INTEGRA LIFESCIENCES HOLDINGS CORP
Form 10-K
February 27, 2012
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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2011

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

COMMISSION FILE NO. 0-26224

INTEGRA LIFESCIENCES HOLDINGS CORPORATION

(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Delaware	**51-0317849**
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	*(I.R.S. EMPLOYER IDENTIFICATION NO.)*
311 Enterprise Drive	**08536** *(ZIP CODE)*
PLAINSBORO, NEW JERSEY *(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)*	

REGISTRANT S TELEPHONE NUMBER, INCLUDING AREA CODE: (609) 275-0500

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	**Name of Exchange on Which Registered**

Common Stock, Par Value $.01 Per Share The Nasdaq Stock Market LLC

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:

NONE

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

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

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 þ No ¨

Indicate by check mark 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 þ No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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. þ

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

Large accelerated filer þ	Accelerated filer ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

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

As of June 30, 2011, the aggregate market value of the registrant s common stock held by non-affiliates was approximately $956.2 million based upon the closing sales price of the registrant s common stock on The Nasdaq Global Market on such date. The number of shares of the registrant s Common Stock outstanding as of February 21, 2012 was 26,879,851.

DOCUMENTS INCORPORATED BY REFERENCE:

Certain portions of the registrant s definitive proxy statement relating to its scheduled May 17, 2012 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

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PART I

ITEM 1. ***BUSINESS***

OVERVIEW

The terms we, our, us, Company and Integra refer to Integra LifeSciences Holdings Corporation, a Delaware corporation, and its subsidiarie unless the context suggests otherwise.

Integra, headquartered in Plainsboro, New Jersey, is a world leader in medical devices. The Company employs approximately 3,400 people around the world who are dedicated to limiting uncertainty for surgeons, so they can concentrate on providing the best patient care. Integra offers innovative solutions in orthopedic extremity surgery, neurosurgery, spine surgery, and reconstructive and general surgery. Revenues grew to $780.1 million in 2011, an increase of 7% from $732.1 million in 2010.

Integra was founded on a technology platform to repair and regenerate tissue with engineered collagen devices. The Company has developed numerous product lines for applications ranging from burn and deep tissue wounds to regeneration of dura mater in the brain and repair of nerve and tendon. Over the past 20 years, Integra has built upon this core regenerative medicine technology, acquiring businesses in markets with overlapping customer bases and developing products to further meet the needs of its target customers. Integra today has three revenue categories in Orthopedics, which includes spine, extremity reconstruction, and private label product lines, Neurosurgery, and Instruments.

Integra s orthopedic products include devices and implants for foot and ankle, hand and wrist, shoulder and elbow, tendon and peripheral nerve protection and repair, wound repair and spine. Integra is a leader in cranial neurosurgery, offering a broad portfolio of implants, devices, instruments and systems used in neurosurgery, neuromonitoring, neurotrauma, and related critical care. In the United States, we are one of the largest providers of surgical instruments to hospitals, surgery centers and alternate care sites, including physician and dental offices.

We aspire to be a diversified global medical device company that helps patients by limiting uncertainty for medical professionals, and is a high quality investment for shareholders. We will achieve these goals by delivering on our Brand Promises to our customers worldwide and by becoming a top player in all markets in which we compete.

STRATEGY

Our goal is to become a global medical devices company whose products touch millions of lives. Key elements of our strategy include:

Geographic Expansion. With less than one quarter of our revenues generated from markets outside the United States, we see an opportunity to accelerate revenue growth by increasing our International presence. We are expanding our infrastructure functions in key markets and developing our distribution and service structures to fuel this expansion.

Margin Expansion. We have a large manufacturing and distribution footprint. We see an opportunity to generate higher marginal profit and increase cash flow through efforts to optimize these operations.

Leverage Platform Synergies. Our diversification in Orthopedics, Neurosurgery and Instruments has some advantages that provide opportunities for further leverage. These opportunities include instrument sourcing in Orthopedics, optimizing our company-wide sourcing strategy, contracting with group purchasing organizations (GPOs) contracting and corporate account management, and regenerative medicine product development projects across all three categories.

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Disciplined Focus and Execution. We have put in place new operating mechanisms and strategic initiatives aimed at improving execution. Organizational changes align and focus employees on achieving a prioritized set of goals. We expect that over time, these efforts will result in better planning and execution.

Global Quality Assurance. We are working toward a common corporate quality system to support our global growth expectations. This updated structure will enable a consistent approach across locations, reduce redundancies, and increase overall efficiency in this function.

Acquiring or In-licensing Products That Fit Existing Sales Channels. We acquire businesses and acquire or in-license new products to increase the efficiency and size of our sales force, stimulate the development of new products, and extend the commercial lives of existing products. During 2011, we completed the acquisitions of SeaSpine, which developed and distributed spinal fixation products, including both hardware and biologics, and Ascension Orthopedics, which developed and sold implants for the shoulder, elbow, wrist, hand, foot and ankle. Through these and over 40 other acquisitions in the history of the Company, we have demonstrated that we can quickly and profitably integrate new products and businesses, and have an active program to evaluate similar opportunities.

Our strategy allows us to expand our presence in hospitals and other health care facilities, to integrate acquired products effectively, to create strong sales platforms, and to drive short- and long-term revenue and earnings growth.

