	Market for Registrant s Common Equity. Related Stockholder Matters and Issuer Purchases of Equity Securities	30
6	Selected Financial Data	31
7	Management s Discussion and Analysis of Financial Condition and Results of Operations	32
7A	Quantitative and Qualitative Disclosures About Market Risk	59
8	Financial Statements and Supplementary Data	61
9	Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	118
9A	Controls and Procedures	119
9B	Other Information	120
	PART III	
10	Directors, Executive Officers and Corporate Governance	120
11	Executive Compensation	120
12	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	120
13	Certain Relationships and Related Transactions, and Director Independence	120
14	Principal Accounting Fees and Services	120
	PART IV	
15	Exhibits, Financial Statement Schedules	120
	Signatures	122

#### PART I

#### **ITEM 1. BUSINESS**

#### OVERVIEW

Wilson Greatbatch, co-inventor of the first successful implanted pacemaker, founded Greatbatch in 1970. Greatbatch, Inc. is a Delaware corporation that was incorporated in 1997. When used in this report, the terms Greatbatch, we, us, our and the Company mean Greatbatch, I and its subsidiaries. The Company had its initial public offering in 2000.

We operate our company in two reportable segments Greatbatch Medical and Electrochem Solutions (Electrochem). Our customers include large multi-national original equipment manufacturers (OEMs). The Greatbatch Medical segment designs and manufactures medical devices and components primarily for the Cardiac Rhythm Management (CRM), Neuromodulation, Vascular Access and Orthopaedic markets. Additionally, Greatbatch Medical offers value-added assembly and design engineering services for products that incorporate Greatbatch Medical components. As a result of our strategy put in place over three years ago, Greatbatch Medical now offers its customers complete medical devices including design, development, manufacturing, regulatory submission and supporting worldwide distribution. This medical device strategy is being facilitated through the QiG Group and leverages the component technology of Greatbatch Medical and Electrochem in our core markets: Cardiovascular, Neuromodulation and Orthopaedic. Once the QiG Group designs and develops a medical device, it is manufactured by Greatbatch Medical.

Electrochem provides technology solutions where safety, reliability, quality and durability are critical. Electrochem s customized primary (non-rechargeable) and secondary (rechargeable) battery solutions are used in markets such as energy, portable medical, military, environmental and more. Electrochem s product lines cover a number of highly-customized battery-powered applications in remote and demanding environments, including down hole drilling tools, military communication devices, automated external defibrillators, oceanographic buoys and more. Electrochem s primary and secondary power solutions and wireless sensing systems are used in markets where failure is not an option.

Since Greatbatch, Inc. was incorporated, it has completed the following acquisitions either directly or indirectly through one of its subsidiaries:

Acquisition Date	Acquired Company	Business at Time of Acquisition
July 1997	Wilson Greatbatch Ltd.	Founded in 1970, designed and manufactured batteries
		for implantable medical and commercial applications.
August 1998	Hittman Materials and Medical Components, Inc.	Founded in 1962, designed and manufactured ceramic
		and glass feedthroughs and specialized porous
		coatings for electrodes used in IMDs.
August 2000	Battery Engineering, Inc.	Founded in 1983, designed and manufactured
		high-energy density batteries for industrial,
		commercial, military and medical applications.

Table of Contents		
Acquisition Date	Acquired Company	Business at Time of Acquisition
June 2001	Sierra-KD Components division of Maxwell Technologies, Inc.	Founded in 1986, designed and manufactured ceramic electromagnetic filtering capacitors and integrated them with wire feedthroughs for use in IMDs as well as military, aerospace and commercial applications.
July 2002	Globe Tool and Manufacturing Company, Inc.	Founded in 1954, designed and manufactured precision enclosures used in IMDs and commercial products used in the aerospace, electronics and automotive sectors.
March 2004	NanoGram Devices Corporation	Founded in 1996, developed nanoscale materials for battery and medical device applications.
April 2007	BIOMEC, Inc.	Established in 1998, provided medical device design and component integration to early-stage and established customers.
June 2007	Enpath Medical, Inc.	Founded in 1981, designed, developed, and manufactured venous introducers and dilators, implantable leadwires, steerable sheaths and steerable catheters.
October 2007	IntelliSensing LLC	Founded in 2005, designed and manufactured battery-powered wireless sensing solutions for commercial applications.
November 2007	Quan Emerteq LLC	Founded in 1998, designed, developed, and manufactured catheters, stimulation leadwires, microcomponents and assemblies.
November 2007	Engineered Assemblies Corporation	Founded in 1984, designed and integrated custom battery solutions and electronics focused on rechargeable systems for industrial, commercial, military and portable medical applications.
January 2008	P Medical Holding SA	Founded in 1994, designed, manufactured and supplied delivery systems, instruments and implants for the orthopaedic industry.
February 2008	DePuy Orthopaedics Chaumont, France manufacturing facility	Manufactured hip and shoulder implants for DePuy Orthopaedics.
December 2011	Micro Power Electronics, Inc.	Founded in 1990, designed custom battery packs, smart chargers and power supplies for industrial, military and portable medical applications.

#### FINANCIAL STATEMENT YEAR END

We utilize a fifty-two, fifty-three week fiscal year ending on the Friday nearest December 31st. Fiscal years 2011, 2010 and 2009 ended on December 30, 2011, December 31, 2010 and January 1, 2010, respectively. Fiscal years 2011, 2010 and 2009 contained fifty-two weeks.

#### SEGMENT INFORMATION

We operate our business in two reportable segments Greatbatch Medical and Electrochem. Segment information including sales from external customers, profit or loss, and assets by segment as well as sales from external customers and long-lived assets by geographic area are set forth at Note 19 Business Segment, Geographic and Concentration Risk Information of the Notes to Consolidated Financial Statements contained in Item 8 of this report.

#### **GREATBATCH MEDICAL**

CRM and Neuromodulation Component products include batteries, capacitors, filtered and unfiltered feedthroughs, engineered components, implantable stimulation leads and enclosures used in implantable medical devices (IMD), Additionally, Greatbatch Medical offers value-added assembly for these IMDs. An IMD is an instrument that is surgically inserted into the body to provide diagnosis and/or therapy. One sector of the IMD market is CRM, which is comprised of devices such as implantable pacemakers, implantable cardioverter defibrillators ( ICD ), cardiac resynchronization therapy ( CRT ) devices, and cardiac resynchronization therapy with backup defibrillation devices ( CRT-D ). Another sector of the IMD market is neuromodulation, which is comprised of pacemaker-type devices that stimulate nerves for the treatment of various conditions. Beyond established therapies of pain control, incontinence and movement disorders (Parkinson s disease and epilepsy), nerve stimulation for the treatment of other disabilities such as migraines, obesity and depression has shown promising results.

The following table sets forth the main categories of battery-powered IMDs and the principal illness or symptoms treated by each device:

Device Principal Illness or Symptom

**Pacemakers ICDs** CRT/CRT-Ds Neurostimulators

Cochlear hearing devices

Abnormally slow heartbeat (Bradycardia) Rapid and irregular heartbeat (Tachycardia) Congestive heart failure Chronic pain, movement disorders, epilepsy, obesity or depression Hearing loss

IMD systems generally include an implantable pulse generator ( IPG ) and one or more stimulation leads. An IPG is a battery powered device that produces electrical pulses. The lead then carries this electrical pulse from the IPG to the heart, spinal cord or other location in the body. Greatbatch Medical s portfolio of proprietary technologies, products and capabilities has been built to provide our CRM and Neuromodulation customers with a single source for the vast majority of the components and subassemblies required to manufacture an IPG or lead, to include complete lead systems. Our investments in research and development have generated proprietary products such as the  $Q_{HR}^{\ 0}$   $Q_{MR}^{\ 0}$  and  $Q_{Capacitor}$ primary battery and capacitor lines, which have enabled our OEM partners to make improvements in their system offerings in terms of device reliability, size, longevity and power. Greatbatch Medical s Xcellion line of Lithium-Ion rechargeable batteries leverages decades of implantable battery research, development and manufacturing expertise. This line of cells now includes the optional CoreGuard feature, which enables batteries to discharge to zero volts without performance degradation.

Despite the current global market challenges for this industry, we believe that the CRM and Neuromodulation markets continue to exhibit fundamentals that position Greatbatch Medical for growth.

Increased demand for Greatbatch Medical technologies will continue to be driven by the following factors:

Advances in medical technology New therapies will allow physicians to use IMDs to treat a wider range of patients with various diseases.

<u>Increasing device complexity</u> Device manufacturers are developing new devices with additional features (such as RF telemetry and MRI conditional capabilities) that will require increased energy, power and filtering capabilities. These new features make Greatbatch Medical technologies and innovations more relevant than ever.

Expanding patient population The patient groups that are eligible for CRM devices are increasing and the number of people in the U.S. that are over age 50 is expected to double in the next 10 years. Additionally, fast growing emerging markets, especially in Asia and Latin America, are getting significant attention from IMD manufacturers given their large population size, under-penetration, expanding purchasing power, and increasing expenditure in medical infrastructure and training. When coupled with the non-elective nature of most CRM technologies, these markets represent growth drivers for the Company.

Growth within neuromodulation Neuromodulation applications are growing at a faster pace than traditional markets, and are expected to expand as new therapeutic applications are identified. Additionally, core neuromodulation markets like spinal cord stimulation that rely significantly on patients for co-pays, are positioned to see stronger growth as global economic markets strengthen. Many CRM OEM companies, which are strategic partners of Greatbatch Medical, are also OEMs in the neuromodulation market, which positions us to capitalize on both drivers of market growth.

<u>Vascular Access</u> Products include introducers, specialty medical coatings, steerable sheaths and catheters that deliver therapies for many end-user markets including coronary and neurovascular disease, peripheral vascular disease, interventional radiology, vascular access, atrial fibrillation, and interventional cardiology, as well as products for medical imaging and drug and pharmaceutical delivery. Several of these markets are expected to experience significant global growth over the next few years. Introducers enable physicians to create a conduit through which they can insert infusion catheters, implantable ports, pacemaker leads and other therapeutic devices into a blood vessel. A catheter is a tube that can be inserted into a blood vessel to allow drainage, injection of fluids, or access by surgical instruments.

Our products seek to capitalize on the growth in the cardiac, neurology and vascular markets, especially since many of the large CRM OEMs are also in the vascular markets. This gives us an opportunity to develop close strategic partnerships that can be leveraged across markets, an opportunity that will grow in significance as OEMs continue to consolidate their operating divisions. In addition to those factors that are driving the CRM and neuromodulation markets, increased demand is also being driven by continued focus on minimally invasive procedures. Patients and health care providers are looking for minimally invasive technologies to treat disease. They are expanding the use of catheter based procedures and associated vascular therapies. We also continue to see strong growth in the vascular markets because of peripheral-vascular disease therapies and new indications for tissue extraction or ablation.

Orthopaedic Products include hip and shoulder joint reconstruction implants, bone plates and spinal devices, and instruments and delivery systems used in hip and knee replacement, trauma fixation and spine surgeries. Orthopaedic implants are used in reconstructive surgeries to replace or repair hips, knees and other joints, such as shoulders, ankles and elbows that have deteriorated as a result of disease or

injury. Trauma implant systems are used primarily to reattach or stabilize damaged bone or tissue while the body heals. Spinal implant systems are used by orthopaedic surgeons and neurosurgeons in the treatment of degenerative diseases, deformities and injuries in various regions of the spine.

Each implant system typically has an associated instrument set that is used in the surgical procedure to insert that specific implant system. Instruments included in a set vary by implant system. Usually, instrument sets are sterilized after each use and then reused, however, recent trends are moving towards single use instrumentation. Cases are used to store, transport and arrange implant systems and other medical devices and related surgical instruments. Cases are generally designed to allow for sterilization and re-use after an implant or other surgical procedure is performed. The majority of cases are tailored for specific implant procedures so that the instruments, implants and other devices are arranged within the case to match the order of use in the procedure and are securely held in clearly labeled, custom-formed pockets.

Many of the factors affecting the Orthopaedic market segment are similar to the CRM and Vascular Access markets. These factors include aging population, new implant and surgical technology, rising rates of obesity, a growing replacements market and emerging affluence in developing nations. As a result, we believe that the Orthopaedic market has strong growth fundamentals.

The following table summarizes information about our Greatbatch Medical products:

<b>Product</b> Batteries	Description Lithium iodine ( Li Iodine )	Principal Product Attributes High reliability and predictability		
	Lithium silver vanadium oxide ( Li SVO )	Long service life		
	Lithium carbon monoflouride ( Li CFx )	Customized configuration		
	Lithium ion rechargeable ( Li Ion )	Light weight		
	Lithium SVO/CFx ( $Q_R$ & $M_R$ )	High energy density, small size		
Capacitors	Storage for energy generated by a battery before delivery to the heart. Used in ICDs and CRT-Ds.	Stores more energy per unit volume (energy density) than other existing technologies Customized configuration		
EMI filters	Filters electromagnetic interference to limit undesirable response, malfunctioning or degradation in the performance of electronic equipment	High reliability attenuation of EMI RF over wide frequency ranges Customized design		
Feedthroughs	Allow electrical signals to be brought from inside hermetically sealed IMD to an electrode	Ceramic to metal seal is substantially more durable than traditional seals Multifunctional		
Coated electrodes	Deliver electric signal from the feedthrough to a body part undergoing stimulation	High quality coated surface Flexible in utilizing any combination of biocompatible coating surfaces Customized offering of surfaces and tips		

Product Precision components	<b>Description</b> Machined	Principal Product Attributes
recision components	Molded and over molded products	High level of manufacturing precision Broad manufacturing flexibility
Enclosures and related components	Titanium Stainless steel	Precision manufacturing, flexibility in configurations and materials
Value-added assemblies	Combination of multiple components in a single package/unit	Leveraging products and capabilities to provide subassemblies and assemblies
		Provides synergies in component technology and procurement systems
Stimulation leads	Cardiac, neuro and hearing restoration stimulation leads	Custom and unique configurations that increase therapy effectiveness, provide finished device design and manufacturing
Introducers	Creates a conduit to insert infusion catheters, guidewires, implantable ports, pacemaker leads and other therapeutic devices into a blood vessel	Variety of sizes and materials that facilitate problem-free access in a variety of clinical applications
Catheters	Delivers therapeutic devices to specific sites in the body	Enable safe, simple delivery of therapeutic and diagnostic devices, soft tip and steerability
		Provide regulatory clearance and finished device
Cases and trays	Delivery systems for cleaning and sterilizing orthopaedic instruments and implants	Deliver turn-key full service kits
Implants	Orthopaedic implants for reconstructive hip, knee, shoulder, trauma and spine procedures	Precision manufacturing, leveraging capabilities and products
		Complete processes including sterile peakering and
		Complete processes including sterile packaging and coatings
Instruments	Orthopaedic instruments for reconstructive and trauma procedures	Designed to improve surgical techniques, reduce surgery time, increase surgical precision and decrease risk of contamination

A majority of the components and devices Greatbatch Medical sells incorporate proprietary technologies. These proprietary technologies provide an entry barrier for new competitors, and further limit existing competitors from duplicating our products. In addition to these proprietary technologies, our proprietary know-how in the manufacture of these products provides further barriers to competition.

