

GREATBATCH, INC.
Form 10-K
March 04, 2014

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 January 3, 2014
Commission File Number 1-16137

GREATBATCH, INC.
(Exact name of Registrant as specified in its charter)

Delaware (State of Incorporation) 2595 Dallas Parkway Suite 310 Frisco, Texas 75034 (Address of principal executive offices) (716) 759-5600 (Registrant's telephone number, including area code)	16-1531026 (I.R.S. Employer Identification No.)
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Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class: Common Stock, Par Value \$0.001 Per Share Securities Registered Pursuant to Section 12(g) of the Act: None	Name of Each Exchange on Which Registered: New York Stock Exchange
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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

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

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

Indicate by 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 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

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

The aggregate market value of common stock held by non-affiliates as of June 28, 2013 (the last business day of the registrant's most recently completed second fiscal quarter), based on the last sale price of \$32.79, as reported on the New York Stock Exchange: \$771.2 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 as of March 4, 2014: 24,649,884

DOCUMENTS INCORPORATED BY REFERENCE

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

Document	Part
Proxy Statement for the 2014 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 Accountant Fees and Services"

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PART I

ITEM 1. BUSINESS
OVERVIEW

Greatbatch, Inc. was founded in 1970 and is a Delaware corporation incorporated in 1997. When used in this report, the terms “Greatbatch,” “we,” “us,” “our” and the “Company” mean Greatbatch, Inc. and its subsidiaries. The Company conducted its initial public offering in 2000.

In connection with the realignment of our operating structure in 2013 to optimize profitable growth, which included changing our management and reporting structure, we reevaluated our operating and reporting segments. Beginning in the fourth quarter of 2013, we have two reportable segments: Greatbatch Medical and QiG Group (“QiG”). As required, prior year amounts have been reclassified in order to conform them to the current year presentation. Greatbatch Medical designs and manufactures products where Greatbatch either owns the intellectual property or has unique manufacturing and assembly expertise. The financial results of Greatbatch Medical include the former Implantable Medical and Electrochem Solutions (“Electrochem”) segments, excluding QiG. These products include medical devices and components for the cardiac, neuromodulation, orthopaedics, portable medical, vascular and energy markets among others. The Greatbatch Medical segment also offers value-added assembly and design engineering services for medical devices that utilize its component products.

QiG focuses on developing medical device systems for some of healthcare’s most pressing challenges and reflects Greatbatch’s strategic evolution of its product offerings in order to raise the growth and profitability profile of the Company. Through the research and development professionals in QiG, the Company is now investing in three areas - new medical device systems commercialization, collaborative programs with OEM customers, and strategic equity positions in start-up companies - to grow a diversified and distinctive portfolio. The medical device systems developed by QiG are manufactured by Greatbatch Medical.

The Company's customers include large multi-national original equipment manufacturers (“OEMs”).

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 implantable medical devices (“IMDs”).
August 2000	Battery Engineering, Inc.	Founded in 1983, designed and manufactured high-energy density batteries for industrial, commercial, military and medical applications.
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 BIOMECH, Inc.

Established in 1998, provided medical device design and component integration to early-stage and established customers.

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Acquisition Date	Acquired Company	Business at Time of Acquisition
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 orthopaedics industry.
February 2008	DePuy Orthopaedics' Chaumont, France manufacturing facility	Manufactured hip and shoulder implants for DePuy Orthopaedics.
December 2011	Micro Power Electronics, Inc. ("Micro Power")	Founded in 1990, designed custom battery packs, smart chargers and power supplies for industrial, military and portable medical applications.
February 2012	NeuroNexus Technologies, Inc. ("NeuroNexus")	Founded in 2004, medical device design firm specializing in developing neural interface technology, components and systems.

FINANCIAL STATEMENT YEAR END

We utilize a fifty-two, fifty-three week fiscal year ending on the Friday nearest December 31st. Fiscal years 2013, 2012 and 2011 ended on January 3, 2014, December 28, 2012 and December 30, 2011, respectively. Fiscal year 2013 contained fifty-three weeks and fiscal years 2012 and 2011 contained fifty-two weeks.