SALES AND DISTRIBUTION

We sell products in three market categories: Orthopedics, Neurosurgery and Instruments. Within the Orthopedics category, we sell through a large direct sales organization and through specialty distributors focused on their respective surgical specialties. Neurosurgery sells products through directly employed sales representatives. Instruments are sold through two sales channels, both directly and through distributors and wholesalers, depending on the customer call point.

PRODUCTS OVERVIEW

We are a fully integrated medical device company that offers thousands of products for the medical specialties which we target. We distinguish ourselves by emphasizing the importance of regenerative medicine, which we define as surgical implants derived from our proprietary collagen matrix technology and other biologic platforms. Our objective is to develop, acquire or otherwise provide products that will limit uncertainty in the surgical theatre. These products include our regenerative medicine implants, metal implants, instruments and equipment for orthopedic surgery, neurosurgery and general surgery.

In 2011, approximately 23% of our revenues came from regenerative medicine. While these products vary in composition and structure, they operate under similar principles. We build our matrix products from collagen, which is the basic structural protein that binds cells together in the body. Our matrices (whether for the dura mater, dermis, peripheral nerves, tendon or bone) provide a scaffold to support the infiltration of the patient s own cells and the growth of blood vessels. Eventually, those infiltrating cells consume the collagen of the implanted matrix and promote the development of new native extracellular matrix. In their interaction with the patient s body, our collagen matrices provide an environment to inhibit the formation of scar tissue, so the implant is absorbed over time, leaving healthy native tissue in its place. This basic technology can be applied to many different procedures. We sell these regenerative medicine products through most of our sales channels.

ORTHOPEDICS PRODUCT PORTFOLIO

Our orthopedics market category includes products that our Extremity Reconstruction and Spine sales organizations sell.

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In September 2011, we acquired Ascension Orthopedics, Inc. (Ascension), a provider of high quality implants for the shoulder, elbow, wrist, hand, foot and ankle. The acquisition provided us with a new entry into the fast-growing shoulder market. Key benefits of the combination include:

Complementary Product Portfolio. Ascension s strong position in upper extremities complements our leading foot and ankle product line.

New Entry Into Shoulder Market. Ascension offers an attractive shoulder technology, opening the $600 million shoulder market to us.

PyroCarbon Technology. This proprietary technology adds exciting new potential to our product development program.

Industry Experience. Ascension s management and development teams provide us with valuable extremities industry experience.

Integra Extremity Reconstruction Product Portfolio

Extremity reconstruction is a growing area of the orthopedic market. We define extremity reconstruction to mean the repair of soft tissue and the orthopedic reconstruction of bone in the foot, ankle and leg below the knee, and the hand, wrist, elbow and shoulder.

Skin and Wound. Our dermal repair and regeneration products are used to treat acute and chronic wounds.

Integra s matrix wound dressings are indicated for the management of wounds, including partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-laser surgery, podiatric, and wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. We estimate that the market opportunity for products used to treat trauma and chronic wounds in the United States exceeds $2 billion.

There are currently 26 million people with diabetes in the United States. Approximately 15% of these patients incur one or more diabetic foot ulcers during their lifetime. This population is also 15 times more likely to suffer an amputation due to non-healing diabetic foot ulcers. However, approximately 85% of all amputations are preventable if proper intervention is provided. Approximately 500,000 adults seek treatment for venous leg ulcers annually in the United States.

Bone and Joint Fixation Devices and Instruments. We offer the extremity reconstruction surgeon a comprehensive set of bone and joint fixation devices for upper and lower extremity, including orthopedic implants and surgical devices for small bone and joint procedures involving the foot, ankle, hand, wrist, shoulder and elbow. Our products address the trauma and reconstructive segments of the extremities market, an estimated $1 billion market in the United States.

Lower Extremity. We are a leading developer and marketer of specialty implants and instruments specifically designed for foot and ankle surgery. Our customers include orthopedic and podiatric surgeons specializing in lower extremity injuries, of which there are approximately 2,300 and 6,200, respectively, in the United States. We have a full suite of products for orthopedic procedures that address pathology in the forefoot, midfoot, hindfoot, and ankle. The lower extremity market is estimated to exceed $700 million in the United States.

Upper Extremity. For upper extremity reconstruction, we are recognized for the premier implant for wrist arthroplasty, a procedure that restores the function of the arthritic wrist. Our other leading products in this therapeutic area are used in small bone fixation, treatment of carpel tunnel syndrome and treatment of cubital tunnel syndrome. This segment of the upper extremity market, excluding shoulder, is estimated to be nearly $250 million in the United States. Our acquisition of Ascension provides us with leading-edge shoulder products, opening up the largest component of the extremities market, estimated at $600 million.

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Bone Graft Substitutes for Extremity Reconstruction. Our comprehensive line of bone graft substitute products includes three distinct products a bone void filler manufactured from beta tri-calcium phosphate and type I bovine collagen; demineralized bone matrix (DBM); and demineralized bone matrix premixed with cancellous bone. Bone graft substitutes are used in many of the more than 700,000 extremity fusion and osteotomy procedures annually. The extremity reconstruction bone graft market is estimated at more than $50 million annually in the United States.

Nerve and Tendon. Surgeons who specialize in foot or hand orthopedic surgery often have to repair nerves and tendons. To address these needs, we offer regenerative medicine products for peripheral nerve repair and protection and tendon repair. We estimate that the worldwide market for the repair of severed, injured, compressed and scarred peripheral nerves is approximately $50 million. Tendon and ligament injuries are some of the most common musculoskeletal disorders. Industry sources estimate that there are approximately 750,000 tendon and ligament repair procedures in the United States annually.