QiG Group As part of the natural evolution of our Company, in 2008, we reassigned 40 Greatbatch Medical engineers to create the QiG Group in order to help facilitate the development of complete medical devices for our customers. In creating QiG, we pooled and focused the tremendous talent, resources and capacity for innovation within our organization. Today, QiG encompasses 130 research and development professionals working in facilities in five states and focused on three compelling therapeutic areas: Cardiovascular, Neuromodulation and, longer-term, Orthopaedics. Additionally, QiG has established relationships with nearly a dozen key physicians who are highly specialized in these areas. These key opinion leaders are helping us to design medical devices from the ground up with features that will meet the needs of today s practicing clinicians.

Within the QiG Group, we are utilizing a disciplined and diversified portfolio approach with three investment modes strategic equity investments in start-up companies, OEM customer discrete projects, and incubating new medical devices to be sold or licensed to an OEM partner. The QiG Group employs a disciplined and thorough process for evaluating these opportunities. A scorecard process is utilized to review and select the most strategically valuable ideas to pursue, taking into account a host of variables including the market opportunity, regulatory pathway and reimbursement; market need and market potential; intellectual property and projected financial return.

As a result of the investments we have made, we are now able to provide our customers with complete medical devices. This includes development and regulatory submissions, as well as manufacturing and supporting worldwide distribution. These medical devices are full product solutions that complement our OEM customers products and utilize the component expertise and capabilities residing within Greatbatch Medical and Electrochem. The benefits to our OEM customers include shortening the time to market for these devices by accelerating the velocity of innovation, optimizing their supply chain and ultimately providing them with cost efficiencies. Once the QiG Group designs and develops a medical device, it is manufactured by Greatbatch Medical.

#### **ELECTROCHEM**

Electrochem provides technology solutions where safety, reliability, quality and durability are of the utmost importance. Our customized primary (non-rechargeable) and secondary (rechargeable) battery solutions are used in a number of critical markets such as energy, portable medical, military, environmental and more. Our product lines cover a vast number of highly-customized battery-powered applications in remote and demanding environments, including down hole drilling tools, military communication devices, automated external defibrillators, oceanographic buoys and more. Electrochem s primary and secondary power solutions and wireless sensing systems are used in markets where failure is not an option.

Our primary lithium power solutions are utilized in extreme climates and can withstand exceptionally high and low temperatures, along with high shock and vibration. Electrochem s product designs incorporate protective circuitry, glass-to-metal hermetic seals, fuses and diodes to help ensure safe, durable and reliable power as devices are subjected to these harsh conditions.

- 9 -

Our secondary power solutions comprise a number of chemistries including lithium, nickel and lead acid. These solutions also provide value-adds that complement each power source, including engineering design expertise, advanced electronics, smart charging and battery management systems, to ensure each solution is ready to perform in mission critical and life-saving applications.

As more fully described in Note 2 Acquisitions of the Notes to Consolidated Financial Statements contained in Item 8 of this report, Electrochem acquired Micro Power Electronics, Inc. (Micro Power) on December 15, 2011. This acquisition is expected to increase Electrochem s market position in both the primary and secondary engineered battery pack market, including chargers and power supplies. The acquisition increases Electrochem s emphasis on portable medical and military market verticals, where specialized portable power solutions in high reliability applications are essential.

Electrochem s unique wireless sensing systems are a complete solution for process industries, incorporating advanced wireless sensors that measure temperature, pressure and flow data, intelligent gateways and customized software. Electrochem s wireless sensing solutions provide real-time control and monitoring in markets where wired sensors can be hazardous and impractical, as well as industrial environments that possess dirty, remote and extreme environmental conditions. These patented systems utilize Electrochem s power sources and are used in existing markets such as energy, and new markets such as computer numerical control machining.

The following table summarizes information about our Electrochem products:

Product	Description	Principal Product Attributes
Primary cells	Low-rate	Optimized rate capability, shock and vibration resistant,
		high and low temperature tolerant, high energy density
	Moderate-rate	
	High rate (spiral)	
Primary and secondary battery packs	Highly-customized pack solutions	Diverse portfolio of cells in various sizes, temperature ranges and rate capabilities, custom-engineered and designed, value-add charging and battery management systems for secondary packs
Wireless sensing systems	Complete solutions measuring temperature, pressure and flow in real-time	Wireless sensors and interactive gateways that withstand the most extreme internal and external industrial environments, provide critical, real-time data delivered directly to a work station

- 10 -

#### RESEARCH AND DEVELOPMENT

Our position as a leading developer and manufacturer of components for IMDs and Electrochem batteries is largely the result of our long history of technological innovation. We invest substantial resources in research, development and engineering. Our scientists, engineers and technicians focus on improving existing products, expanding the use of our products and developing new products. In addition to our internal technology and product development efforts, we also engage outside research institutions for unique technology projects. In order to facilitate the development of new and improved medical devices, in 2008 we significantly increased our investments in research and development. Investments in medical device products, which is being facilitated through the QiG Group, totaled \$29 million, \$22 million and \$15 million for 2011, 2010 and 2009, respectively. Further information regarding the QiG Group is set forth under the Greatbatch Medical segment description of this Item 1 and Product Development section of Item 7 of this report.

#### PATENTS AND PROPRIETARY TECHNOLOGY

We rely on a combination of patents, licenses, trade secrets and know-how to establish and protect our proprietary rights to our technologies and products. Often, several patents covering various aspects of the design protect a single product. We believe this provides broad protection of the inventions employed.

As of December 30, 2011, we have 484 active U.S. patents and 363 active foreign patents. We also have 256 U.S. and 310 foreign pending patent applications at various stages of approval. During the past three years, we have been granted 143 new U.S. patents, 57 of which were granted in 2011. As a result of the QiG Group s efforts to develop complete medical devices, the amount of intellectual property being generated by the Company has accelerated as of late. We currently have 86 pending patent applications and 42 patents have been granted to us relating to our medical devices.

We are also a party to several license agreements with third parties under which we have obtained, on varying terms, exclusive or non-exclusive rights to patents held by them. An example of these agreements is for the basic technology used in our wet tantalum capacitors, filtered feedthroughs, biomimetic coatings, safety needles and MRI compatible lead systems. We have also granted rights in our patents to others under license agreements.

It is our policy to require our management and technical employees, consultants and other parties having access to our confidential information to execute confidentiality agreements. These agreements prohibit disclosure of confidential information to third parties except in specified circumstances. In the case of employees and consultants, the agreements generally provide that all confidential information relating to our business is the exclusive property of Greatbatch.

#### MANUFACTURING AND QUALITY CONTROL

We primarily manufacture small lot sizes, as most customer orders range from a few hundred to a few thousand units. As a result, our ability to remain flexible is an important factor in maintaining high levels of productivity. Each of our production teams receives assistance from representatives from our quality, engineering, manufacturing, materials and procurement departments. Our quality systems are compliant with and certified to various recognized international standards, requirements and directives.

Our facilities in Alden, NY, and Minneapolis, MN are certified under the International Organization for Standardization ( ISO ): 9001 quality system standard, which requires compliance with regulations regarding product design (where applicable), supplier control, manufacturing processes and component quality. This certification can only be achieved after completion of an audit conducted by an independent authority followed by periodic inspections to maintain this certification.

- 11 -

The quality systems of our manufacturing facilities in Tijuana, Mexico, Plymouth, MN, Clarence, NY, Chaumont, France, Orvin, Switzerland, Columbia City, IN, Indianapolis, IN and Raynham, MA are certified under the ISO: 13485 quality system standard, which requires, among other things, an implemented quality system that applies to the design (where applicable) and manufacture of components, assemblies and finished medical devices, including component quality and supplier control. Along with ISO: 13485, the facilities (where applicable) are subject to regulation by numerous regulatory bodies, including the Food and Drug Administration (FDA) and comparable international regulatory agencies in order to ship product worldwide.

We are required to register with the FDA as a device manufacturer and as a result, we are subject to periodic inspection by the FDA for compliance with their Quality System Regulation (QSR) requirements. Compliance with applicable regulatory requirements is subject to continual review and is rigorously monitored through periodic inspections by the FDA. In the European Community, we are required to maintain certain ISO certifications in order to sell products, and we undergo periodic inspections by notified bodies to obtain and maintain these certifications. Maintaining these certifications gives us the ability to serve as a manufacturing partner to medical device manufacturers, which we believe will improve our competitive position. Our Plymouth, MN, Columbia City, IN, Indianapolis, IN, Orvin, Switzerland and Chaumont, France facilities are registered with the FDA.

#### SALES AND MARKETING

Products from our Greatbatch Medical business are sold directly to our customers. In our Electrochem business, we utilize a combination of direct and indirect sales methods, depending on the particular product. In 2011, approximately 45% of our products were sold in the U.S. Sales outside the U.S. are primarily to customers whose corporate offices are located and headquartered in the U.S. Information regarding our sales by geographic area is set forth at Note 19 Business Segment, Geographic and Concentration Risk Information of the Notes to Consolidated Financial Statements contained in Item 8 of this report.

Although the majority of our medical customers contract with us to develop custom components and assemblies to fit their product specifications, we also provide system and device solutions ready for market distribution by OEMs. As a result, we have established close working relationships between our internal program managers and our customers. We market our products and technologies at industry meetings and trade shows domestically and internationally.

Internal sales managers support all activity and involve engineers and technology professionals in the sales process to address customer requests appropriately. For system and device solutions, we partner with our customers—research, marketing, and clinical groups to jointly develop technology platforms in alignment with their product roadmaps and therapy needs.

Electrochem utilizes a direct and indirect selling model to end users and OEMs. Additionally, we have a small number of strategic partner organizations, which enable us to sell into markets where language or geographical barriers are present. We leverage our strategic account managers with appropriate support from engineering, to design and sell product solutions into our targeted markets. Our strategic account managers are trained to assist our customers in selecting appropriate chemistries and configurations. We market our products and services through well-defined selling strategies and marketing campaigns that are customized for each of the industries we target.

Firm backlog orders at December 30, 2011 and December 31, 2010 were approximately \$191 million and \$159 million, respectively. The majority of the orders outstanding at December 30, 2011 are expected to be shipped within one year.

- 12 -

#### **CUSTOMERS**

Our Greatbatch Medical customers include large multi-national OEMs and their affiliated subsidiaries such as, in alphabetical order here and throughout this report, Biotronik, Boston Scientific, Johnson & Johnson, Medtronic, Smith & Nephew, Sorin Group, St. Jude Medical, Stryker and Zimmer. During 2011, 2010, and 2009, Boston Scientific, Johnson & Johnson, Medtronic and St. Jude Medical collectively accounted for 59%, 62% and 63% of our total sales, respectively. The Company has been successful in leveraging our diversified product line to further penetrate these customers and selling into more of their operating divisions, which cover the CRM, Neuromodulation, Vascular Access and Orthopaedic markets.

The nature and extent of our selling relationship with each OEM customer is different in terms of products purchased, selling prices, product volumes, ordering patterns and inventory management. For customers with long-term contracts, we have negotiated fixed pricing arrangements for pre-determined volume levels with pricing fixed at each level. In general, the higher the volume level, the lower the pricing. We have pricing arrangements with our customers that at times do not specify minimum order quantities. We recognize revenue when it is realized or realizable and earned. This occurs when persuasive evidence of an arrangement exists, delivery has occurred, the price is fixed or determinable, the buyer is obligated to pay us (i.e., not contingent on a future event), the risk of loss is transferred, there is no obligation of future performance, collectability is reasonably assured and the amount of future returns can reasonably be estimated. Those criteria are met at the time of shipment when title passes.

Our visibility to customer ordering patterns is over a relatively short period of time. Our customers may have inventory management programs, vertical integration plans and/or alternate supply arrangements which we are unaware of. Additionally, the relative market share among the OEM manufacturers changes periodically. Consequently, these and other factors can significantly impact our sales in any given period. Our customers may initiate field actions with respect to market-released products. These actions may include product recalls or communications with a significant number of physicians about a product or labeling issue. The scope of such actions can range from very minor issues affecting a small number of units to more significant actions. There are a number of factors, both short-term and long-term, related to these field actions that may impact our results. In the short-term, if a product has to be replaced, or customer inventory levels have to be restored, demand will increase. Also, changing customer order patterns due to market share shifts or accelerated device replacements may also have a positive or negative impact on our sales results in the near-term. These same factors may have longer-term implications as well. Customer inventory levels may ultimately have to be rebalanced to match new demand.

Our Electrochem customers are primarily companies involved in demanding markets where highly sophisticated power solutions or wireless sensing needs exist, such as energy, portable medical, military and environmental monitoring. Some of our larger OEM customers include General Electric, Halliburton Company, Scripps Institution of Oceanography, Thales, Weatherford International and Zoll Medical Corp.

#### SUPPLIERS AND RAW MATERIALS

We purchase certain critical raw materials from a limited number of suppliers due to the technically challenging requirements of the supplied product and/or the lengthy process required to qualify these materials both internally and with our customers. We cannot quickly establish additional or replacement suppliers for these materials because of these rigid requirements. For these critical raw materials, we maintain minimum safety stock levels and contractually partner with suppliers to help ensure the continuity of supply. Historically, we have not experienced any significant interruptions or delays in obtaining critical raw materials.

- 13 -

For non-critical raw material purchases, we utilize competitive pricing methods such as bulk purchases, precious metal pool buys, blanket orders, and long-term contracts to secure supply. We believe that there are alternative suppliers or substitute products available at competitive prices for all of these non-critical raw materials.

#### **COMPETITION**

Existing and potential competitors in our Greatbatch Medical business include leading IMD manufacturers such as Biotronik, Boston Scientific, Johnson & Johnson, Medtronic, Smith & Nephew, Sorin Group, St. Jude Medical, Stryker and Zimmer that currently have vertically integrated operations and may expand their vertical integration capability in the future. Competitors also include independent suppliers who typically specialize in one type of component. Competition for Electrochem varies and is dependent on the targeted industry. Our known non-vertically integrated competitors include the following:

Product Line Competitors

Greatbatch Medical

Medical batteries Eagle-Picher

Quallion

Capacitors Critical Medical Components

Feedthroughs Alberox (subsidiary of The Morgan Crucible Co. PLC)

EMI filtering AVX (subsidiary of Kyocera)

Eurofarad

Enclosures Heraeus

Hudson

National

Machined and molded

components

Numerous

Value added assembly Numerous
Catheters Creganna

Teleflex

Introducers Pressure Products

Thomas Medical

Stimulation leads Oscor

Orthopaedic trays,

Accelent

instruments and implants

Avalign Technologies

**IMDS** 

Micropulse, Inc.