SEGMENT INFORMATION

In connection with the realignment of our operating structure in 2013, which included changing our management and reporting structure, we reevaluated our operating and reporting segments. Beginning in the fourth quarter of 2013, we have two reportable segments: Greatbatch Medical and QiG. 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

Greatbatch Medical's products include medical devices and components for the cardiac, neuromodulation, orthopaedics, portable medical, vascular and energy markets among others. A brief description of these products and markets follows:

Cardiac and neuromodulation – Products include batteries, capacitors, filtered and unfiltered feedthroughs, engineered components, implantable stimulation leads and enclosures used in IMDs. Additionally, we offer 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 cardiac, 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	Market Size (in billions)	Principal Illness or Symptom
Pacemakers	\$4.0	Abnormally slow heartbeat (Bradycardia)
ICDs	\$3.7	Rapid and irregular heartbeat (Tachycardia)
CRT/CRT-Ds	\$3.0	Congestive heart failure
Neurostimulators	\$2.6	Chronic pain, movement disorders, epilepsy, obesity or depression
Cochlear hearing devices	\$0.8	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. Our portfolio of proprietary technologies, products and capabilities has been built to provide our cardiac 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 has generated proprietary products such as the QHR[®], QMR[®] and QCapacitor[®] 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. Our 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.

We believe that the cardiac and neuromodulation markets continue to exhibit fundamentals that position this product line for growth. Factors that are impacting these markets are as follows:

Growing patient population – Implantable pacemakers and ICDs remain primary therapies for a number of critical clinical conditions, most of which are non-elective in nature. As the prevalence of many of these clinical conditions increase with age, underlying population demographics in developed countries will provide an engine for procedure growth.

Focus on emerging markets – OEM’s have increased their focus and investment to expand physicians' awareness of these life changing therapies, which we believe will result in increased utilization to improve quality of life for more patients globally. These growth initiatives will drive increased utilization of existing cardiac technologies and provide an avenue for new device and technology development as device manufacturers look to develop unique products for these markets.

Trends in device features – IMD evolution continues to favor the development of smaller, longer lasting devices with increased functionality and more physiologic shapes. Innovative battery, capacitor, enclosure, and filtering solutions such as those provided by Greatbatch Medical are critical to the realization of these market needs.

Growth within neuromodulation – Neuromodulation applications continue to grow at a faster pace than traditional markets, and are expected to continue to expand as new therapeutic applications are identified. There continues to be growth in clinical data supporting new applications and a growing focus and excitement from clinicians looking for treatment alternatives for challenging patient conditions. 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 cardiac OEM companies are also OEMs in the neuromodulation market, which positions us to capitalize on both drivers of market growth.

Disruptive Technologies - Two disruptive device technologies, sub-cutaneous ICDs and leadless pacemakers, gained significant visibility in 2013. Our portfolio of technologies and next generation development efforts are vital to the advancement of these new therapy platforms.

Orthopaedics – 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, extremity 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. Orthopaedic trays 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 to match the order of use in the procedure and are securely held in clearly labeled, custom-formed pockets or brackets.

Many of the factors affecting the orthopaedics market segment are similar to the cardiac and neuromodulation markets and include:

Aging population in developed markets - Conditions like osteoarthritis and spine degeneration are underlying drivers of a diverse spectrum of reconstructive therapies, and increase significantly with age. Continued growth in the 65+ population, along with an increased desire to remain active, will provide a driver for procedural growth.

Rates of obesity—Rates of obesity globally have continued to rise, and are expected to do so for the foreseeable future. Excess weight carriage exacerbates wear on joints and will drive the need for replacement and revision procedures.

New implant and surgical technology - The orthopaedic market continues to see a growing focus on minimally invasive procedures across a number of sectors including joint reconstruction and spinal fusion, potentially expanding the use of these therapeutic approaches.

Growth in emerging markets—Growing affluence in emerging markets has provided an opportunity for global growth of a number of orthopaedic procedures. Patient populations outside of developed markets continue to be underpenetrated, and investment from large device manufacturers in these markets will provide for procedural growth of established therapies.

We estimate that the orthopaedics market represents a \$3 billion market opportunity for Greatbatch Medical.