Integra Spine Product Portfolio

Orthopedic and neurological spine surgeons treat debilitating pain arising from a variety of disorders, which include degenerative disk disease (DDD), deformity, trauma and tumors. DDD is the most common disorder and is expected to increase in the United States due to the aging population. To treat the pain arising from spinal disorders, surgeons could need to perform spinal fusion procedures. We offer comprehensive spinal fusion technologies that surgeons use from the occiput to the sacrum, and a full line of related orthobiologics.

The United States spinal implant market, consisting of thoracolumbar fusion devices, cervical fusion devices, interbody fusion devices, and motion preservation technologies, is valued at approximately $5 billion. The United States market size for bone graft substitutes in orthopedic spinal procedures is estimated to be over $750 million.

In May 2011, we acquired SeaSpine, Inc., a provider of high quality, innovative products for the spine fusion market. This acquisition doubled our distribution network and revenue base in spinal hardware. Key benefits of the combination include:

Scale. Doubled our revenue base in spinal hardware.

Expanded Customer Base. Brought new distributors and customers, doubling existing distribution network in the U.S. and establishing a new base of business outside the U.S.

Expertise and Resources. Brought management team with industry experience and a West Coast facility with a product development cadaver lab.

Comprehensive Product Portfolio. Combined two comprehensive product portfolios to offer our surgeons more options for their patients.

In addition to successfully integrating the SeaSpine acquisition, our Spine division launched multiple new implants into targeted growth markets including the integrated interbody fusion device market, the minimally invasive market, and the deformity market.

Integrated Interbody Fusion Devices. In 2011, we created a cornerstone of the latest technology for standalone interbody fusion devices by launching products applicable to both the cervical and lumbar spine. Integrated interbody devices consist of an interbody device integrated with a plate or screws. These devices eliminate the multiple steps required to implant traditional devices, while also limiting the uncertainty around implant stability and expulsion. As an example, our integrated anterior lumbar interbody device reduces the need for a surgeon to provide additional posterior fixation, thereby simplifying the procedure and expanding the market in which we participate.

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Minimally Invasive Solutions. Minimally invasive fixation systems offer surgeons an opportunity to deliver pedicle screws with a small incision, potentially reducing blood loss and recovery time. Between increased patient demand and the increase of surgeons able to offer this technically demanding technique, the market for minimally invasive solutions will continue to rise. Our latest minimally invasive system features extended tabs for a small incision profile and two rod delivery options for both mini-open and percutaneous approaches. This product is expected to drive growth in our portfolio in 2012.

Deformity Correction. To enhance our treatment options for deformity procedures, we introduced a titanium system for spinal deformity correction procedures. This system features polyaxial and uniplanar pedicle screws, built-in rod reduction, straight and pre-contoured rods, and a comprehensive derotation system. The deformity market in the United States is estimated to be nearly $400 million. This system has been well received by our surgeon customers and is expected to help us establish a footprint in this important strategic market in 2012.

Orthobiologics. We also market and sell a complete line of demineralized bone products, collagen ceramic matrices and pure synthetic bone grafting solutions. Our third generation osteoinductive DBM, utilizing a patented technology, is unique in the market and has developed significant market share in a short period of time. This growth has been powered by its ability to provide both early and easy accessibility to a full cascade of growth factors combined with the slower-releasing traditional DBM particles. Separately, we have capitalized on our long history of collagen expertise to create and sell different variations of our collagen ceramic osteoconductive products in multiple configurations. The multiple configurations address surgeons differing procedural needs, which include strip, putty and morsels. Finally, we offer traditional cancellous chips, pure synthetic granules, and recently we introduced our cancellous bone sponge and strip.

NEUROSURGERY PRODUCT PORTFOLIO

Our Integra Neurosurgery sales organization sells a full line of products specifically for neurosurgery and neuro critical care. We have products for each step of a cranial procedure and the care of the patient after surgery. We sell equipment used in the neurosurgery operating room and neurosurgery intensive care unit (NICU).

Dural Repair Products. In the United States, over 225,000 craniotomy procedures are performed each year representing a market estimated to be over $500 million. Most of these surgeries require an incision of the dura mater, which is the tough, fibrous membrane that surrounds and protects the brain and spinal cord. The incision must be repaired, either by suturing or applying a dural graft to prevent cerebrospinal fluid leaks and facilitate healing. Since our introduction of the original DuraGen® Dural Graft Matrix in 1999, the first onlay collagen graft for dural repair, we have become the market leader in sutureless closure of dural defects in the United States. Our dural repair products are alternatives to tissue being removed and grafted from another location in the patient s body or synthetic grafts that require extensive suturing.

Cerebral Spinal Fluid (CSF) Management Devices. CSF drainage is an important component of managing the intracranial pressure of the neurologically compromised patient or a patient undergoing abdominal aortic aneurysm surgery. Over 250,000 procedures are performed annually in the United States using lumbar or ventricular drainage systems, including permanently implanted shunt systems and external ventricular drainage, representing an estimated $150 million market.