Norwood Medical

# Edgar Filing: GREATBATCH, INC. - Form 10-K

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- 14 -

#### Edgar Filing: GREATBATCH, INC. - Form 10-K

#### **Table of Contents**

Product LineCompetitorsOrthopaedic trays,Sandvik

instruments and implants

Symmetry

(con t)

Paragon

Teleflex

Electrochem

Primary Power Solutions Tracer Technologies, Engineered Power, Saft, Ultralife

Secondary Power Solutions ICC, Nexergy, Ultralife, Saft

Wireless Sensing Solutions Vektek GOVERNMENT REGULATION

Except as described below, our business is not subject to direct governmental regulation other than the laws and regulations generally applicable to all businesses in the jurisdictions in which we operate. We are subject to federal, state and local environmental laws and regulations governing the emission, discharge, use, storage and disposal of hazardous materials and the remediation of contamination associated with the release of these materials at our facilities and at off-site disposal locations. Our manufacturing and research, development and engineering activities may involve the controlled use of small amounts of hazardous materials. Liabilities associated with hazardous material releases arise principally under the Federal Comprehensive Environmental Response, Compensation and Liability Act and analogous state laws that impose strict, joint and several liabilities on owners and operators of contaminated facilities and parties that arrange for the off-site disposal of hazardous materials. We are not aware of any material noncompliance with the environmental laws currently applicable to our business and we are not subject to any material claim for liability with respect to contamination at any Company facility or any off-site location. We may, however, become subject to these environmental liabilities in the future as a result of our historic or current operations.

Our products are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. For some of our component technology, we have master files on record with the FDA. Master files may be used to provide proprietary and confidential detailed information about technology, facilities, processes, or articles used in the manufacturing, processing, packaging and storing of one or more medical device components. These master files for devices may be used by device manufacturers to support their premarket approval application (PMA), investigational device exemption application (IDE) or premarket notification (510(k)).

In the U.S., our introducer and delivery catheter products are considered Class II devices. The 510(k) process requires us to demonstrate that our new medical devices are substantially equivalent to a legally marketed medical device. In order to support a substantial equivalence claim, we must submit supporting data. In Europe, these devices are considered Class IIa and Class III, respectively, under European Medical Device Directives. These Directives require companies that wish to manufacture and distribute medical devices in European Union member countries to obtain a CE Marking for those products, which indicate that the products meet minimum standards of performance, essential requirements, safety conformity assessment and quality.

The PMA process is a more rigorous process that is required to demonstrate that a new medical device is safe and effective. This is demonstrated by generating data regarding the design, manufacturing processes, materials, bench testing, and animal testing and typically requiring human clinical data. Some of our products that we are developing are Class III medical devices that require a PMA or, in the European Union, premarket approval through submission of a Design Dossier.

In 2010, Greatbatch Medical received clearance from the FDA for its OptiSeal Valved Peelable Introducer. We also received approval in Canada and CE Marking for distribution in Europe. OptiSeal is significant in that it represents the first 510(k) regulatory clearance received under the Greatbatch Medical brand and is the first product commercialized in connection with our systems and device strategy.

During the first quarter of 2012, we received FDA 510(k) clearance on our transradial catheter sheath introducer and steerable delivery sheath for AF ablation.

As a manufacturer of medical devices and components that go into medical devices, we are also subject to periodic inspection by the FDA for compliance with the FDA s Quality System Requirements and the applicable notified body in the European Union to ensure conformity to the Medical Device Directives and Active Implantable Medical Device Directives. We believe that our quality controls, development, testing, manufacturing, labeling, marketing and distribution of our medical devices conform to the requirements of all pertinent regulations. During 2011, our Greatbatch Medical facility in Chaumont, France was successfully inspected by the FDA without any Form 483 observations issued.

Our sales and marketing practices are subject to regulation by the U.S. Department of Health and Human Services pursuant to federal anti-kickback laws, and are also subject to similar state laws.

We are also subject to various other environmental, transportation and labor laws as well as various other directives and regulations both in the U.S. and abroad. We believe that compliance with these laws will not have a material impact on our capital expenditures, earnings or competitive position. Given the scope and nature of these laws, however, they may have a material impact on our operational results in the future. We assess potential product related liabilities on a quarterly basis. At present, we are not aware of any such liabilities that would have a material impact on our business.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act (collectively Health Care Reform ) legislating broad-based changes to the U.S. health care system. Health Care Reform could significantly impact our business operations and financial results, including increasing or decreasing revenue, as well as increasing employee medical costs and taxes.

Health Care Reform imposes significant new taxes on OEMs, which will result in a significant increase in the tax burden on our industry and which could have a material, negative impact on our results of operations and our cash flows. Other elements of Health Care Reform such as comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business, results of operations and financial condition.

Many significant parts of Health Care Reform will be phased in over the next seven years and require further guidance and clarification in the form of regulations. As a result, many of the impacts of Health Care Reform will not be known until those regulations are enacted, which we expect to occur over the next several years.

- 16 -

Since January 2010, there have been various actions by the U.S. Congress and the U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration to amend requirements in the hazardous materials regulations on the transportation of lithium cells and batteries, including lithium cells and batteries packed or contained in equipment. If enacted, these actions could have negatively impacted our results of operations in the form of increased compliance costs for our lithium batteries. On February 14, 2012, President Obama signed into law the Federal Aviation Administration Modernization and Reform Act, which reconciles the nation standards with global rules on the air shipment of lithium batteries, except for narrow exceptions. As a result of this legislation, we do not expect that any future U.S. legislative or administrative actions regarding the transportation of lithium cells and batteries will materially impact our results of operations, unless current global standards are revised.

On December 15, 2010, the U.S. Securities and Exchange Commission (SEC) issued a proposed rule under Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Section 1502 relates to reporting requirements regarding conflict minerals originating in the Democratic Republic of the Congo and adjoining countries. Under the proposed rule, issuers would be required to perform a reasonable due-diligence process to ascertain whether conflict minerals are necessary to the functionality or production of their manufactured or contracted to be manufactured products. If conflict minerals are used, the issuer would be required to make certain disclosures in its annual report on Form 10-K. We would incur additional, new compliance costs if the proposed rule is adopted since our Greatbatch Medical business utilizes some of the minerals specified in the proposed rule.

#### RECRUITING AND TRAINING

We invest substantial resources in our recruiting efforts to focus on a quality workforce that will support our business objectives. Our goal is to provide our associates with growth opportunities by attempting to fill more than half of our open employment positions internally. We further meet our hiring needs through outside sources, as required. We have an active succession planning process including a comprehensive development program in place for senior management in order to ensure we are able to implement our strategic plan.

We provide training for our associates designed to educate them on safety, quality, business strategy, and our culture. Our safety training programs educate associates on basic industrial safety practices while emphasizing the importance of knowing emergency response procedures. Our training programs focus on the methodologies and technical competencies required to support current and future business needs with a strong focus on quality and continuous improvement.

Supporting our commitment to learning, we offer our associates tuition reimbursement and encourage them to continue their education at accredited colleges and universities. We have established a number of programs designed to challenge and motivate our associates specifically encouraging continuous improvement, supervisory and leadership skills. We believe ongoing development is necessary to ensure our associates utilize best practices, and share a common understanding of work practices and performance expectations.

- 17 -

#### **EMPLOYEES**

The following table provides a breakdown of employees as of December 30, 2011:

Manufacturing	1,621
General and administrative	121
Sales and marketing	65
Research, development and engineering	296
Chaumont, France facility	236
Switzerland facilities	231
Tijuana, Mexico facility	701
Total	3.271

We also employ a number of temporary employees to assist us with various projects and service functions and address peaks in staff requirements. Our employees at our Chaumont, France and Tijuana, Mexico facilities are represented by a union. Approximately 171 and 230 positions at our Switzerland and France locations, respectively, are manufacturing in nature. The positions at our Tijuana, Mexico facility are primarily manufacturing. Approximately 192 positions were added as a result of our acquisition of Micro Power of which approximately 118 positions are manufacturing in nature. We believe that we have a good relationship with our employees.

#### EXECUTIVE OFFICERS OF THE COMPANY

Information concerning our executive officers is presented below as of February 28, 2012. The officers terms of office run from year to year until the first meeting of the Board of Directors after our Annual Meeting of Stockholders, which meeting takes place immediately following our Annual Meeting of Stockholders, and until their successors are elected and qualified, except in the case of earlier death, retirement, resignation or removal.

Mauricio Arellano, age 45, is President of our Greatbatch Medical segment, and has served in that office since December 2010. He served as Senior Vice President and Business Leader of our Cardiac and Neurology Group from October 2008 until December 2010, Senior Vice President and Business Leader of our CRM and Neuromodulation Group from January 2008 to October 2008, Senior Vice President and Business Leader of our Medical Solutions Group from November 2006 to January 2008, and as Vice President of Greatbatch Mexico from January 2005 to November 2006. Mr. Arellano joined our Company in October 2003 as the Plant Manager of our former Carson City, NV facility. Prior to joining our Company, he served in a variety of human resources and operational roles with Tyco Healthcare Especialidades Medicas Kenmex and with Sony de Tijuana Este.

**Susan M. Bratton**, age 55, is Senior Vice President and Business Leader for our Electrochem segment, and has served in that office since January 2005. She served as Vice President of Corporate Quality from March 2001 to January 2005, as General Manager of our Electrochem Division from July 1998 to March 2001 and as Director of Procurement from June 1991 to July 1998. Ms. Bratton has held various other positions with our Company since joining us in 1976.

Michelle Graham, age 45, is Senior Vice President for Human Resources, and has served in that office since joining our Company in December 2010. From 2005 until December 2010, she held a number of senior human resources positions at Bausch & Lomb, most recently as Vice President of Human Resources for its Global Vision Care division.

**Thomas J. Hook**, age 49, has served as our President & Chief Executive Officer since August 2006. Prior to August 2006, he was our Chief Operating Officer, a position he assumed upon joining our Company in September 2004. From August 2002 until September 2004, Mr. Hook was employed by CTI Molecular Imaging where he had served as President, CTI Solutions Group.

**Thomas J. Mazza**, age 58, is Senior Vice President & Chief Financial Officer, and has served in that office since August 2005. He joined our Company in November 2003 as Vice President and Corporate Controller. Prior to that, Mr. Mazza served in a variety of financial roles with Foster Wheeler Ltd., including Vice President and Corporate Controller.

**Timothy G. McEvoy**, age 54, is Vice President, General Counsel & Secretary, and has served in that office since joining our Company in February 2007. From 1992 until January 2007, he was employed in a variety of legal roles by Manufacturers and Traders Trust Company.

#### AVAILABLE INFORMATION

We make available free of charge through our Internet website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file those reports with, or furnish them to, the SEC. Our Internet address is <a href="https://www.greatbatch.com">www.greatbatch.com</a>. The information contained on our website is not incorporated by reference in this annual report on Form 10-K and should not be considered a part of this report. These items may also be obtained free of charge by written request made to Christopher J. Thome, Director of External Reporting and Investor Relations, Greatbatch, Inc., 10000 Wehrle Drive, Clarence, New York 14031.

#### CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

Some of the statements contained in this annual report on Form 10-K and other written and oral statements made from time to time by us and our representatives are not statements of historical or current fact. As such, they are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We have based these forward-looking statements on our current expectations, and these statements are subject to known and unknown risks, uncertainties and assumptions. Forward-looking statements include statements relating to:

future sales, expenses and profitability;

future development and expected growth of our business and industry;

our ability to execute our business model and our business strategy;

our ability to identify trends within our industries and to offer products and services that meet the changing needs of those markets; and

projected capital expenditures.

You can identify forward-looking statements by terminology such as may, will, should, could, expects, intends, plans, anticipates, estimates, predicts, potential or continue or the negative of these terms or other comparable terminology. These statements are only predictions Actual events or results may differ materially from those stated or implied by these forward-looking statements. In evaluating these statements and our prospects, you should carefully consider the factors set forth below. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by these cautionary factors and to others contained throughout this report. We are under no duty to update any of the forward-looking statements after the date of this report or to conform these statements to actual results.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from the results expressed or implied by our forward-looking statements or that may affect our future results, some of these factors include the following: our dependence upon a limited number of customers; customer ordering patterns; product obsolescence; our inability to market current or future products; pricing pressure from customers; our ability to timely and successfully implement cost reduction and plant consolidation initiatives; our reliance on third party suppliers for raw materials, products and subcomponents; fluctuating operating results; our inability to maintain high quality standards for our products; challenges to our intellectual property rights; product liability claims; our inability to successfully consummate and integrate acquisitions and to realize synergies and to operate these acquired businesses in accordance with expectations; our unsuccessful expansion into new markets; our failure to develop new products including system and device products; our inability to obtain licenses to key technology; regulatory changes or consolidation in the healthcare industry; global economic factors including currency exchange rates and interest rates; the resolution of various legal actions brought against the Company; and other risks and uncertainties that arise from time to time and are described in Item 1A Risk Factors of this report.

#### ITEM 1A. RISK FACTORS.

Our business faces many risks. Any of the risks discussed below, or elsewhere in this report or in our other SEC filings, could have a material impact on our business, financial condition or results of operations.

#### **Risks Related To Our Business**

We depend heavily on a limited number of customers, and if we lose any of them or they reduce their business with us, we would lose a substantial portion of our revenues.

In 2011, Boston Scientific, Johnson & Johnson, Medtronic and St. Jude Medical, collectively accounted for approximately 59% of our revenues. Our supply agreements with these customers may not be renewed. Furthermore, many of our supply agreements do not contain minimum purchase level requirements and therefore there is no guaranteed source of revenue that we can depend upon under these agreements. The loss of any large customer or a reduction of business with that customer for any reason would harm our business, financial condition and results of operations.

If we do not respond to changes in technology, our products may become obsolete and we may experience a loss of customers and lower revenues.

We sell our products to customers in several industries that experience rapid technological changes, new product introductions and evolving industry standards. Without the timely introduction of new products and enhancements, our products and services will likely become technologically obsolete over time and we may lose a significant number of our customers. In addition, other new products introduced by our customers may require fewer of our components. We dedicate a significant amount of resources to the development of our products and technologies and we would be harmed if we did not meet customer requirements and expectations. Our inability, for technological or other reasons, to successfully develop and introduce new and innovative products could result in a loss of customers and lower revenues.