Vascular – Products include introducers, steerable sheaths and catheters that deliver minimally invasive 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. Most of these markets are expected to experience significant global procedural 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 deliver a therapeutic device or allow drainage, injection of fluids, or access by surgical instruments.

Our products seek to capitalize on the growth in the cardiac and vascular markets, especially since many of the large cardiac 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 cardiac and neuromodulation markets, increased demand is also being driven by continued focus on minimally invasive procedures. Patients, healthcare providers, and payors are looking for minimally invasive technologies to treat disease, expanding the use of catheter based procedures and associated vascular therapies. We also continue to see strong growth in the vascular markets because of the increased prevalence and treatment of peripheral artery disease as well as new indications for tissue extraction or ablation.

We believe that the vascular market represents a \$1.3 billion market opportunity for Greatbatch Medical.

Portable Medical, Energy, Military and Environmental - Greatbatch Medical also provides customized battery power and management systems, charging and docking stations, and power supplies. We design customized primary (non-rechargeable) and secondary (rechargeable) battery solutions which are used in the portable medical, energy, military and environmental markets. Our primary and secondary power solutions are used where failure is not an option.

Greatbatch Medical's primary lithium power solutions, which include high, moderate and low rate non-rechargeable cell solutions, are utilized in extreme conditions and can withstand exceptionally high and low temperatures, sterilization, and high shock and vibration. Our 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. Our primary batteries are often used in remote and demanding environments, including down hole drilling tools, military communication devices, oceanographic buoys and more.

In addition to primary power solutions, Greatbatch Medical offers customized secondary or rechargeable battery packs, in a diverse range of chemistries for critical applications requiring rechargeable solutions. Rechargeable

chemistries include lithium ion, lithium ion polymer, nickel metal hydride, nickel cadmium, lithium iron phosphate and sealed lead acid. Greatbatch Medical's rechargeable battery packs include advanced electronics, smart charging and battery management systems and are used in critical and life-saving applications, including automated external defibrillators, ventilators, powered surgical instruments and portable oxygen concentrators, among others.

The portable medical market trends continue to be favorable with an aging population and the shift from clinical to home settings for portable equipment to monitor and provide therapy. This market represents a strong opportunity despite cost pressure from healthcare reform. New product development in this market is vibrant as our customers continue to invest in the

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future to position for growth. We estimate that the portable medical market represents a \$1.0 billion market opportunity for Greatbatch Medical.

The following table summarizes information about our Greatbatch Medical products:

Product	Description	Principal Product Attributes
Batteries	Lithium iodine (“Li Iodine”)	High reliability and predictability;
	Lithium silver vanadium oxide (“Li SVO”)	Long service life;
	Lithium carbon monofluoride (“Li CFx”)	Customized configuration;
	Lithium ion rechargeable (“Li Ion”)	Light weight;
	Lithium SVO/CFx (“QHR” & “QMR”)	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
Precision components	Machined 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, neuromodulation 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		

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Delivers therapeutic devices to specific sites in the body

Enable safe and effective delivery of therapeutic and diagnostic devices, providing the right balance of steerability, trackability and crossability to reach the intended location

Cases and trays

Delivery systems for cleaning and sterilizing orthopaedic instruments and implants

High degree of customization;
Short, predictable development and production timelines

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Product	Description	Principal Product Attributes
Implants	Orthopaedic implants for large joint, spine, extremity and trauma procedures	Precision manufacturing, leveraging capabilities and product processes including sterile packaging and coatings
Instruments	Reusable and single use orthopaedic instruments for large joint, spine, extremity and trauma procedures	Designed to improve surgical techniques, reduce surgery time, and increase surgical precision
Primary cells	Low-rate Moderate-rate High rate (spiral) Wide Range	Optimized rate capability, shock and vibration resistant, high and low temperature tolerant, high energy density; Ability to operate in low and high temp applications
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

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

QiG focuses on developing medical device systems for some of healthcare’s most pressing challenges and reflects Greatbatch’s strategic evolution of its product offerings in order to raise the growth and profitability profile of the Company. QiG encompasses 120 research and development professionals across the U.S. working on a portfolio of new and innovative product opportunities. QiG has established relationships with highly specialized physicians across the U.S. and Europe that help support the design of medical device systems with unique benefits to improve clinical outcomes. QiG provides differentiated medical devices to OEM customers by accelerating the velocity of innovation while delivering optimized supply chain and cost efficiencies. We are utilizing our market research to drive our intellectual property portfolio with a goal of improved return on investment.