Hydrocephalus is a condition in which the primary characteristic is excessive accumulation of CSF in the brain. It is most commonly treated by inserting a shunt catheter into the ventricular system of the brain. The shunt is designed to divert the flow of CSF out of the brain to an appropriate drainage site, such as the peritoneal cavity or the heart s right atrium, and through a pressure control valve to maintain a normal level of CSF. Each year there are approximately 50,000 new shunt implants and revision cases to treat hydrocephalus. We currently offer a diverse line of hydrocephalus management products, including a wide variety of valves and ventricular, lumbar, peritoneal and cardiac catheters.

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Tissue Ablation Equipment. Our tissue ablation equipment uses high frequency acoustic pulses to selectively dissect soft tissues according to their density. Integra s CUSA® tissue ablation system facilitates the ablation of unwanted tissue (such as tumors) adjacent to or attached to vital structures, helping to limit uncertainty for the surgeon. The CUSA® tissue ablation system has been the leading ultrasonic surgical aspirator for over 25 years, and the related accessories for these products generate a recurring revenue stream.

Our systems are used in over 100,000 procedures annually at over 2,000 centers around the world for the removal of brain tumors, epilepsy foci, and gynecological and liver tumors. According to industry sources, the total United States market for ultrasonic tissue ablation products is estimated at over $60 million. Applications for ultrasonic tissue ablation technology continue to expand, both within neurosurgery and in other surgical specialties, and we are developing accessories to meet these new clinical applications. In 2011, we introduced the CUSA® NXT Extended Length Tip for Integra s CUSA® NXT and CUSA® Selector® Ultrasonic Tissue Ablation Systems that allows surgeons to use ultrasonic tissue ablation in procedures characterized by a long path to the target tissue.

Intracranial Monitoring Equipment. The NICU monitors a patient s post-operative condition, following most neurosurgical procedures involving craniotomy. We offer the leading products for monitoring intracranial pressure and brain tissue oxygenation and also offer equipment for the drainage of excess CSF.

Our monitoring systems are also used in the treatment of traumatic brain injury (TBI). TBI is a major public health problem and costs the United States an estimated $56 billion a year. More than five million Americans alive today have had a TBI, resulting in a permanent need for help in performing daily activities, and TBI survivors are often left with significant cognitive, behavioral, and communicative disabilities. Research has shown that not all brain damage occurs at the moment of impact, but frequently evolves over the ensuing hours and days after the initial injury. The secondary damage may be controlled, in part, by using our products to monitor and manage intracranial pressure and brain tissue oxygen.

Cranial Stabilization Equipment. Most neurosurgery procedures require rigid fixation of the head. Our MAYFIELD® line of cranial stabilization equipment rigidly fixes the head in an orientation determined by the surgeon. The device fixes the head via skull pins that are held in a frame that is anchored to the operating table and can be adjusted in multiple planes of movement to properly position the head for the surgical procedure. This system is used worldwide in over 400,000 brain procedures annually.

Intraoperative real-time imaging is being utilized more frequently in neurosurgical procedures and we market stabilization equipment that is made from a composite material that reduces the distortion in images compared to metal systems.

INSTRUMENTS PRODUCT PORTFOLIO

We are the largest surgical instrument company in the United States, providing more than 60,000 instrument patterns and surgical products to hospitals, surgery centers, and dental, podiatry, veterinary and physician offices. In addition to hand-held instruments, we sell surgical headlight systems and table-mounted retractors. Our instruments are sold and marketed via separate organizations to acute care and alternate site customers.

The Jarit® and Miltex® brands of hand-held reusable surgical instrumentation encompass all of the clinical specialties within the acute care and alternate site clinical setting. Our markets include minimally invasive endoscopy surgery, general surgery, cardiovascular, neurosurgery, gynecological, orthopedic, ear, nose and throat, ophthalmology and all other venues that provide surgical care inside and outside the hospital setting. We are also a major player in animal health specialties, such as dentistry and orthopedics, as well as the emerging life sciences sector.

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We are a premium manufacturer of dental instruments related to hygiene, oral surgery, periodontal and endodontic instrumentation. We offer the dental market the largest array of choices in extraction forceps, market leadership in sterilization cassettes, and unique intra-oral lighting technologies. The Miltex® brand has successfully incorporated Integra s regenerative medicine materials into its oral surgery and periodontal offerings.

RESEARCH AND DEVELOPMENT STRATEGY

Our research and development activities focus on identifying unmet surgical needs and meeting those needs with innovative solutions and products. We apply our core competency in regenerative medicine to products for neurosurgical, orthopedic and spinal applications, and have extensive programs in neuro-monitoring and CSF management, cranial stabilization, tissue ablation, spine, soft tissue, extremity small bone, and joint fixation. Our activities include the acquisition or in-licensing of new products.

Regenerative Medicine. Because regenerative medicine implants represent a fast-growing, high-margin opportunity for us, we allocate a large portion of our research and development budget to these products. Our regenerative medicine development program applies our expertise in biomaterials and collagen matrices to neurosurgical, orthopedic and spinal surgery applications, as well as dermal regeneration, tendon and nerve repair, and chronic and acute wounds.

Extremity Reconstruction. We develop fixation devices and other implants and instruments for upper and lower extremities.

Spine. Our expertise in implant engineering, biomaterials development and biomechanical testing provides a strong foundation for developing new products for the spine. Additionally, we hold a number of spine patents that serve as a platform for future products, with particular emphasis in minimally invasive technologies. While we plan to continue filling the gaps in our portfolio so our current customers can use our products for more procedures, we are also developing novel technologies and new indications.