If we are unable to successfully market our current or future products, our business will be harmed and our revenues and operating results will be reduced.

The market for our medical and commercial products has been growing in recent years. If the market for our products does not grow as forecasted by industry experts, our revenues could be less than expected. In addition, it is difficult to predict the rate at which the market for our products will grow or at which new and increased competition will result in market saturation. Slower growth in the CRM,

Orthopaedic, Vascular Access or Energy markets in particular would negatively impact our revenues. In addition, we face the risk that our products will lose widespread market acceptance. Our customers may not continue to utilize the products we offer and a market may not develop for our future products.

We may at times determine that it is not technically or economically feasible for us to continue to manufacture certain products and we may not be successful in developing or marketing them. Additionally, new technologies that we develop may not be rapidly accepted because of industry-specific factors, including the need for regulatory clearance, entrenched patterns of clinical practice and uncertainty over third party reimbursement. If this occurs, our business will be harmed and our operating results will be negatively affected.

#### We are subject to pricing pressures from customers, which could harm operating results.

We have made price reductions to some of our large customers in recent years and we expect customer pressure for price reductions will continue. Price concessions or reductions may cause our operating results to suffer. In addition, any delay or failure by a large customer to make payments due to us would harm our operating results and financial condition.

We rely on third party suppliers for raw materials, key products and subcomponents and if we are unable to obtain these materials, products and subcomponents on a timely basis or on terms acceptable to us, our ability to manufacture products will suffer.

Our business depends on a continuous supply of raw materials. The principal raw materials used in our business include lithium, iodine, tantalum, platinum, ruthenium, gallium trichloride, tantalum pellets, vanadium pentoxide, iridium, and titanium. The supply and price of these raw materials are susceptible to fluctuations due to transportation, government regulations, price controls, economic climate or other unforeseen circumstances. Increasing global demand for these raw materials has caused prices of these materials to increase significantly. In addition, there are a limited number of worldwide suppliers of several raw materials needed to manufacture our products. We may not be able to continue to procure raw materials critical to our business or to procure them at acceptable price levels.

We rely on third party manufacturers to supply many of our products and subcomponents. Manufacturing problems may occur with these and other outside sources, as a supplier may fail to develop and supply products and subcomponents to us on a timely basis, or may supply us with products and subcomponents that do not meet our quality, quantity and cost requirements. If any of these problems occur, we may be unable to obtain substitute sources for these products and subcomponents on a timely basis or on terms acceptable to us, which could harm our ability to manufacture our own products and components profitably or on time. In addition, to the extent the processes that our suppliers use to manufacture products and subcomponents are proprietary, we may be unable to obtain comparable subcomponents from alternative suppliers.

#### We may never realize the full value of our intangible assets, which represent a significant portion of our total assets.

At December 30, 2011, we had \$459.2 million of intangible assets, representing 52% of our total assets. These intangible assets consist primarily of goodwill, trademarks, tradenames, customer lists and patented technology arising from our acquisitions. Goodwill and other intangible assets with indefinite lives are not amortized, but are tested annually or upon the occurrence of certain events which indicate that the assets may be impaired. Definite lived intangible assets are amortized over their estimated useful lives and are tested for impairment upon the occurrence of certain events which indicate that the assets may be impaired. We may not receive the recorded value for our intangible assets if we sell or liquidate our business or assets. In addition, the material concentration of intangible assets increases the risk of a large charge to earnings in the event that the recoverability of these intangible assets is

- 21 -

impaired. In the event of such a charge to earnings, the market price of our common stock could be affected. In addition, intangible assets with definite lives, which represent \$100.3 million of our net intangible assets at December 30, 2011, will continue to be amortized. We incurred total amortization expenses relating to these intangible assets of \$10.5 million in 2011. These expenses will reduce our future earnings or increase our future losses.

# Quality problems with our products could harm our reputation for producing high quality products and erode our competitive advantage.

Our products are held to high quality and performance standards. In the event our products fail to meet these standards, our reputation could be harmed, which could damage our competitive advantage and result in lower revenues.

#### Quality problems with our products could result in warranty claims and additional costs.

We generally allow customers to return defective or damaged products for credit, replacement, or exchange. We generally warrant that our products will meet customer specifications and will be free from defects in materials and workmanship. Additionally, we carry a safety stock of inventory for our customers which may be impacted by warranty claims. We reserve for our exposure to warranty claims based upon recent historical experience and other specific information as it becomes available. However, these reserves may not be adequate to cover future warranty claims and additional warranty costs or inventory write-offs may be incurred which could harm our operating results.

# Regulatory issues resulting from product complaints, or recalls, or regulatory audits could harm our ability to produce and supply products or bring new products to market.

Our products are designed, manufactured and distributed globally in compliance with all applicable regulations and standards. However, a product complaint, recall or negative regulatory audit may cause products to be removed from the market and harm our operating results or financial condition. In addition, during the period in which corrective action is being taken by us to remedy a complaint, recall or negative audit, regulators may not allow new products to be cleared for marketing and sale.

#### If we become subject to product liability claims, our operating results and financial condition could suffer.

The manufacturing and sale of our products expose us to potential product liability claims and product recalls, including those that arise from failure to meet product specifications, misuse or malfunction, or design flaws, or use of our products with components or systems not manufactured or sold by us. Many of our products are components and function in interaction with our customers medical devices. For example, our batteries are produced to meet electrical performance, longevity and other specifications, but the actual performance of those products is dependent on how they are utilized as part of the customers devices over the lifetime of the products. Product performance and device interaction from time to time have been, and may in the future be, different than expected for a number of reasons. Consequently, it is possible that customers may experience problems with their medical devices that could require device recall or other corrective action, where our batteries met the specification at delivery, and for reasons that are not related primarily or at all to any failure by our product to perform in accordance with specifications. It is possible that our customers (or end-users) may in the future assert that our products caused or contributed to device failure. Even if these assertions do not lead to product liability or contract claims, they could harm our reputation and our customer relationships.

Provisions contained in our agreements with key customers attempting to limit our damages, including provisions to limit damages to liability for negligence, may not be enforceable in all instances or may otherwise fail to protect us from liability for damages. Product liability claims or product recalls,

regardless of their ultimate outcome, could require us to spend significant time and money in litigation and require us to pay significant damages. The occurrence of product liability claims or product recalls could affect our operating results and financial condition.

We carry liability insurance coverage that is limited in scope and amount. We may not be able to maintain this insurance at a reasonable cost or on reasonable terms, or at all. This insurance may not be adequate to protect us against a product liability claim that arises in the future.

Our operating results may fluctuate, which may make it difficult to forecast our future performance and may result in volatility in our stock price.

Our operating results have fluctuated in the past and are likely to fluctuate significantly from quarter to quarter due to a variety of factors, including the following:

a substantial percentage of our costs are fixed in nature, which results in our operations being particularly sensitive to fluctuations in production volumes;

changes in the relative portion of our revenue represented by our various products and customers, which could result in reductions in our profits if the relative portion of our revenue represented by lower margin products increases;

timing of orders placed by our principal customers who account for a significant portion of our revenues; and

increased costs of raw materials or supplies.

#### If we are unable to protect our intellectual property and proprietary rights, our business could be affected.

We rely on a combination of patents, licenses, trade secrets and know-how to establish and protect our rights to our technologies and products. As of December 30, 2011, we held 484 active U.S. patents and 363 active foreign patents. However, the steps we have taken and will take in the future to protect our rights may not be adequate to deter misappropriation of our intellectual property. In addition to seeking formal patent protection whenever possible, we attempt to protect our proprietary rights and trade secrets by entering into confidentiality and non-compete agreements with employees, consultants and third parties with which we do business. However, these agreements may be breached and if breached, there may be no adequate remedy available to us and we may be unable to prevent the unauthorized disclosure or use of our technical knowledge, practices and/or procedures. If our trade secrets become known, we may lose our competitive advantages. Additionally, as patents and other intellectual property protection expire we may lose our competitive advantage.

If third parties infringe or misappropriate our patents or other proprietary rights, our business could be seriously harmed. We may be required to spend significant resources to monitor our intellectual property rights, we may not be able to detect infringement of these rights and may lose our competitive advantages associated with our intellectual property rights before we do so. In addition, competitors may design around our technology or develop competing technologies that do not infringe on our proprietary rights.

We may be subject to intellectual property claims, which could be costly and time consuming and could divert our management from our business operations.

In producing our products, third parties may claim that we are infringing on their intellectual property rights, and we may be found to have infringed those intellectual property rights. We may be unaware of intellectual property rights of others that may be used in our technology and products. In addition, third parties may claim that our patents have been improperly granted and may seek to invalidate our existing

or future patents. If any claim for invalidation prevailed, the result could be greatly expanded opportunities for third parties to manufacture and sell products that compete with our products and our revenues from any related license agreements would decrease accordingly. We also typically do not receive significant indemnification from parties that license technology to us against third party claims of intellectual property infringement.

Any litigation or other challenges regarding our patents or other intellectual property could be costly and time consuming and could divert our management and key personnel from our business operations. The complexity of the technology involved in producing our products, and the uncertainty of intellectual property litigation increases these risks. Claims of intellectual property infringement might also require us to enter into costly royalty or license agreements. However, we may not be able to obtain royalty or license agreements on terms acceptable to us, or at all. We also may be made subject to significant damages or injunctions against development and sale of our products.

We may not be able to attract, train and retain a sufficient number of qualified employees to maintain and grow our business.

Our success will depend in large part upon our ability to attract, train, retain and motivate highly skilled employees. There is currently aggressive competition for employees who have experience in technology and engineering. We compete intensely with other companies to recruit and hire from this limited pool. The industries in which we compete for employees are characterized by high levels of employee attrition. Although we believe we offer competitive salaries and benefits, we may have to increase spending in order to attract, train and retain personnel.

We are dependent upon our senior management team and key personnel and the loss of any of them could significantly harm us.

Our future performance depends to a significant degree upon the continued contributions of our senior management team and key technical personnel. Our products are highly technical in nature. In general, only highly qualified and trained scientists have the necessary skills to develop our products. The loss or unavailability to us of any member of our senior management team or a key technical employee could significantly harm us. We face intense competition for these professionals from our competitors, customers and companies operating in our industry. To the extent that the services of members of our senior management team and key technical personnel would be unavailable to us for any reason, we would be required to hire other personnel to manage and operate our company and to develop our products and technology. We may not be able to locate or employ such qualified personnel on acceptable terms.

We may make acquisitions that could subject us to a number of operational risks and we may not be successful in integrating companies we acquire into our existing operations.

We have made and expect to make in the future acquisitions that complement our core competencies in technology and manufacturing to enable us to manufacture and sell additional products to our existing customers and to expand our business into related markets. Implementation of our acquisition strategy entails a number of risks, including:

inaccurate assessments of potential liabilities associated with the acquired businesses;

the existence of unknown or undisclosed liabilities associated with the acquired businesses;

diversion of our management s attention from our core businesses;

potential loss of key employees or customers of the acquired businesses;

difficulties in integrating the operations and products of an acquired business or in realizing projected revenue growth, efficiencies and cost savings; and

Table of Contents 27

increases in indebtedness and limitation in our ability to access capital if needed.

- 24 -

Our acquisitions have increased the size and scope of our operations, and may place a strain on our managerial, operational and financial resources and systems. Any failure by us to manage this growth and successfully integrate these acquisitions could harm our business and our financial condition and results.

#### If we are not successful in making acquisitions to expand and develop our business, our operating results may suffer.

One facet of our growth strategy is to make acquisitions that complement our core competencies in technology and manufacturing to enable us to manufacture and sell additional products to our existing customers and to expand our business into related markets. Our continued growth may depend on our ability to identify and acquire companies that complement or enhance our business on acceptable terms. We may not be able to identify or complete future acquisitions. Some of the risks that we may encounter include expenses associated with and difficulties in identifying potential targets, the costs associated with unsuccessful acquisitions, and higher prices for acquired companies because of competition for attractive acquisition targets.

#### Accidents at any of our facilities could delay production and affect our operations.

Our business involves complex manufacturing processes and hazardous materials that can be dangerous to our employees. Although we employ safety procedures in the design and operation of our facilities, there is a risk that an accident or death could occur. Any accident, such as a chemical spill or fire, could result in significant manufacturing delays or claims for damages resulting from injuries, which would harm our operations and financial condition. The potential liability resulting from any such accident or death, to the extent not covered by insurance, could harm our financial condition or operating results. Any disruption of operations at any of our facilities could harm our business.

# We may face competition that could harm our business and we may be unable to compete successfully against new entrants and established companies with greater resources.

Competition in connection with the manufacturing of our medical products may intensify in the future. One or more of our medical customers may undertake additional vertical integration initiatives and begin to manufacture some or all of their components that we currently supply them which could cause our operating results to suffer. The market for commercial power sources is competitive, fragmented and subject to rapid technological change. Many other commercial power source suppliers are larger and have greater financial, operational, personnel, sales, technical and marketing resources than us. These and other companies may develop products that are superior to ours, which could result in lower revenues and operating results.

#### We intend to develop new products and expand into new markets, which may not be successful and could harm our operating results.

We intend to expand into new markets and develop new and modified products based on our existing technologies and engineering capabilities, including the development of complete medical devices. These efforts have required and will continue to require us to make substantial investments, including significant research, development and engineering expenditures and capital expenditures for new, expanded or improved manufacturing facilities. Additionally, many of the new products we are working on take longer and more resources to develop and commercialize, including obtaining regulatory approval.

Specific risks in connection with expanding into new products and markets include: longer product development cycles, the inability to transfer our quality standards and technology into new products, the failure to receive regulatory approval for new products or modifications to existing products, and the failure of our customers to accept the new or modified products.

Our failure to obtain licenses from third parties for new technologies or the loss of these licenses could impair our ability to design and manufacture new products and reduce our revenues.

We occasionally license technologies from third parties rather than depending exclusively on our own proprietary technology and developments. Our ability to license new technologies from third parties is and will continue to be critical to our ability to offer new and improved products. We may not be able to continue to identify new technologies developed by others and even if we are able to identify new technologies, we may not be able to negotiate licenses on favorable terms, or at all. Additionally, we could lose rights granted under licenses for reasons beyond our control.

Our international sales and operations are subject to a variety of risks and costs that could affect our profitability and operating results.

Our sales outside the U.S., which accounted for 55% of sales for 2011, and our operations in Mexico, Switzerland and France, are and will continue to be subject to a number of risks and potential costs, including:

changes in foreign regulatory requirements;
local product preferences and product requirements;
longer-term receivables than are typical in the U.S.;
difficulties in enforcing agreements through certain foreign legal systems;
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

complex tax and cash management issues.