QiG utilizes a disciplined and diversified portfolio approach with three investment modes: new medical device systems commercialization, collaborative programs with OEM customers, and strategic equity positions in start-up companies. The development of certain new medical device systems are facilitated through the establishment of limited liability corporations (“LLC”). These LLCs do not own, but have the exclusive right to use the technology of Greatbatch Medical in certain, specifically designed fields of use and have an exclusive manufacturing agreement with Greatbatch Medical. QiG currently owns 89% - 100% of three LLCs. The minority interest of these LLCs was granted to key opinion leaders, clinicians and strategic partners at or near the time the LLC was established. Under the LLC agreement, QiG is liable for 100% of the expenses incurred by the LLC. However, no income is distributed to the minority holders of the LLC until QiG is reimbursed for all expenses paid. Once QiG has been fully reimbursed, all future net income is distributed based upon the respective LLCs ownership percentages. One of the LLCs established by QiG is for our spinal cord stimulator to treat chronic intractable pain of the trunk and/or limbs. This product was submitted for Food and Drug Administration (“FDA”) and CE Mark approval near the end of 2013. Another medical device system being developed by QiG is an implantable loop recorder for cardiac arrhythmia diagnostics. QiG is in the early stages of development of two additional medical device systems, which are targeting approved and emerging indications. Additionally, based upon the technology acquired from NeuroNexus, QiG is developing a platform of thin-film electrodes for neuromodulation leads, sub-systems and components.

Current QiG revenue includes sales of neural interface technology, components and systems to the neuroscience and clinical markets. Future income of QiG is expected to come from various sources including investment gains from the sales of LLC ownership interests, technology licensing fees, royalty revenue, and/or the sales of medical device systems to OEM customers.

RESEARCH AND DEVELOPMENT

Our position as a leading developer and manufacturer of medical devices and components 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

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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. Net investments in medical device systems (including gross profit and SG&A), which are being facilitated through QiG, totaled \$30.5 million, \$32.6 million and \$27.3 million for 2013, 2012 and 2011, respectively. Further information regarding our research and development activities can be found in the “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 January 3, 2014, we have 625 active U.S. patents and 344 active foreign patents. We also have 279 U.S. and 241 foreign pending patent applications at various stages of approval. During the past three years, we have been granted 189 new U.S. patents, 55 of which were granted in 2013. As a result of QiG’s development of complete medical device systems, the amount of intellectual property being generated by the Company has accelerated. Of the 1,489 patents and patents pending, approximately 537 of these relate to our medical device systems.

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 the license of basic technology used in our wet tantalum capacitors, filtered feedthroughs, biomimetic coatings, safety needles and MRI compatible lead systems. We have also granted rights to 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 leverage our strength as an innovative designer and manufacturer of finished devices and components to the medical device industry. Our manufacturing and engineering services include: design, testing, component production, and device assembly. We have integrated our proprietary technologies in our own products and those of our customers throughout the medical device industry. Our flexible, high productivity manufacturing capabilities span sites in Tijuana, Mexico, Beaverton, OR, Plymouth, MN, Minneapolis, MN, Ft. Wayne, IN, Indianapolis, IN, Alden, NY, Clarence, NY, Raynham, MA, and Chaumont, France.

Due to the highly regulated nature of the products we produce, we have implemented strong quality systems which are harmonized across our enterprise. The quality systems at our sites are compliant with and certified to various recognized international standards, requirements, and directives. Each site quality system is certified under an applicable International Organization for Standardization (“ISO”) quality system standard, such as ISO 13485 or ISO 9001. This certification requires, among other things, an implemented quality system that applies (where applicable) to the design and manufacture of components, assemblies and finished medical devices, including component quality and supplier control. Maintenance of these certifications for each facility requires periodic re-examination from an independent notified body.