We have based our strong orthobiologic product development capability that on our bone matrix technology and our collagen technology, which is the basis of our osteoconductive collagen ceramic scaffold. We continue to develop line extensions based on these foundation technologies that further complete our offerings. In 2011, we created a complete portfolio of orthobiologic products specifically for our spine distribution network. We will continue to invest in the development of new novel technologies for bone grafting.

Neurosurgery. Our research and product development efforts are focused on protecting and extending our leadership positions in dural repair, developing the next generation tissue ablation system, a new critical care neuro monitoring system, and an advanced hydrocephalus shunt valve.

COMPETITION

Our competition in extremity reconstruction includes Johnson & Johnson, Synthes, Inc., Stryker Corporation, Tornier, Inc., Wright Medical Group, Inc., Zimmer, Inc., and Small Bone Innovations, Inc., as well as other major orthopedic companies that carry a full line of small bone and joint fixation and soft tissue products.

Competitors in the spine and orthobiologics markets include Medtronic, Inc., Johnson & Johnson, Globus Medical Inc., NuVasive, Inc., Orthofix, Stryker Corporation, Synthes, Inc., Zimmer, Inc., and Alphatec Spine, Inc., and also include several smaller, biologic-focused companies.

Our competitors in the neurosurgery markets are Johnson & Johnson, Medtronic, Inc. and Stryker Corporation. In addition, many of our neurosurgery product lines compete with smaller specialized companies and larger companies that do not otherwise focus on neurosurgery.

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We compete with the Aesculap division of B. Braun Medical Inc., as well as V. Mueller, a division of CareFusion in the United States. In addition, we compete with Johnson & Johnson and many smaller instrument companies in the reusable and disposable specialty instruments markets. We rely on the depth and breadth of our sales and marketing organization and our procurement operation to maintain our competitive position in surgical instruments and allied surgical products.

Finally, in certain cases our products compete primarily against medical practices that treat a condition without using a medical device or any particular product, such as medical practices that use autograft tissue instead of our dermal regeneration products, duraplasty products and nerve repair products. Depending on the product line, we compete on the basis of our products features, strength of our sales force or distributor, sophistication of our technology and cost effectiveness of our solution to the customer s medical requirements.

GOVERNMENT REGULATION

As a manufacturer and marketer of medical devices, we are subject to extensive regulation by the FDA and the Center for Medicare Services of the U.S. Department of Health and Human Services and other federal governmental agencies and, in some jurisdictions, by state and foreign governmental authorities. These regulations govern the introduction of new medical devices, the observance of certain standards with respect to the design, manufacture, testing, labeling, promotion and sales of the devices, the maintenance of certain records, the ability to track devices, the reporting of potential product defects, the import and export of devices, and other matters. We believe that we are in substantial compliance with these governmental regulations. We did, however, receive a warning letter from the FDA in December, 2011, related to quality systems and compliance issues at our manufacturing facility located in Plainsboro, New Jersey. The letter resulted from an inspection held at that facility in August 2011, and did not identify any new observations that were not provided in the Form 483 that followed the inspection. The warning letter does not restrict our ability to manufacture or ship products, nor does it require the recall of any product. Since the conclusion of the inspection, we have undertaken significant efforts to remediate the observations that the FDA has made and continue to do so. We have provided detailed monthly responses to the FDA as to our corrective actions, remain on track with our remediation program and are addressing the issues that the FDA identified. We completed remediation-related construction activities at the facility at the end of 2011, but continue to remediate process and quality system procedures.

The regulatory process of obtaining product approvals and clearances can be onerous and costly. The FDA requires, as a condition to marketing a medical device in the United States, that we secure a Premarket Notification clearance pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (the FD&C Act), an approved Premarket Approval application (or supplemental PMA application). Obtaining these approvals and clearances can take up to several years and involves preclinical studies and clinical testing. On December 27, 2011 the FDA issued a Draft Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k).* These changes to the 510(k) Premarket Notification process may result in more extensive testing, clinical trial requirements and other requirements. To perform clinical trials for significant risk devices in the United States on an unapproved product, we are required to obtain an Investigational Device Exemption (IDE) from the FDA. The FDA may also require a filing for FDA approval prior to marketing products that are modifications of existing products or new indications for existing products. Moreover, after clearance/approval is given, if the product is shown to be hazardous or defective, the FDA and foreign regulatory agencies have the power to withdraw the clearance or require us to change the device, its manufacturing process or its labeling, to supply additional proof of its safety and effectiveness or to recall, repair, replace or refund the cost of the medical device. Because we currently export medical devices manufactured in the United States that have not been approved by the FDA for distribution in the United States, we are required to obtain approval/registration in the country we are exporting to and maintain certain records relating to exports and make these available to the FDA for inspection, if required.

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The FDA Medical Device User Fee and Modernization Act of 2002 and the FDA Amendments Act of 2007 established regulations governing user fees for certain regulatory submissions to the FDA. Currently user fees are required for 510(k) PMA s, certain PMA supplements, PMA annual reports, FDA establishment registrations and other regulatory submissions.

Human Cells, Tissues and Cellular and Tissue-Based Products

Integra manufactures medical devices derived from human tissue (demineralized bone tissue).

The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing, or consisting of, human cells or tissue intended for transplantation into a human patient. Examples include bone, ligament, skin and cornea.