We earn revenue and incur expenses related to our foreign sales and operations that are denominated in a foreign currency. Historically, foreign currency fluctuations have not had a material effect on our consolidated financial statements. However, fluctuations in foreign currency exchange rates could have a significant negative impact on our profitability and operating results.

The current economic environment and credit market uncertainty could interrupt our access to capital markets, borrowings, or financial transactions to hedge certain risks, which could affect our financial condition.

As of December 30, 2011, we had \$236.0 million of long-term debt, including our convertible subordinated notes and revolving line of credit, which mature in 2013 and 2016, respectively. These facilities have allowed us to make investments in growth opportunities and fund working capital requirements. In addition, we enter into financial transactions to hedge certain risks, including foreign exchange and interest rate risk. Our continued access to capital markets, the stability of our lenders and their willingness to support our needs, and the stability of the parties to our financial transactions that hedge risks are essential for us to meet our current and long-term obligations, fund operations, and fund our

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strategic initiatives. An interruption in our access to external financing or financial transactions to hedge risk could affect our business prospects and financial condition.

The failure of our information technology systems to perform as anticipated could disrupt our business affect our financial condition.

The efficient operation of our business is dependent on our information technology ( IT ) systems. Accordingly, we rely upon the capacity, reliability and security of our IT hardware and software infrastructure and our ability to expand and update this infrastructure in response to our changing needs. Despite our implementation of security measures, our systems are vulnerable to damages from computer viruses, natural disasters, incursions by intruders or hackers,

failures in hardware or software, power fluctuations, cyber terrorists and other similar disruptions. The failure of our IT systems to perform as anticipated for any reason or any significant breach of security could disrupt our business and result in numerous consequences, including reduced effectiveness and efficiency of operations, inappropriate disclosure of confidential information, increased overhead costs and loss of important information, which could have a material effect on our business and results of operations. In addition, we may be required to incur significant costs to protect against damage caused by these disruptions or security breaches in the future.

#### **Risks Related To Our Industries**

The healthcare industry is subject to various political, economic and regulatory changes that could force us to modify how we develop and price our products.

The healthcare industry is highly regulated and is influenced by changing political, economic and regulatory factors. Several of our product lines are subject to international, federal, state and local health and safety, packaging and product content regulations. In addition, IMDs produced by our medical customers are subject to regulation by the FDA and similar governmental agencies. These regulations cover a wide variety of product activities from design and development to labeling, manufacturing, promotion, sales and distribution. Compliance with these regulations may be time consuming, burdensome and expensive and could negatively affect our customers—abilities to sell their products, which in turn would affect our ability to sell our products. This may result in higher than anticipated costs or lower than anticipated revenues.

Regulations issued in the healthcare industry are also complex, change frequently and have tended to become more stringent over time. Federal and state legislatures have periodically considered programs to reform or amend the U.S. healthcare system at both the federal and state levels. In addition, these regulations may contain proposals to increase governmental involvement in healthcare, lower reimbursement rates or otherwise change the environment in which healthcare industry participants operate. We may be required to incur significant expenses to comply with these regulations or remedy past violations of these regulations. Our failure to comply with applicable government regulations could also result in cessation of portions or all of our operations, impositions of fines and restrictions on our ability to carry on or expand our operations. In addition, because many of our products are sold into regulated industries, we must comply with additional regulations in marketing our products.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the Obama administration, members of Congress, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. The 2010 Health Care Reform Act imposes significant new taxes on OEMs, which will result in a significant increase in the tax burden on our industry and which could have a material, negative impact on our results of operations and our cash flows. Other elements of Health Care Reform such as comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business, results of operations and financial condition.

Many significant parts of Health Care Reform will be phased in over time and require further guidance and clarification in the form of regulations. As a result, many of the impacts of Health Care Reform will not be known until those regulations are enacted, which we expect to occur over the next several years.

- 27 -

#### Our business is subject to environmental regulations that could be costly to comply with.

Federal, state and local regulations impose various environmental controls on the manufacturing, transportation, storage, use and disposal of batteries and hazardous chemicals and other materials used in, and hazardous waste produced by, the manufacturing of our products. Conditions relating to our historical operations may require expenditures for clean-up in the future and changes in environmental laws and regulations may impose costly compliance requirements on us or otherwise subject us to future liabilities. Additional or modified regulations relating to the manufacture, transportation, storage, use and disposal of materials used to manufacture our products or restricting disposal or transportation of batteries may be imposed that may result in higher costs or lower operating results. In addition, we cannot predict the effect that additional or modified environmental regulations may have on us or our customers.

#### Consolidation in the healthcare industry could result in greater competition and reduce our revenues and harm our business.

Many healthcare industry companies are consolidating to create new companies with greater market power. As the healthcare industry consolidates, competition to provide products 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 our products. If we are forced to reduce our prices, our revenues would decrease and our operating results would suffer.

#### Our business is indirectly subject to healthcare industry cost containment measures that could result in reduced sales of our products.

Several of our customers rely on third party payors, such as government programs and private health insurance plans, to reimburse some or all of the cost of the procedures in which our products are used. The continuing efforts of government, insurance companies and other payors of healthcare costs to contain or reduce those costs could lead to patients being unable to obtain approval for payment from these third party payors. If that occurred, sales of medical devices may decline significantly and our customers may reduce or eliminate purchases of our products. The cost containment measures that healthcare payors are instituting, both in the U.S. and internationally, could reduce our revenues and harm our operating results.

#### Our Electrochem revenues are heavily dependent on conditions in the oil and natural gas industry, which historically have been volatile.

Sales of our Electrochem products depend to a great extent upon the condition of the oil and gas industry. In the past, oil and natural gas prices have been volatile and the oil and gas exploration and production industry has been cyclical, and it is likely that oil and natural gas prices will continue to fluctuate in the future. The current and anticipated prices of oil and natural gas influence the oil and gas exploration and production business and are affected by a variety of political and economic factors, including worldwide demand for oil and natural gas, worldwide and domestic supplies of oil and natural gas, the ability of the Organization of Petroleum Exporting Countries (OPEC) to set and maintain production levels and pricing, the level of production of non-OPEC countries, the price and availability of alternative fuels, political stability in oil producing regions and the policies of the various governments regarding exploration and development of their oil and natural gas reserves. A change in the oil and gas exploration and production industry or a reduction in the exploration and production expenditures of oil and gas companies could cause our Electrochem revenues to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS None.

- 28 -

#### ITEM 2. PROPERTIES

The following table sets forth information about our significant facilities as of December 30, 2011:

Location	Sq. Ft.	Own/Lease	Principal Use
Alden, NY	125,000	Own	Medical battery and capacitor manufacturing
Beaverton, OR	62,200	Lease	Commercial battery manufacturing
Blaine, MN	32,400	Own	Medical device engineering
Chaumont, France	59,200	Own	Manufacturing of orthopaedic and surgical goods
Clarence, NY	117,800	Own	Corporate offices and RD&E
Clarence, NY	20,800	Own	Machining and assembly of components
Clarence, NY	18,600	Lease	Machining and assembly of components
Cleveland, OH	16,900	Lease	Office and lab space for design engineering team
Columbia City, IN	40,000	Lease	Manufacturing of orthopaedic and surgical goods
Corgemont, Switzerland	34,400	Lease	Manufacturing of orthopaedic and surgical goods
Indianapolis, IN	82,600	Own	Manufacturing of orthopaedic and surgical goods
Minneapolis, MN	72,000	Own	Enclosure manufacturing and engineering
Orvin, Switzerland	40,400	Own	Manufacturing of orthopaedic and surgical goods
Plymouth, MN	95,700	Lease	Introducers, catheters and leads manufacturing
Raynham, MA	81,000	Own	Commercial battery manufacturing and RD&E
Tijuana, Mexico			Value-added assembly, and feedthrough, electrode
	144,000	Lease	and EMI filtering manufacturing
Warsaw, IN	3,000	Lease	Orthopaedic rapid prototyping design center

In 2011, we began construction on an 80,000 square foot manufacturing facility in Allen County, IN., which is expected to be completed by mid-2012. In 2011, we also initiated a multi-faceted plan to further enhance, optimize and leverage our Orthopaedics operations. This plan includes the opening of two Orthopaedic design centers, transferring production of certain Orthopaedic product lines to other lower cost manufacturing facilities and the consolidation of our Orthopaedic operations in Switzerland into a new facility. These initiatives are expected to be completed over the next two to three years. Total capital investment under these initiatives is expected to be between \$50 million and \$60 million of which approximately \$13 million has been incurred to date.

Near the end of 2011, we initiated plans to upgrade and expand our manufacturing infrastructure in order to support our medical device strategy. This will include expansion of two of our existing facilities, the purchase of equipment, as well as the transfer of certain product lines to create additional capacity for the manufacture of medical devices. These initiatives are expected to be completed over the next two to three years. Total capital investment under these initiatives is expected to be between \$15 million to \$20 million of which approximately \$1 million has been incurred to date.

#### ITEM 3. LEGAL PROCEEDINGS

We are party to various legal actions arising in the normal course of business. A description of pending legal actions against the Company is set forth at Note 14 Commitments and Contingencies of the Notes to Consolidated Financial Statements contained in Item 8 of this report. We do not believe that the ultimate resolution of any pending legal actions will have a material effect on our consolidated results of operations, financial position or cash flows. However, litigation is subject to inherent uncertainties. If an unfavorable ruling(s) were to occur, there exists the possibility of a material impact in the period in which the ruling occurs and beyond.

#### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

#### **PART II**

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

The Company s common stock trades on the New York Stock Exchange ( NYSE ) under the symbol GB. The following table sets forth information on our common stock as reported by the NYSE:

2010	High	Low	Close
First Quarter	\$ 21.69	\$ 18.99	\$ 20.90
Second Quarter	24.43	19.94	22.00
Third Quarter	24.00	21.35	22.84
Fourth Quarter	25.11	21.61	24.15

<u>2011</u>	High	Low	Close
First Quarter	\$ 26.92	\$ 22.91	\$ 26.12
Second Quarter	29.06	25.20	27.23
Third Quarter	28.33	18.55	20.01
Fourth Quarter	23.10	18.78	22.10

As of February 28, 2012, there were approximately 170 record holders of the Company s common stock. The Company stock account included in our 401(k) plan is considered one record holder for the purposes of this calculation. There is approximately 1,300 active and former employees holding Company stock in the 401(k) plan. We have not paid cash dividends and currently intend to retain any earnings to further develop and grow our business.

#### PERFORMANCE GRAPH

The following graph compares, for the five year period ended December 30, 2011, the cumulative total stockholder return for Greatbatch, Inc., the S&P SmallCap 600 Index, and the Hemscott Peer Group Index. The Hemscott Peer Group Index includes approximately 150 comparable companies included in the Hemscott Industry Group 520 *Medical Instruments & Supplies* and 521 *Medical Appliances & Equipment*. The graph assumes that \$100 was invested on December 29, 2006 and assumes reinvestment of dividends. The stock price performance shown on the following graph is not necessarily indicative of future price performance:

#### ITEM 6. SELECTED FINANCIAL DATA

The following table provides selected financial data for the periods indicated. You should read this data along with Item 7, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Item 8, Financial Statements and Supplementary Data appearing elsewhere in this report. The consolidated statement of operations data and the consolidated balance sheet data for the fiscal years indicated have been derived from our consolidated financial statements and related notes (in thousands, except per share amounts):

	Dec. 30, 2011(1)(2)	Dec. 31, 2010 <sup>(2)(4)</sup>	Years Ended Jan. 1, 2010 <sup>(2)(4)</sup>	Jan. 2, 2009(2)(3)	Dec. 28, 2007 <sup>(2)(3)</sup>
Statement of Operations Data:	2011	2010	2010	2009	2007
Sales	\$ 568,822	\$ 533,425	\$ 521,821	\$ 546,644	\$ 318,746
Net income (loss)	33,122	33,138	(9,001)	14,148	11,950
Earnings (loss) per share					
Basic	\$ 1.42	\$ 1.44	\$ (0.39)	\$ 0.63	\$ 0.54
Diluted	1.40	1.40	(0.39)	0.62	0.53
Balance Sheet Data:					
Working capital	\$ 170,907	\$ 150,922	\$ 119,926	\$ 142,219	\$ 116,816
Total assets	881,347	776,976	830,543	848,033	662,769
Long-term obligations	320,015	289,560	317,575	379,890	247,239

- On December 15, 2011, we acquired Micro Power Electronics, Inc. This data includes the results of operations of this company subsequent to the acquisition. Additional information is set forth in Note 2 Acquisitions of the Notes to Consolidated Financial Statements contained in Item 8 of this report. On January 5, 2011, the Company sold its cost method investment in IntElect Medical, Inc. This transaction resulted in a pre-tax gain of \$4.5 million.
- From 2007 to 2011, we recorded material charges in Other Operating Expenses, Net, primarily related to our cost savings and consolidation initiatives. Additional information is set forth in Note 12 Other Operating Expenses, Net of the Notes to Consolidated Financial Statements contained in Item 8 of this report.
- During 2008, we acquired P Medical Holding, SA (January 2008) and DePuy Orthopaedics Chaumont, France facility (February 2008). During 2007, we acquired BIOMEC, Inc. (April 2007), Enpath Medical, Inc. (June 2007), IntelliSensing, LLC (October 2007), Quan Emerteq, LLC (November 2007), and Engineered Assemblies Corporation (November 2007). This data includes the results of operations of these companies subsequent to their acquisition. In connection with these acquisitions, we recorded charges in 2008 and 2007 of \$8.7 million and \$18.4 million, respectively, related to inventory step-up amortization and the write-off of in process research and development.
- (4) In 2009, we recorded a \$34.5 million charge related to litigation involving Electrochem and a \$15.9 million write-down of trademarks and tradenames. In 2010, we settled the Electrochem litigation which resulted in a \$9.5 million gain. Additional information is set forth in Note 14 Commitments and Contingencies and Note 6 Intangible Assets of the Notes to Consolidated Financial Statements contained in Item 8 of this report.

**Our Business** 

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS YOU SHOULD READ THE FOLLOWING DISCUSSION AND ANALYSIS OF OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS IN CONJUNCTION WITH OUR FINANCIAL STATEMENTS AND RELATED NOTES INCLUDED ELSEWHERE IN THIS REPORT.