Along with ISO 13485, the facilities producing finished medical devices are subject to extensive and rigorous regulation by numerous government bodies, including the FDA and comparable international regulatory agencies in order to ship product worldwide. For these facilities, we maintain FDA registration and compliance to all applicable domestic and international regulations. Compliance with applicable regulatory requirements is subject to continual review and is monitored through periodic inspections by FDA and other international regulatory bodies.

SALES AND MARKETING

We sell our products directly to our customers. In 2013, approximately 49% 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 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 account executives 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.

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We leverage our account executives with support from engineering to design and sell product solutions into our targeted markets. Our account executives 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.

Over the last several years we have significantly enhanced our sales and marketing capabilities. This has included moving account executives closer to our major customers, upgrading our sales force with new sales talent, enhancing our sales commission programs, and intensifying our market research. Additionally, we have placed additional emphasis on reaching long-term agreements with our OEM customers in order to secure our revenue base. At times, we have provided our customers with price concessions in exchange for entering into long-term agreements and certain volume commitments. We estimate that approximately 70 percent of our revenue is generated from long-term (three- to seven-year) agreements.

Firm backlog orders at January 3, 2014 and December 28, 2012 were approximately \$170 million and \$160 million, respectively. The majority of the orders outstanding at January 3, 2014 are expected to be shipped within one year.

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, Halliburton Company, Johnson & Johnson, Medtronic, Philips Healthcare, Smith & Nephew, Sorin Group, St. Jude Medical, Stryker, and Zimmer. During 2013, 2012, and 2011, Johnson & Johnson, Medtronic and St. Jude Medical collectively accounted for 49%, 46% and 51% of our total sales, respectively. We have been successful in leveraging our diversified product line to further penetrate these customers and selling into more of their operating divisions, which cover the cardiac, neuromodulation, vascular and orthopaedic markets. QiG customers include numerous scientists, hospitals and universities throughout the world who perform research for the neuroscience and clinical markets.

The nature and extent of our selling relationship with each OEM customer is different in terms of breadth 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. payment is 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.

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.

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.

As discussed more fully in Item 1A "Risk Factors," our business depends on a continuous supply of raw materials from a limited number of suppliers. If an unforeseen interruption of supply were to occur, we may be unable to obtain substitute

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sources for these raw materials on a timely basis or on terms acceptable to us, which could harm our ability to manufacture our products profitably or on time. Additionally, we may be unable to quickly establish additional or replacement suppliers for these materials as there are a limited number of worldwide suppliers.

COMPETITION

Our existing and potential competitors 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. Our known non-vertically integrated competitors include the following:

Product Line	Competitors
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 Vention medical
Introducers	Pressure Products Theragenics (Galt) Merit Medical
Stimulation leads	Oscor
Orthopaedic trays, instruments and implants	Accelent Avalign Technologies IMDS Micropulse, Inc. Juno Orchid Sandvik Symmetry Paragon Tecomet

Primary Power Solutions
Tracer Technologies
Engineered Power
Saft
Ultralife

Secondary Power Solutions
Totex
Palladium
ICC/Nexergy
BMZ
Ultralife
Saft

GOVERNMENT REGULATION

As described below, our business is subject to direct governmental regulation including 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 of our facilities 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 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.

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.

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.

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. healthcare 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 medical device 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 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 several years and require further guidance and clarification in the form of regulations. The new medical device tax, which was effective in 2013, increased our cost of sales by \$0.5 million.

On August 22, 2012, the U.S. Securities and Exchange Commission (“SEC”) issued a rule under Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act requiring companies to publicly disclose their use of conflict minerals that originated in the Democratic Republic of the Congo (“DRC”) or an adjoining country. Under the rule, issuers are required

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to conduct a reasonable due diligence process to ascertain the source of conflict minerals, defined as tantalum, tin, gold or tungsten, that are necessary to the functionality or production of their manufactured or contracted to be manufactured products. Companies are required to provide this disclosure on a new form to be filed with the SEC called Form SD. Companies are required to file Form SD by May 31, 2014 for the 2013 calendar period and annually by May 31 every year thereafter. We anticipate additional, new compliance costs to be incurred since we utilize all of the minerals specified in the rule. We are unable to quantify the cost of implementing this new regulation at this time.