Some HCT/Ps also meet the definition of a biological product, medical device or drug regulated under the FD&C Act. These biologic, device or drug HCT/Ps must comply both with the requirements exclusively applicable to HCT/Ps and, in addition, with requirements applicable to biologics, devices or drugs, including premarket clearance or approval from FDA.

Section 361 of the Public Health Service Act (PHSA), authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as 361 HCT/Ps are subject to requirements relating to registering facilities and listing products with FDA, screening and testing for tissue donor eligibility, Good Tissue Practice when processing, storing, labeling, and distributing HCT/Ps, including required labeling information, stringent record keeping, and adverse event reporting.

The American Association of Tissue Banks (AATB) has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become an AATB-accredited tissue establishment. In addition, some states have their own tissue banking regulations. We are licensed or have permits for tissue banking in California, Florida, New York and Maryland.

National Organ Transplant Act. Procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act (NOTA), which prohibits the transfer of certain human organs, including skin and related tissue for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue that they provide to us for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses, and costs associated with development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we may recover in our pricing for our products, thereby reducing our future revenue and profitability.

Postmarket Requirements. After a device is cleared or approved for commercial distribution, numerous regulatory requirements apply. These include the FDA Quality System Regulations which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of medical devices; the FDA s general prohibition against promoting products for unapproved or off-label uses; the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and the Reports of Corrections and Removals regulation, which require manufacturers to report recalls and field corrective actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act.

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We are also required to register with the FDA as a medical device manufacturer. As such, our manufacturing sites are subject to periodic inspection by the FDA for compliance with the FDA s Quality System Regulations. These regulations require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and control activities. Further, we are required to comply with various FDA requirements and other legal requirements for labeling and promotion. If the FDA believes that a company is not in compliance with applicable regulations, it may issue a warning letter, institute proceedings to detain or seize products, issue a recall order, impose operating restrictions, enjoin future violations and assess civil penalties against that company, its officers or its employees and may recommend criminal prosecution to the Department of Justice.

Medical device regulations also are in effect in many of the countries outside the United States in which we do business. These laws range from comprehensive medical device approval and Quality System requirements for some or all of our medical device products to simpler requests for product data or certifications. The number and scope of these requirements are increasing. Under the European Union Medical Device Directive, medical devices must meet the Medical Device Directive standards and receive CE Mark Certification prior to marketing in the European Union (the EU). CE Mark Certification requires a comprehensive Quality System program, comprehensive technical documentation and data on the product, which are then reviewed by a Notified Body. A Notified Body is an organization designated by the national governments of the European Union member states to make independent judgments about whether a product complies with the protection requirements established by each CE marking directive. The Medical Device Directive, ISO 9000 series and ISO 13485 are recognized international quality standards that are designed to ensure that we develop and manufacture quality medical devices. Other countries are also instituting regulations regarding medical devices. Compliance with these regulations requires extensive documentation and clinical reports for all of our products, revisions to labeling, and other requirements such as facility inspections to comply with the registration requirements. A recognized Notified Body audits our facilities annually to verify our compliance with these standards.

In the EU, our products that contain human derived tissue, including those containing demineralized bone material, are not medical devices as defined in the Medical Device Directive (93/42/EC). They are also not medicinal products as defined in Directive 2001/83/EC. Today, regulations, if applicable, are different from one EU member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the EU, the approval process for human-derived cell or tissue-based medical products may be extensive, lengthy, expensive, and unpredictable.

Certain countries, as well as the EU, have issued regulations that govern products that contain materials derived from animal sources. Regulatory authorities are particularly concerned with materials infected with the agent that causes bovine spongiform encephalopathy (BSE), otherwise known as mad cow disease. These regulations affect our dermal regeneration products, duraplasty products, biomaterial products for the spine, nerve and tendon repair products and certain other products, all of which contain material derived from bovine tissue. Although we take great care to provide that our products are safe and free of agents that can cause disease, products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for prion transmission. Significant new regulations, or a ban of our products, could have a material adverse effect on our current business or our ability to expand our business. See Item 1A. Risk Factors Certain of our products contain materials derived from animal sources and may become subject to additional regulation.

We are subject to laws and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws that regulate the means by which companies in the health care industry may market their products to hospitals and health care professionals and may compete by discounting the prices of their products. The delivery of our products is subject to regulation regarding reimbursement, and federal healthcare laws apply when a customer submits a claim for a product that is reimbursed under a federally funded healthcare program. These rules require that we exercise care in structuring our sales and marketing practices and customer discount arrangements. See Item 1A. Risk Factors Oversight of the medical device industry might affect the manner in which we may sell medical devices and compete in the marketplace.

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Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export, laws regarding transactions in foreign countries, the U.S. Foreign Corrupt Practices Act and local anti-bribery and other laws regarding interactions with healthcare professionals. Among other things, these laws restrict, and in some cases prohibit, United States companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices in foreign countries.

Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by the controlling laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of this type of accident, we could be held liable for any damages that may result and any liability could exceed our resources. Although we believe that we are in compliance in all material respects with applicable environmental laws and regulations, we could incur significant costs to comply with environmental laws and regulations in the future, and our operations, business or assets could be materially adversely affected by current or future environmental laws or regulations.

In addition to the above regulations, we are and may be subject to regulation under federal and state laws, including, but not limited to, requirements regarding occupational health and safety, laboratory practices and the maintenance of personal information, including personal health information. As a public company, we are subject to the securities laws and regulations, including the Sarbanes-Oxley Act of 2002. We also are subject to other present, and could be subject to possible future, local, state, federal and foreign regulations.