	Our business
	Our acquisitions
	Our customers
	Strategic and financial overview
	Government regulation
Our Critic	Product development cal Accounting Estimates
	Valuation of goodwill and other identifiable intangible assets
	Stock-based compensation
	Inventories
	Tangible long-lived assets
Cost Savir	Provision for income taxes  ngs and Consolidation Efforts
Our Finan	acial Results
	Results of operations table

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Fiscal 2011 compared with fiscal 2010
Fiscal 2010 compared with fiscal 2009
Liquidity and capital resources
Off-balance sheet arrangements
Litigation
Contractual obligations
Inflation

Impact of recently issued accounting standards

### **Our Business**

We operate our business in two reportable segments Greatbatch Medical and Electrochem Solutions (Electrochem). The Company s customers include large multi-national original equipment manufacturers (OEMs). Greatbatch Medical designs and manufactures medical devices and components for the cardiac rhythm management (CRM), neuromodulation, vascular access and orthopaedic markets. Additionally, Greatbatch Medical offers value-added assembly and design engineering services for products that incorporate Greatbatch Medical components. As a result of the strategy put in place over three years ago, Greatbatch Medical now offers its customers complete medical devices including design, development, manufacturing, regulatory submission and supporting worldwide distribution. This medical device strategy is being facilitated through the QiG Group and leverages the component technology of Greatbatch Medical and Electrochem in our core markets: cardiovascular, neuromodulation and orthopaedic. Once the QiG Group designs and develops a medical device, it is manufactured by Greatbatch Medical. The operating expenses of the QiG Group are included within the Greatbatch Medical segment.

- 32 -

Electrochem provides technology solutions where safety, reliability, quality and durability are critical. Electrochem s customized primary (non-rechargeable) and secondary (rechargeable) battery solutions are used in markets such as energy, portable medical, military, environmental and more. Electrochem s product lines cover a number of highly-customized battery-powered applications in remote and demanding environments, including down hole drilling tools, military communication devices, automated external defibrillators, oceanographic buoys and more. Electrochem s primary and secondary power solutions and wireless sensing systems are used in markets where failure is not an option.

#### **Our Acquisitions**

On December 15, 2011, Electrochem acquired all of the outstanding stock of Micro Power Electronics, Inc. (Micro Power) headquartered in Beaverton, OR. Micro Power is a leading supplier of custom battery solutions, serving the portable medical, military and handheld automatic identification and data collection markets. Micro Power s commercial portfolio is highly complementary to the products and services offered by Electrochem. The results of Micro Power s operations were included in our Electrochem segment from the date of acquisition. The aggregate purchase price of Micro Power was \$71.7 million, which we funded with cash on hand at Greatbatch and \$45 million borrowed under our revolving credit facility. Total assets acquired from Micro Power were \$88.2 million, of which \$60.8 million were intangible assets.

On February 16, 2012, we purchased all of the outstanding common stock of NeuroNexus Technologies, Inc. (NeuroNexus) headquartered in Ann Arbor, MI. NeuroNexus is an active implantable medical device design firm specializing in developing and commercializing high-value neural interface technology, components and systems for neuroscience and clinical markets. NeuroNexus has an extensive intellectual property portfolio, core technologies and capabilities to support the development and manufacturing of innovative neural interface devices across a wide range of functions including neuromodulation, sensing, optical stimulation and targeted drug delivery applications. This transaction will be accounted for under the acquisition method of accounting. Accordingly, the results of NeuroNexus s operations will be included in our consolidated financial statements from the date of acquisition. The aggregate purchase price, which includes the repayment of NeuroNexus debt at closing, was approximately \$12 million and was funded with cash on hand.

Going forward, we will continue to pursue potential acquisitions.

#### **Our Customers**

Our products are designed to provide reliable, long-lasting solutions that meet the evolving requirements and needs of our customers and the end users of their products. The nature and extent of our selling relationships with each customer are different in terms of breadth of products purchased, purchased product volumes, length of contractual commitment, ordering patterns, inventory management and selling prices.

Our Greatbatch Medical customers include large multi-national OEMs, such as Biotronik, Boston Scientific, Johnson & Johnson, Medtronic, Smith & Nephew, Sorin Group, St. Jude Medical, Stryker and Zimmer. During 2011, Boston Scientific, Johnson & Johnson, Medtronic and St. Jude Medical collectively accounted for 59% of our total sales.

Our Electrochem customers are primarily companies involved in demanding markets where highly sophisticated power solutions or wireless sensing needs exist, such as energy, portable medical, military and environmental. Some of our larger OEM customers include General Electric, Halliburton Company, Scripps Institution of Oceanography, Thales, Weatherford International and Zoll Medical Corp.

- 33 -

#### **Strategic and Financial Overview**

In 2007, we initiated a diversification strategy in order to enter new higher growth markets and provide a more stable foundation from which to grow over the long-term. The benefits of this strategy were evident over the last two years as growth in our Vascular Access, Orthopaedic and Electrochem product lines offset the slowdown in our CRM business. As a result, sales increased 7% and 2% in 2011 and 2010, respectively, despite flat CRM/Neuromodulation revenue over that two year period. Further evidence of the benefits of this strategy was the reduction of CRM/Neuromodulation revenue to 53% of our total sales in 2011, compared to 80% in 2007. Furthermore, with Electrochem s acquisition of Micro Power in December 2011, CRM/Neuromodulation revenue is expected to comprise less than 50% of total revenue in 2012. Additionally, the concentration of sales to our top three customers in the CRM market was reduced to 46% of revenues in 2011, versus 67% for those same three customers in 2007. Our goal is to reduce our concentration in the CRM market to below one-third of our revenue within the next five years.

Simultaneous with the initiation of our growth and diversification strategy, we began evolving our Company strategy to include the development of innovative medical devices in order to raise the growth and profitability profile of the Company. This medical device strategy is being facilitated through our QiG Group and leverages the component technology of Greatbatch Medical and Electrochem. Investments in medical device products totaled \$29 million, \$22 million and \$15 million for 2011, 2010 and 2009, respectively, and included charges to selling, general and administrative expenses (SG&A) and net research, development and engineering (RD&E). As a result, SG&A increased to 12.8% of total sales in 2011 compared to 12.1% in 2010 and RD&E costs increased to 8.0% of total sales in 2011 compared to 5.8% in 2008. In 2011, we began to see the financial benefit of these investments as the products that had shorter development lead times, primarily in the Vascular Access market, began to commercialize. During 2011, sales from medical devices that were developed under the Greatbatch name totaled \$5 million and were the first medical device revenues in the 40 year history of our Company. We expect the growth and cadence of new medical device product introductions to accelerate over the next several years as our longer lead time systems and device products, which we have invested in over the last four years, will also begin to commercialize.

We have a longstanding history of operational excellence, which is one of our core competencies. As we move forward, investing in our operations will continue to be critical to the success of our growth and medical device strategies. Since 2007, we have invested substantial resources in integrating our acquisitions and streamlining our operations. The benefits of these initiatives can be seen in our improvement in adjusted operating income to \$67.6 million in 2011 from \$58.1 million in 2008, which equates to 5% compound annual growth and was achieved despite the significant increase in spending on research and development. The benefits of these initiatives can also be seen in the substantial increase in our cash flow from operating activities during that time to \$89.9 million in 2011 from \$57.1 million in 2008. This strong cash flow helped to fund the repayment of debt, which totaled approximately \$164.5 million over the last three years. Our goal is to continuously improve operating margin over the next three to five years through our initiatives to improve operating performance and through the development of innovative products to drive future revenue growth, including medical device products. Consistent with this strategy, during 2011, we began implementing a multi-faceted plan to further expand, optimize and leverage our manufacturing infrastructure. These initiatives will take the better part of 2012 and 2013 to complete, but once finished, will leave us with a more capable and cost effective Orthopaedic operations and an infrastructure that will support the manufacturing of medical devices. Total capital investment in connection with these initiatives is expected to be between \$40 million and \$50 million with an additional \$15 million to \$20 million of expense.

- 34 -

To date, we have been successful in the implementation of all three facets of our strategy despite the macro-economic challenges that we are facing. Our strategy has positioned our Company for higher growth and profitability over the next several years and provides us multiple levers to achieve this growth. Namely, organic growth, growth through targeted acquisitions and growth through commercialization of our medical devices. Fundamental to this growth strategy will be our underlying core competency of sustaining operational excellence.

We prepare our consolidated financial statements in accordance with generally accepted accounting principles in the United States of America (GAAP). Additionally, we consistently report and discuss in our quarterly earnings releases and investor presentations adjusted operating income and margin, adjusted net income and adjusted earnings per diluted share, which are non-GAAP measures. These adjusted amounts consist of GAAP amounts and, to the extent occurring during a period, excludes (i) acquisition-related charges, (ii) facility consolidation, manufacturing transfer and system integration charges, (iii) asset write-down and disposition charges, (iv) severance charges in connection with corporate realignments or a general reduction in force (v) litigation charges and gains, (vi) the impact of non-cash charges to interest expense due to the accounting change governing convertible debt, (vii) unusual or infrequently occurring items, (viii) certain R&D expenditures (such as DVT expenses incurred in connection with the development of our Neuromodulation platform), (ix) gain/loss on the sale of investments and (x) the income tax (benefit) related to these adjustments. We believe that reporting these amounts provides important supplemental information to our investors and creditors seeking to understand the financial and business trends relating to our financial condition and results of operations. Additionally, the performance based compensation of our executive management is determined utilizing these adjusted amounts.

A reconciliation of GAAP operating income to adjusted operating income is as follows (in thousands):

	Year Ended					
	December 30, 2011	Dec	ember 31, 2010	January 1, 2010		
Operating income as reported	\$ 61,699	\$	68,994	\$	1,048	
Adjustments:						
Inventory step-up amortization (COS)	177					
Executive death benefits (SG&A)			885			
Neuromodulation platform DVT expense (RD&E)	5,133					
Electrochem Litigation charge (gain)			(9,500)		34,500	
Intangible asset write-down					15,921	
Consolidation costs	425		1,573		7,069	
Integration costs			42		3,077	
Asset dispositions, severance and other	168		2,943		948	
Operating income adjusted	\$ 67,602	\$	64,937	\$	62,563	
Operating margin adjusted	11.9%		12.2%		12.0%	

- 35 -

A reconciliation of GAAP income (loss) before tax to adjusted net income and adjusted diluted earnings per share ( EPS ) is as follows (in thousands, except per share amounts):

	December 30, 2011	 ear Ended ember 31, 2010	Ja	nuary 1, 2010
Income (loss) before tax as reported	\$ 48,392	\$ 49,325	\$	(18,177)
Adjustments:				
Inventory step-up amortization (COS)	177			
Executive death benefits (SG&A)		885		
Neuromodulation platform DVT expense (RD&E)	5,133			
Electrochem Litigation charge (gain)		(9,500)		34,500
Intangible asset write-down				15,921
Consolidation costs	425	1,573		7,069
Integration costs		42		3,077
Asset dispositions, severance and other	168	2,943		948
(Gain) loss on cost method investments, net	(4,232)	150		
CSN conversion option discount amortization	8,483	7,876		7,311
Adjusted income before taxes	58,546	53,294		50,649
Adjusted provision for income taxes	18,824	17,576		14,688
Adjusted net income	\$ 39,722	\$ 35,718	\$	35,961
Adjusted diluted EPS	\$ 1.68	\$ 1.51	\$	1.52
Number of shares <sup>(a)</sup>	23,636	23,802		23,983

<sup>(</sup>a) Adjusted shares outstanding used for calculating adjusted diluted EPS for 2009 include the dilutive impact of outstanding equity awards and convertible subordinated notes of 1,057,000 that were not dilutive for GAAP purposes.

For 2012, we expect adjusted operating margin to be between 11.5% and 12.5% of sales. This guidance assumes continued investment in medical device projects, as well as a lower mix of higher margin CRM/Neuromodulation revenue. Adjusted operating income is expected to consist of GAAP operating income less approximately \$15 million to \$20 million of adjustments, of which approximately \$5 million are non-cash expenses.

Consolidated annual sales for 2012 are projected to be approximately \$645 million to \$665 million. This would equate to an increase of 13% to 17% over 2011. For 2012, adjusted diluted EPS is expected to be in the range of \$1.75 to \$1.85 per diluted share. This would equate to an increase of 4% to 10% over 2011 adjusted diluted EPS. Adjusted diluted EPS is GAAP diluted EPS excluding the after-tax impact of the adjusted amounts described above and \$9.1 million (\$5.9 million net of tax) of non-cash convertible debt interest expense. This guidance also assumes approximately 24 million average diluted shares outstanding.

#### **Government Regulation**

The Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act (collectively Health Care Reform ) legislated broad-based changes to the U.S. health care system that could significantly impact our business operations and financial results, including higher or lower revenue, as well as higher employee medical costs and taxes. Health Care Reform imposes significant new taxes on OEMs of medical devices, which will result in a significant increase in the tax burden on our industry and which could have a material, negative impact on our financial condition, results of operations and our cash flows. Other elements of Health Care Reform such as comparative effectiveness research, an independent payment advisory board, payment system reforms including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business, results of operations and financial condition. Many significant parts of Health Care Reform will be phased in over the next seven years and require further guidance and clarification in the form of regulations. As a result, many of the impacts of Health Care Reform will not be known until those regulations are enacted.

Since January 2010, there have been various actions by the U.S. Congress and the U.S. Department of Transportation, Pipeline and Hazardous Materials Safety Administration to amend requirements in the hazardous materials regulations on the transportation of lithium cells and batteries, including lithium cells and batteries packed or contained in equipment. If enacted, these actions could have negatively impacted our results of operations in the form of increased compliance costs for our lithium batteries. On February 14, 2012, President Obama signed into law the Federal Aviation Administration Modernization and Reform Act, which reconciles the nation standards with global rules on the air shipment of lithium batteries, except for narrow exceptions. As a result of this legislation, we do not expect any future U.S. legislative or administrative actions regarding the transportation of lithium cells and batteries will materially impact our results of operations, unless current global standards are revised.

On December 15, 2010, the U.S. Securities and Exchange Commission (SEC) issued a proposed rule under Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Section 1502 relates to reporting requirements regarding conflict minerals originating in the Democratic Republic of the Congo and adjoining countries. Under the proposed rule, issuers would be required to perform a reasonable due-diligence process to ascertain whether conflict minerals are necessary to the functionality or production of their manufactured or contracted to be manufactured products. If conflict minerals are used, the issuer would be required to make certain disclosures in its annual report on Form 10-K. We would incur additional, new compliance costs if the proposed rule is adopted since our Greatbatch Medical business utilizes some of the minerals specified in the proposed rule.