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 many of our open employment positions internally. We further meet our hiring needs through outside sources, as required. We have an active talent review 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.

EMPLOYEES

The following table provides a breakdown of our employees:

Manufacturing – U.S.	1,746
General and administrative – U.S.	147
Sales and marketing – U.S.	72
Research, development and engineering – U.S.	253
Chaumont, France facility	247
Switzerland facility	5
Tijuana, Mexico facility	915
Total	3,385

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. Nearly all of the positions at our Chaumont, France and Tijuana, Mexico facilities are manufacturing related.

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 March 4, 2014. The officers' terms of office run from year to year until the first meeting of the Board of Directors occurring 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 47, is Executive Vice President for Global Operations and has served in that office since June 2013. From December 2010 to June 2013, he was President of Greatbatch Medical. Mr. Arellano 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.

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George M. Cintra, age 52, is Senior Vice President & Chief Technology Officer, and has served in that role since June 2013. Mr. Cintra had previously served as Vice President of Research, Development & Engineering of our Electrochem Solutions business since joining Greatbatch in August 2010. Prior to joining Greatbatch, he was Section Head & Technical Manager, Research & Development with Procter & Gamble from January 2007 to July 2010. Mr. Cintra previously held positions with Gillette Co, Duracell, W.R. Grace and Alcoa.

Michael Dinkins, age 59, is Executive Vice President & Chief Financial Officer, and has served in that office since joining our Company in May 2012. From 2008 until May 2012, he was Executive Vice President and Chief Financial Officer of USI Insurance Services, an insurance intermediary company. From 2005 until 2008, he was Executive Vice President and Chief Financial Officer of Hilb Rogal & Hobbs Co., an insurance and risk management services company. Prior to that, Mr. Dinkins held senior positions at Guidant Corporation, Access Worldwide Communications, Cadmus Communications Group and General Electric Company.

Michelle Graham, age 47, 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.

Andrew P. Holman, age 46, is Executive Vice President, Global Sales & Marketing, and has served in that role since June 2013. He joined Greatbatch in April 2012 as Vice President of Sales and Marketing for Greatbatch Medical. From September 2009 to October 2011, Mr. Holman served as Executive Vice President, Sales & Marketing for DJO Global, Inc., and from October 2005 to June 2009, he served as President of the Americas for the Orthopaedics business unit of Smith & Nephew, Inc. Mr. Holman previously held various sales and marketing leadership positions at Johnson & Johnson, Inc., Boston Scientific Corporation and Xerox Corporation.

Thomas J. Hook, age 51, 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.

Timothy G. McEvoy, age 56, is Senior 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 www.greatbatch.com. 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, Assistant Corporate Controller – Reporting and Shared Services, 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;
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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,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or “variations” 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

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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 our 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 medical device systems; 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 2013, Johnson & Johnson, Medtronic and St. Jude Medical, collectively accounted for approximately 49% 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 adversely affected.

The markets for our products have been growing in recent years. If the markets for our products do 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 markets for our products will grow or at which new and increased competition will result in market saturation. Slower growth in the cardiac and neuromodulation, orthopaedic, portable medical, vascular 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.

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

We have made price concessions to some of our larger customers in recent years and we expect customer pressure for price concessions 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, gold, palladium, stainless steel, aluminum, cobalt chrome, 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, foreign civil unrest, 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.

In addition, 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 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 January 3, 2014, we had \$443.1 million of intangible assets, representing 50% 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 significant amount of intangible assets increases the risk of a large charge to earnings in the event that the recoverability of these intangible assets is 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 \$76.1 million of our net intangible assets at January 3, 2014, will continue to be amortized. We incurred total amortization expenses relating to these intangible assets of \$13.2 million in 2013. These expenses will reduce our future earnings or increase our future losses.

Quality problems with our products could harm our reputation 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, cause us to lose customers 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

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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 product liability insurance with 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 mix of our revenue represented by our various products and customers could result in reductions in our profits if the mix 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 January 3, 2014, we held 625 active U.S. patents and 344 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-