Third-Party Reimbursement. Healthcare providers that purchase medical devices generally rely on third-party payors, including the Medicare and Medicaid programs and private payors, such as indemnity insurers, employer group health insurance programs and managed care plans, to reimburse all or part of the cost of the products. As a result, demand for our products is and will continue to be dependent in part on the coverage and reimbursement policies of these payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. Reimbursement from Medicare, Medicaid and other third-party payors may be subject to periodic adjustments as a result of legislative, regulatory and policy changes as well as budgetary pressures. Possible reductions in, or eliminations of, coverage or reimbursement by third-party payors as a result of these changes may affect our customers revenue and ability to purchase our products. Any changes in the healthcare regulatory, payment or enforcement landscape relative to our customers healthcare services has the potential to significantly affect our operations and revenue.

INTELLECTUAL PROPERTY

We seek patent and trademark protection for our key technology, products and product improvements, both in the United States and in selected foreign countries. When determined appropriate, we have enforced and plan to continue to enforce and defend our patent and trademark rights. In general, however, we do not rely solely on our patent and trademark estate to provide us with any significant competitive advantages as it relates to our existing product lines. We also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position. In an effort to protect our trade secrets, we have a policy of requiring our employees, consultants and advisors to execute proprietary information and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements also provide that all confidential information developed or made known to the individual during the course of their relationship with us must be kept confidential, except in specified circumstances.

AccuDrain®, Accell®, Accell Evo3®, Advansys®, Atoll , Ascension®, Auragen , Bold®, Budde®, Buzz , Camino®, CRW®, Coral®, CUSA® , Daytona , DenLite®, DuraGen®, DuraGen Plus®, DynaGraft® II, First Choice®, Hallu®, HeliCote®, HeliPlug®, HeliTape®, HeliMEND®, Helistat®, Helitene®, HINTEGRA®, ICOS , Inforce®, Integra®, Integra Mozaik , Integra OS®, Jarit®, Licox®, LimiTorr , Luxtec®, Malibu ,

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EMPLOYEES

At December 31, 2011, we had approximately 3,400 employees engaged in production and production support (including warehouse, engineering and facilities personnel), quality assurance/quality control, research and development, regulatory and clinical affairs, sales, marketing, administration and finance. Except for certain employees at our facilities in France and Mexico, none of our employees is subject to a collective bargaining agreement.

FINANCIAL INFORMATION ABOUT GEOGRAPHIC AREAS

Financial information about our geographical areas is set forth under Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations International Revenues and Operations and in our financial statements Note 13, Segment and Geographic Information, to our Consolidated Financial Statements.

SOURCES OF RAW MATERIALS

In general, raw materials essential to our businesses are readily available from multiple sources. For reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from a sole supplier. Our policy is to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time.

Certain of our products, including our dermal regeneration products, duraplasty products, biomaterial products for the spine, nerve and tendon repair products and certain other products, contain material derived from bovine tissue. We take great care to provide that our products are safe and free of agents that can cause disease. In particular, the collagen used in the products that Integra manufactures is derived only from the deep flexor tendon of cattle less than 24 months old from New Zealand, a country that has never had a reported case of bovine spongiform encephalopathy, or from the United States. The World Health Organization classifies different types of cattle tissue for relative risk of BSE transmission. Deep flexor tendon is in the lowest-risk category for BSE transmission (the same category as milk, for example), and is therefore considered to have a negligible risk of containing the agent that causes BSE.

Certain of our demineralized bone matrix products contain human tissue in the form of ground cortical and cancellous bone. We source the bone tissue only from FDA and the American Association of Tissue Banks (AATB) registered and inspected tissue banks. The donors are rigorously screened, tested, and processed in accordance with the FDA and AATB requirements. Only donated tissue from FDA and AATB registered, inspected, non-profit tissue banks is qualified to source for our raw materials. Additionally, each donor must pass all of the FDA-specified bacterial and viral testing before the raw material is distributed to Integra for further processing. We receive with each donor lot a certification of the safety of the raw material from the tissue bank s medical director.

As an added assurance of safety, each lot of bone is released into the manufacturing process only after our staff of quality assurance microbiologists screens the incoming bone and serology test records. During our manufacturing process, the bone particles are subjected to our proprietary process and terminally sterilized. We have demonstrated through our testing that this type of rigorous processing further enhances the safety and effectiveness of our demineralized bone material products.

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SEASONALITY

Revenues during our fourth quarter tend to be stronger than other quarters because many hospitals increase their purchases of our products during the fourth quarter to coincide with the end of their budget cycles.