#### **Product Development**

We continue to develop new component products for applications in our core markets, such as:

- 1. Q power solutions QHR<sup>®</sup> & QMR<sup>®</sup>, which maximize device performance and longevity with minimal size;
- QCAPS which, when paired with QHR batteries, provides the smallest, longest-lived, highest energy power solutions for tachycardia devices:
- 3. orthopaedic capabilities in order to improve quality and shorten lead-times, including the opening of additional regional development centers:
- 4. minimally invasive surgical techniques for the Orthopaedic industry;
- 5. disposable instrumentation for the Orthopaedic industry; and
- 6. next generation power sources for Electrochem s energy and portable medical customers.

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- 37 -

As part of the natural evolution of our Company, in 2008, we reassigned 40 Greatbatch Medical engineers to create the QiG Group in order to help facilitate the development of complete medical devices for our customers. In creating QiG, we pooled and focused the tremendous talent, resources and capacity for innovation within our organization. Today, QiG encompasses 130 research and development professionals working in facilities in five states and focused on three compelling therapeutic areas: cardiovascular, neuromodulation and, longer-term, orthopaedics. Additionally, QiG has established relationships with nearly a dozen key physicians who are highly specialized in these areas. These key opinion leaders are helping us to design medical devices from the ground up with features that will meet the needs of today s practicing clinicians.

Within the QiG Group, we are utilizing a disciplined and diversified portfolio approach with three investment modes strategic equity investments in start-up companies, OEM customer discrete projects, and incubating new medical devices to be sold or licensed to an OEM partner. The QiG Group employs a disciplined and thorough process for evaluating these opportunities. A scorecard process is utilized to review and select the most strategically valuable ideas to pursue, taking into account a host of variables including the market opportunity, regulatory pathway and reimbursement; market need and market potential; intellectual property and projected financial return.

As a result of the investments we have made, we are now able to provide our customers with complete medical devices. This includes development and regulatory submissions, as well as manufacturing and supporting worldwide distribution. These medical devices are full product solutions that complement our OEM customers products and utilize the component expertise and capabilities residing within Greatbatch Medical and Electrochem. The benefits to our OEM customers include shortening the time to market for these devices by accelerating the velocity of innovation, optimizing their supply chain and ultimately providing them with cost efficiencies.

We are currently in various stages of production or development on 15 to 20 medical devices, either through partnerships with our OEM customers or independently. While we do not discuss each of these projects individually each quarter, we will discuss significant milestones as they occur. Some of the medical device projects that we currently are working on include:

<u>Cardiovascular portfolio</u> Venous and arterial introducers, anti-microbial coatings, steerable delivery systems, and MRI conditional brady, gastric stimulation and sleep apnea leads. During the first quarter of 2012, we received FDA 510(k) clearance on our transradial catheter sheath introducer and steerable delivery sheath for AF ablation. We expect sales of these medical devices to ramp up during the second half of 2012.

<u>Neuromodulation portfolio</u> Algostim spinal cord stimulator for the treatment of chronic pain of the trunk and limbs. We are in the final stages of development of this device and are half way through the design verification testing phase. We are on track to make the applicable regulatory submissions on this device near the end of 2012.

- 38 -

#### **Our Critical Accounting Estimates**

The preparation of our consolidated financial statements in accordance with GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. The methods, estimates and judgments we use in applying our accounting policies have a significant impact on the results we report in our financial statements. Management considers an accounting estimate to be critical if (1) it requires assumptions to be made that were uncertain at the time the estimate was made; and (2) changes in the estimate or different estimates that could have been selected could have a material impact on our consolidated results of operations, financial position or cash flows. Our most critical accounting estimates are described below. We also have other policies that we consider key accounting policies, such as our policies for revenue recognition; however, these policies do not meet the definition of critical accounting estimates, because they do not generally require us to make estimates or judgments that are difficult or subjective.

### Valuation of goodwill and other identifiable intangible assets

When we acquire a company, we allocate the purchase price to the tangible and intangible assets we acquire and liabilities we assume based on their fair value at the date of acquisition. Some of our intangible assets are considered non-amortizing intangible assets as they are expected to generate cash flows indefinitely. Goodwill is recorded when the purchase price paid for an acquisition exceeds the estimated fair value of the net identified tangible and intangible assets acquired. Indefinite lived intangibles and goodwill are not amortized but are required to be assessed for impairment on an annual basis or more frequent if certain indicators are present. Definite-lived intangible assets are amortized over their estimated useful lives and are assessed for impairment if certain indicators are present.

#### Assumptions/Approach Used

We base the fair value of identifiable tangible and intangible assets on detailed valuations that use information and assumptions provided by management. The fair values of the assets acquired and liabilities assumed are determined using one of three valuation approaches: market, income or cost. The selection of a particular method for a given asset depends on the reliability of available data and the nature of the asset. The market approach values the asset based on available market pricing for comparable assets. The income approach values the asset based on the present value of risk adjusted cash flows projected to be generated by that asset. The projected cash flows for each asset considers multiple factors, including current revenue from existing customers, attrition trends, reasonable contract renewal assumptions from the perspective of a marketplace participant, and expected profit margins giving consideration to historical and expected margins. The cost approach values the asset by determining the current cost of replacing that asset with another of equivalent economic utility. The cost to replace the asset reflects the estimated reproduction or replacement cost, less an allowance for loss in value due to depreciation or obsolescence, with specific consideration given to economic obsolescence if indicated.

We perform an annual review on the last day of each fiscal year, or more frequently if indicators of potential impairment exist, to determine if the recorded goodwill and other indefinite lived intangible assets are impaired. We assess goodwill for impairment by comparing the fair value of our reporting units to their carrying value to determine if there is potential impairment. If the fair value of a reporting unit is less than its carrying value, an impairment loss is recorded to the extent that the implied fair value of the goodwill within the reporting unit is less than its carrying value. Fair values for reporting units are determined based on the income and market approaches. Indefinite lived intangible assets are evaluated for impairment by using the income approach. Definite-lived intangible assets are reviewed at least quarterly to determine if any conditions exist or a change in circumstances has occurred that would indicate impairment or a change in their remaining useful life.

- 39 -

We do not believe that the indefinite lived intangible assets or goodwill allocated to our Greatbatch Medical or Electrochem segments are at risk of failing step one of future annual impairment tests unless operating conditions significantly deteriorate, given the significant amount that our estimated fair value for these assets was in excess of their respective book values as of December 30, 2011.

#### Effect of Variation of Key Assumptions Used

The use of alternative valuation assumptions, including estimated cash flows and discount rates, and alternative estimated useful life assumptions could result in different purchase price allocations. Significant changes in these estimates and assumptions could impact the value of the assets and liabilities recorded, which would change the amount and timing of future intangible asset amortization expense.

We make certain estimates and assumptions that affect the expected future cash flows of our reporting units for our goodwill impairment testing. These include discount rates, terminal values and projections of future revenues and expenses. Significant changes in these estimates and assumptions could create future impairment losses to our goodwill. The assumptions used in our 2011 impairment test incorporate growth rates disclosed in 2012 Sales Outlook of this section as well as other forward-looking statements made in this Management Discussion and Analysis of Financial Condition and Results of Operations section.

For our indefinite lived intangible assets, we make estimates of royalty rates, future revenues and discount rates. Significant changes in these estimates could create future impairments of these assets.

Estimation of the useful lives of indefinite and definite lived intangible assets is based upon the estimated cash flows of the respective intangible asset and requires significant management judgment. Events could occur that would materially affect our estimates of the useful lives. Significant changes in these estimates and assumptions could change the amount of future amortization expense or could create future impairments of these intangible assets.

As of December 30, 2011, we have \$459.2 million of intangible assets recorded on our consolidated balance sheet representing 52% of total assets. This includes \$100.3 million of amortizing intangible assets, \$20.2 million of indefinite lived intangible assets and \$338.7 million of goodwill. A 1% change in the amortization of our intangible assets would change 2011 net income by approximately \$0.07 million, or approximately \$0.003 per diluted share.

#### **Stock-based compensation**

We record compensation costs related to our stock-based awards which include stock options, restricted stock and restricted stock units. We measure stock-based compensation cost at the grant date based on the fair value of the award.

Compensation cost for service-based awards is recognized ratably over the applicable vesting period. Compensation cost for performance awards based on Company financial metrics is reassessed each period and recognized based upon the probability that the performance targets will be achieved. Compensation cost for performance awards based on market metrics (such as total shareholder return) is expensed each period whether the performance metrics are achieved or not. The amount of stock-based compensation expense recognized during a period is based on the portion of the awards that are ultimately expected to vest, as well as market and nonmarket performance award considerations. The total expense recognized over the vesting period will only be for those awards that ultimately vest, as well as market and nonmarket performance award considerations.

## Assumptions/Approach Used

We utilize the Black-Scholes Option Pricing Model to determine the fair value of stock options. We are required to make certain assumptions with respect to selected Black Scholes model inputs, including expected volatility, expected life, expected dividend yield and the risk-free interest rate. Expected volatility is based on the historical volatility of our stock over the most recent period commensurate with the estimated expected life of the stock options. The expected life of stock options granted, which represents the period of time that the stock options are expected to be outstanding, is based, primarily, on historical data. The expected dividend yield is based on our history and expectation of dividend payouts. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant for a period commensurate with the estimated expected life.

The fair value of time-based as well as nonmarket-based performance restricted stock and restricted stock unit awards is equal to the fair value of the Company s stock on the date of grant. The fair value of market-based performance restricted stock unit awards is determined by utilizing a Monte Carlo simulation model, which projects the value of Greatbatch stock versus our peer group under numerous scenarios and determines the value of the award based upon the present value of these projected outcomes.

Compensation cost for nonmarket-based performance awards is reassessed each period and recognized based upon the probability that the performance targets will be achieved. That assessment is based upon actual and expected future performance.

Stock-based compensation expense is only recorded for those awards that are expected to vest, as well as market and nonmarket performance award considerations. Forfeiture estimates for determining appropriate stock-based compensation expense are estimated at the time of grant based on historical experience and demographic characteristics. Revisions are made to those estimates in subsequent periods if actual forfeitures differ from estimated forfeitures.

#### Effect of Variation of Key Assumptions Used

Option pricing models were developed for use in estimating the value of traded options that have no vesting restrictions and are fully transferable. Because our share-based payments have characteristics significantly different from those of freely traded options, and because changes in the subjective input assumptions can materially affect our estimates of fair values, existing valuation models may not provide reliable measures of the fair values of our share-based compensation. Consequently, there is a risk that our estimates of the fair values of our share-based compensation awards may bear little resemblance to the actual values realized upon the exercise, expiration or forfeiture of those share-based payments in the future. Stock options may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our consolidated financial statements. Alternatively, value may be realized from these instruments that are significantly in excess of the fair values originally estimated on the grant date and reported in our consolidated financial statements. There are significant differences among valuation models. This may result in a lack of comparability with other companies that use different models, methods and assumptions.

There is a high degree of subjectivity involved in selecting assumptions to be utilized to determine fair value and forfeiture assumptions. If factors change and result in different assumptions in future periods, the expense that we record for future grants may differ significantly from what we have recorded in the current period. Additionally, changes in performance of the Company and its stock price will affect the likelihood that performance-based targets are achieved and could materially impact the amount of stock-based compensation expense recognized.

- 41 -

A 1% change in our stock-based compensation expense would increase/decrease 2011 net income by approximately \$0.05 million, or approximately \$0.002 per diluted share.

#### **Inventories**

Inventories are stated at the lower of cost, determined using the first-in, first-out method, or market.

#### Assumptions/Approach Used

Inventory costing requires complex calculations that include assumptions for overhead absorption, scrap, sample calculations, manufacturing yield estimates and the determination of which costs may be capitalized. The valuation of inventory requires us to estimate obsolete or excess inventory, as well as inventory that is not of saleable quality.

## Effect of Variation of Key Assumptions Used

Variations in methods or assumptions could have a material impact on our results. If our demand forecast for specific products is greater than actual demand and we fail to reduce manufacturing output accordingly, we could be required to record additional inventory write-downs or expense a greater amount of overhead costs, which would have a negative impact on our net income. As of December 30, 2011, we have \$109.9 million of inventory recorded on our balance sheet representing 12% of total assets. A 1% write-down of our inventory would decrease 2011 net income by approximately \$0.7 million, or approximately \$0.03 per diluted share.

#### **Tangible long-lived assets**

Property, plant and equipment and other tangible long-lived assets are carried at cost. The cost of property, plant and equipment is charged to depreciation expense over the estimated life of the operating assets primarily using straight-line rates. Tangible long-lived assets are subject to impairment assessment if certain indicators are present.

# Assumptions/Approach Used

We assess the impairment of tangible long-lived assets when events or changes in circumstances indicate that the carrying value of the asset (asset group) may not be recoverable. Factors that we consider in deciding when to perform an impairment review include, but are not limited to: a significant decrease in the market price of the asset (asset group); a significant change in the extent or manner in which a long-lived asset (asset group) is being used or in its physical condition; A significant change in legal factors or in the business climate that could affect the value of a long-lived asset (asset group), including an action or assessment by a regulator; an accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction; a current-period operating or cash flow loss combined with a history of operating or cash flow losses or a projection or forecast that demonstrates continuing losses associated with the use of a long-lived asset (asset group); or a current expectation that, more likely than not, a long-lived asset (asset group) will be sold or otherwise disposed of significantly before the end of its previously estimated useful life. Recoverability potential is measured by comparing the carrying amount of the asset (asset group) to the related total future undiscounted cash flows. The projected cash flows for each asset (asset group) considers multiple factors, including current revenue from existing customers, proceeds from the sale of the asset (asset group), reasonable contract renewal assumptions, and expected profit margins giving consideration to historical and expected margins. If an asset s (assets group s) carrying value is not recoverable through

related cash flows, the asset (asset group) is considered to be impaired. Impairment is measured by comparing the asset s (asset group s) carrying amount to its fair value. When it is determined that useful lives of assets are shorter than originally estimated, and there are sufficient cash flows to support the carrying value of the assets, we accelerate the rate of depreciation in order to fully depreciate the assets over their shorter useful lives.

#### Effect of Variation of Key Assumptions Used

Estimation of the useful lives of tangible assets that are long-lived requires significant management judgment. Events could occur, including changes in cash flow that would materially affect our estimates and assumptions related to depreciation. Unforeseen changes in operations or technology could substantially alter the assumptions regarding the ability to realize the return of our investment in long-lived assets. Also, as we make manufacturing process conversions and other facility consolidation decisions, we must make subjective judgments regarding the remaining useful lives of our assets, primarily manufacturing equipment and buildings. Significant changes in these estimates and assumptions could change the amount of future depreciation expense or could create future impairments of these long-lived assets (asset groups).

As of December 30, 2011 we have \$145.8 million of tangible long-lived assets recorded on our consolidated balance sheet representing 17% of total assets. A 1% write-down in our tangible long-lived assets would decrease 2011 net income by approximately \$0.9 million, or approximately \$0.04 per diluted share.

### **Provision for income taxes**

Our consolidated financial statements have been prepared using the asset and liability approach in accounting for income taxes, which requires the recognition of deferred income taxes for the expected future tax consequences of net operating losses, credits, and temporary differences between the financial statement carrying amounts and the tax bases of assets and liabilities. A valuation allowance is provided on deferred tax assets if it is determined that it is more likely than not that the asset will not be realized.

#### Assumptions/Approach Used

In relation to recording the provision for income taxes, management must estimate the future tax rates applicable to the reversal of temporary differences based upon the timing of expected reversal. Also, estimates are made as to whether taxable operating income in future periods will be sufficient to fully recognize any gross deferred tax assets. If recovery is not likely, we must increase our provision for income taxes by recording a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. Alternatively, we may make estimates about the potential usage of deferred tax assets that decrease our valuation allowances.

The calculation of our tax liabilities involves dealing with uncertainties in the application of complex tax regulations. Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. We establish reserves for uncertain tax positions when we believe that certain tax positions do not meet the more likely than not threshold. We adjust these reserves in light of changing facts and circumstances, such as the outcome of a tax audit or the lapse of statutes of limitations. The provision for income taxes includes the impact of reserve provisions and changes to the reserves that are considered appropriate.

- 43 -

## Effect of Variation of Key Assumptions Used

Changes could occur that would materially affect our estimates and assumptions regarding deferred taxes. Changes in current tax laws and tax rates could affect the valuation of deferred tax assets and liabilities, thereby changing the income tax provision. Also, significant declines in taxable income could materially impact the realizable value of deferred tax assets. At December 30, 2011, we had \$33.3 million of gross deferred tax assets on our consolidated balance sheet and a valuation allowance of \$7.8 million has been established for certain deferred tax assets as it is more likely than not that they will not be realized. A 1 percentage point change in the effective tax rate would impact the current year provision for income taxes by \$0.5 million, and 2011 diluted earnings per share by \$0.02 per diluted share.

#### **Cost Savings and Consolidation Efforts**

In 2011, 2010 and 2009, we recorded charges in Other Operating Expenses, Net in the Consolidated Statements of Operations in connection with various cost savings and consolidation initiatives. These initiatives were undertaken to improve our operational efficiencies and profitability. Additional information regarding the timing, cash flow and amount of future expenditures is set forth in Note 12 Other Operating Expenses, Net of the Notes to Consolidated Financial Statements contained in Item 8 of this report.

In 2011, we began construction on an 80,000 square foot manufacturing facility in Allen County, IN., which is expected to be completed by mid-2012. In 2011, we also initiated a multi-faceted plan to further enhance, optimize and leverage our orthopaedics operations. This plan includes the opening of two Orthopaedic design centers, transferring production of certain Orthopaedic product lines to other lower cost manufacturing facilities and the consolidation of our Orthopaedic operations in Switzerland into a new facility. As part of the Switzerland consolidation, a Letter of Intent was received from the Canton of Bern for a new Tax Holiday, which is contingent on the purchase or construction of a new facility. If the new Tax Holiday is granted, we believe it will positively impact our effective tax rate. These initiatives are expected to be completed over the next two to three years. Total capital investment under these initiatives is expected to be between \$50 million and \$60 million of which approximately \$1 million has been incurred to date. Total expenses expected to be incurred on these projects is between \$10 million to \$15 million of which approximately \$1 million has been incurred to date.

Near the end of 2011, we initiated plans to upgrade and expand our manufacturing infrastructure in order to support our medical device strategy. This will include expansion of two of our existing facilities, the purchase of equipment, as well as the transfer of certain product lines to create additional capacity for the manufacture of medical devices. These initiatives are expected to be completed over the next two to three years. Total capital investment under these initiatives is expected to be between \$15 million to \$20 million of which approximately \$1 million has been incurred to date. Total expenses expected to be incurred on these projects is between \$2 million to \$3 million of which none has been incurred to date.

We expect the above initiatives to generate approximately \$4 million to \$7 million of annual cost savings, which is expected to fund the increased infrastructure costs also associated with these initiatives.

In 2011, we initiated plans to upgrade our existing global ERP system. This initiative is expected to be completed over the next two years. Total capital investment and expense to be incurred under this initiative is approximately \$10 million of which approximately half is to be expensed and relates to consulting costs to be incurred during the implementation.

- 44 -

# **Our Financial Results**

We utilize a fifty-two, fifty-three week fiscal year ending on the Friday nearest December 31st. Fiscal years 2011, 2010 and 2009 ended on December 30, 2011, December 31, 2010 and January 1, 2010, respectively. Fiscal years 2011, 2010 and 2009 all contained fifty-two weeks.

# **Results of Operations Table**

			Ye	ar Ended			2011 vs. 2010			2010 vs. 2009			
	I	Dec. 30,	I	Dec. 31,		Jan. 1,	\$ %		\$		%		
(Dollars in thousands, except per share data)		2011		2010		2010	C	hange	Cha	inge	(	Change	Change
Sales: Greatbatch Medical													
CRM/Neuromodulation	Φ.	303,690	Ф	303,521	¢	305,354	\$	169		0%	Ф	(1,833)	-1%
Vascular Access	φ.	45.098	Ф	38,000	Ф	35,816	Ф	7,098		19%	Ф	2,184	6%
Orthopaedic		140,277		118,748		113,897		21,529		18%		4,851	4%
Orthopacuic		140,277		110,740		113,697		21,329		10 /0		7,051	7/0
Total Greatbatch Medical		489.065		460,269		455,067		28,796		6%		5,202	1%
Electrochem		79,757		73,156		66,754		6,601		9%		6,402	10%
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Total sales		568.822		533,425		521,821		35,397		7%		11.604	2%
Cost of sales		388,469		359,844		355,402		28,625		8%		4,442	1%
		,		,		,		,				,	
Gross profit		180,353		173,581		166,419		6,772		4%		7,162	4%
Gross profit as a % of sales		31.7%		32.5%		31.9%						.,	
Selling, general and administrative expenses		70.540		(4.510		70.204		0.020		100		(5.704)	0.07
(SG&A)		72,548		64,510		70,294		8,038		12%		(5,784)	-8%
SG&A as a % of sales		12.8%		12.1%		13.5%							
Research, development and engineering costs, net													
(RD&E)		45,513		45,019		33,562		494		1%		11,457	34%
RD&E as a % of sales		8.0%		8.4%		6.4%							
Electrochem Litigation charge (gain)				(9,500)		34,500		9,500	-	100%	(	(44,000)	NA
Intangible asset write-down						15,921					(	(15,921)	-100%
Other operating expenses, net		593		4,558		11,094		(3,965)		-87%		(6,536)	-59%
Onewating income		61,699		68,994		1,048		(7.205)		-11%		67.046	N/A
Operating income Operating margin		10.8%		12.9%		0.2%		(7,295)		-1170		67,946	IN/A
Operating margin													
Interest expense		16,928		18,519		20,071		(1,591)		-9%		(1,552)	-8%
Interest income		(21)		(10)		(324)		(11)		NA		314	-97%
(Gain) loss on cost method investments		(4,232)		150				(4,382)		NA		150	NA
Other (income) expense, net		632		1,010		(522)		(378)		-37%		1,532	NA
Provision (benefit) for income taxes		15,270		16,187		(9,176)		(917)		-6%		25,363	NA
Effective tax rate		31.6%		32.8%		50.5%							
Net income (loss)	\$	33,122	\$	33,138	\$	(9,001)	\$	(16)		0%	\$	42,139	NA
Net margin		5.8%		6.2%		-1.7%							
Diluted earnings (loss) per share	\$	1.40	\$	1.40	\$	(0.39)	\$				\$	1.79	NA

Table of Contents 52

- 45 -

### Fiscal 2011 Compared with Fiscal 2010

Sales

Changes to sales by major product lines were as follows (in thousands):

	Year	Ended	2011 vs. 2010			
	December 30,	December 31,	\$	%		
	2011	2010	Change	Change		
Sales:						
Greatbatch Medical						
CRM/Neuromodulation	\$ 303,690	\$ 303,521	\$ 169	0%		
Vascular Access	45,098	38,000	7,098	19%		
Orthopaedic	140,277	118,748	21,529	18%		
Total Greatbatch Medical	489,065	460,269	28,796	6%		
Electrochem	79,757	73,156	6,601	9%		
Total sales	\$ 568,822	\$ 533,425	\$ 35,397	7%		

*Greatbatch Medical* Our 2011 revenue from our Greatbatch Medical business increased \$28.8 million or 6% from 2010 as double digit growth in our Vascular Access and Orthopaedic product lines offset the slow-down in the CRM market. Greatbatch Medical sales for 2011 included the benefit of approximately \$5 million of medical device sales and the favorable impact of approximately \$8 million from foreign currency exchange rate fluctuations. On a constant currency basis, 2011 sales for Greatbatch Medical increased 5% over the prior year.

For the year, CRM/Neuromodulation sales were consistent with 2010. During the first half of 2011, CRM revenue included the benefit of customer inventory builds and product launches, which did not recur in the second half of 2011. Additionally, CRM/Neuromodulation sales continue to be impacted by pricing pressures and a slowdown in the underlying market. As a result of these headwinds, we expect CRM/Neuromodulation revenue for 2012 to be lower in the first half of 2012 but begin to rebound in the second half of the year as the CRM market stabilizes.

Full year 2011 Vascular Access sales increased 19% over 2010. This increase was primarily attributable to growth in the underlying market and market share gains. Additionally, Vascular Access revenue for 2011 included approximately \$4 million from sales of medical devices that were developed under the Greatbatch name, including sales of our OptiSeal Valved Peelable Introducer which received FDA clearance in 2010. For 2011, approximately \$1 million of device sales were included within the CRM/Neuromodulation product line. For 2012, we expect that medical device sales will be up to \$15 million, with the majority of that revenue being realized in the second half of the year and within the Vascular Access product line.

Orthopaedic sales of \$140.3 million for 2011 were 18% above 2010, and included approximately \$8 million of favorable foreign currency exchange rate benefit. Excluding this benefit, sales increased 11% organically over the prior year despite slower than expected underlying market growth. These increases occurred across all of our orthopaedic products, which benefitted from customer product launches, as well as from market share gains during the quarter. These market share gains are a result of the investments made over the last several years to expand capabilities, shorten lead times, and improve quality and on-time delivery. Even though we have made significant improvements in this area, organic growth in 2012 will remain challenging given the weakness in the underlying healthcare markets and global economic headwinds.

Our visibility to our customer ordering patterns is over a relatively short period of time. Our customers have various inventory management, dual sourcing, and vertical integration initiatives, and the relative market share among OEM manufacturers—changes continuously. Additionally, we face pricing pressures from our customers and in particular our four largest OEM customers upon which a significant portion of our sales is dependent. These pressures have increased over the last several years due to the downturn in the global economy, and more specifically, the contracting CRM market. Consequently, these and other factors will continue to significantly impact our sales.

**Electrochem** For 2011, sales for the Electrochem business segment increased 9% in comparison to 2010. Fourth quarter 2011 sales for Electrochem included \$2.5 million of additional revenue from the Micro Power acquisition. Excluding the additional revenue provided by Micro Power, sales for 2011 increased 6% on an organic basis. During 2011, Electrochem revenue varied from quarter to quarter due to the timing of various customer inventory pulls. For the full year, the increase in Electrochem revenue was a result of an increased investment in sales and marketing, which resulted in market share gains and several new customer contracts, as well as continued strength in the energy markets.

**2012 Sales Outlook** 2012 annual product line revenue growth rates are expected to be as follows:

CRM & Neuromodulation:

Vascular Access:

0rthopaedic:

Electrochem<sup>(a)</sup>:

-3% to 0%

10% to 20%

5% to 15%

Approximately 5%

(a) Percentage increase assuming full year Micro Power revenue in 2011.

Based upon these growth rates, consolidated annual sales for 2012 are projected to be approximately \$645 million to \$665 million for 2012. This would equate to an increase of 13% to 17% over 2011. Given the underlying weakness in the healthcare markets, as well as the tough comparables versus the first and second quarters of 2011, we currently expect revenue for Greatbatch Medical for the first half of 2012 to be below 2011 levels, but rebound in the second half of the year as the healthcare markets stabilize. These growth projections may be impacted by a variety of factors including a continued softening in the healthcare markets, changes in pricing or exchange rates, changes in health care reimbursement policies, further dual sourcing/vertical integration initiatives by our customers and other factors described in Cautionary Factors That May Affect Future Results contained in Item 1 of this report.

#### Gross Profit

Changes to gross profit as a percentage of sales were primarily due to the following:

	2011-2010 % Point
	Change
Capacity & productivity <sup>(a)</sup>	0.9%
Performance-based compensation <sup>(b)</sup>	-0.9%
Mix change <sup>(c)</sup>	-0.5%
Selling price <sup>(d)</sup>	-0.8%
Other	0.5%
Total percentage point change to gross profit as a percentage of sales	-0.8%

- (a) Our gross profit percentage for 2011 benefitted from higher sales volumes, which absorbed excess capacity, as well as productivity gains from our various lean initiatives.
- (b) Our gross profit percentage for 2011 includes a higher level of performance-based compensation. Performance-based compensation is accrued based upon management s expectation of what level of performance will be achieved relative to targets set.
- (c) Our gross profit percentage for 2011 was negatively impacted by a lower mix of higher-margin CRM/Neuromodulation sales as a percentage of total sales compared to 2010.
- (d) Our gross profit percentage throughout 2011 was negatively impacted, in comparison to 2010, by price concessions made to our larger OEM customers near the end of 2010, which were given in exchange for long-term contracts.

Although down slightly for 2011, over the long-term, we expect our gross profit margin to improve as higher margin medical device products are introduced, as we continue to implement cost saving initiatives, and as revenue increases, which will absorb excess capacity.

#### SG&A Expenses

Changes to SG&A expenses were primarily due to the following (in thousands):

	11-2010 Change
Performance-based compensation <sup>(a)</sup>	\$ 3,935
Professional and consulting expense <sup>(b)</sup>	5,224
Litigation related fees and charges <sup>(c)</sup>	(808)
Executive death benefits <sup>(d)</sup>	(885)
Micro Power SG&A costs <sup>(e)</sup>	358
Other	214
Net increase in SG&A	\$ 8,038

(a) SG&A costs for 2011 include a higher level of performance-based compensation expense due to meeting our targets in 2011 combined with lower than expected results in 2010. Performance-based compensation is accrued based upon management s expectation of performance relative to targets set.

- 48 -

(b)