AVAILABLE INFORMATION

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, (the Exchange Act). In accordance with the Exchange Act, we file annual, quarterly and special reports, proxy statements and other information with the Securities and Exchange Commission. You may view our financial information, including the information contained in this report, and other reports we file with the Securities and Exchange Commission, on the Internet, without charge as soon as reasonably practicable after we file them with the Securities and Exchange Commission, in the SEC Filings page of the Investor Relations section of our website at www.integralife.com. You may also obtain a copy of any of these reports, without charge, from our investor relations department, 311 Enterprise Drive, Plainsboro, NJ 08536. Alternatively, you may view or obtain reports filed with the Securities and Exchange Commission at the SEC Public Reference Room at 100 F Street, N.E. in Washington, D.C. 20549, or at the Securities and Exchange Commission s Internet site at www.sec.gov. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made statements in this report, including statements under Business and Management s Discussion and Analysis of Financial Condition and Results of Operations that constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Exchange Act. These forward-looking statements are subject to a number of risks, uncertainties and assumptions about us including, among other things:

- general economic and business conditions, both nationally and in our international markets;
- our expectations and estimates concerning future financial performance, financing plans and the impact of competition;
- anticipated trends in our business;
- anticipated demand for our products, particularly capital equipment products;
- our ability to produce collagen-based products in sufficient quantities to meet sales demands;
- our expectations concerning our ongoing restructuring, integration and manufacturing transfer and expansion activities;
- existing and future regulations affecting our business;
- our ability to obtain additional debt and equity financing to fund capital expenditures and working capital requirements and acquisitions;
- physicians willingness to adopt our recently launched and planned products, third-party payors willingness to provide or continue reimbursement for these products and our ability to secure regulatory approval for products in development;
- initiatives launched by our competitors;
- our ability to protect our intellectual property, including trade secrets;
- our ability to complete acquisitions, integrate operations post-acquisition and maintain relationships with customers of acquired entities;
- our ability to remediate all matters identified in the FDA warning letter that we received in December 2011; and
- other risk factors described in the section entitled Risk Factors in this report.

You can identify these forward-looking statements by forward-looking words such as believe, may, could, might, will, estimate, continu anticipate, intend, seek, plan, expect, should, would and similar expressions in this report. We undertake no obligation to publicly upda revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks and uncertainties, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially from those anticipated or implied in the forward-looking statements.

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ITEM 1A. ***RISK FACTORS***
Risks Related to Our Business

Our operating results may fluctuate.

Our operating results, including components of operating results such as gross margin and cost of product sales, may fluctuate from time to time, and such fluctuations could affect our stock price. Our operating results have fluctuated in the past and can be expected to fluctuate from time to time in the future. Some of the factors that may cause these fluctuations include:

- economic conditions in the United States or abroad, especially in Europe, which could affect the ability of hospitals and other customers to purchase our products and could result in a reduction in elective and non-reimbursed operative procedures;
- the impact of acquisitions;
- the impact of our restructuring activities;
- the timing of significant customer orders, which tend to increase in the fourth quarter to coincide with the end of budget cycles for many hospitals;
- market acceptance of our existing products, as well as products in development;
- the timing of regulatory approvals;
- changes in the rates of exchange between the U.S. dollar and other currencies of foreign countries in which we do business, such as the euro and the British pound;
- expenses incurred and business lost in connection with product field correction actions or recalls;
- changes in the cost or decreases in the supply of raw materials, including energy and steel;
- our ability to manufacture our products efficiently or in sufficient quantities to meet sales demands;
- the timing of our research and development expenditures;
- reimbursement for our products by third-party payors such as Medicare, Medicaid and private health insurers;
- inspections of our manufacturing facilities for compliance with Quality System Regulations (Good Manufacturing Practices) which could result in Form 483 observations, warning letters, injunctions or other adverse findings from the FDA or from equivalent regulatory bodies;

the FDA s reform to the 510(k) Premarket Notification process which could make it more difficult to obtain clearance of our medical devices and could result in the requirement of clinical trial data in order to obtain FDA clearance; and

the increased regulatory scrutiny of certain of our products, including products which we manufacture for others, could result in their being removed from the market.

The industry and market segments in which we operate are highly competitive, and we may be unable to compete effectively with other companies.

In general, there is intense competition among medical device companies. We compete with established medical technology companies in many of our product areas. Competition also comes from early-stage companies that have alternative technological solutions for our primary clinical targets, as well as universities, research institutions and other non-profit entities. Many of our competitors have access to greater financial, technical, research and development, marketing, manufacturing, sales, distribution, administrative, consulting and other resources than we do. Our competitors may be more effective at developing commercial products. Our competitors may be able to gain market share by offering lower-cost products or by offering products that enjoy better reimbursement methodologies from third-party payors, such as Medicare, Medicaid and private healthcare insurance.

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Our competitive position will depend on our ability to achieve market acceptance for our products, develop new products, implement production and marketing plans, secure regulatory approval for products under development, obtain and maintain reimbursement coverage under Medicare, Medicaid and private healthcare insurance and obtain patent protection. We may need to develop new applications for our products to remain competitive. Technological advances by one or more of our current or future competitors or their achievement of superior reimbursement from Medicare, Medicaid and private healthcare insurance could render our present or future products obsolete or uneconomical. Our future success will depend upon our ability to compete effectively against current technology as well as to respond effectively to technological advances. Competitive pressures could adversely affect our profitability. Additionally, purchasing decisions of our customers may be based on clinical evidence or comparative effectiveness and because of our vast array of products, we might not be able to fund the studies necessary or provide the required information to compete effectively. Other companies may have more resources available to fund such studies. For example, competitors have launched and have been developing products to compete with our duraplasty products, extremity reconstruction implants, neuro critical care monitors and ultrasonic tissue ablation devices, among others.

Our largest competitors in the neurosurgery markets are Medtronic, Inc., Johnson & Johnson and Stryker Corporation. In addition, many of our neurosurgery product lines compete with smaller specialized companies or larger companies that do not otherwise focus on neurosurgery. Our competitors in extremity reconstruction include Johnson & Johnson, Synthes, Inc. and Stryker Corporation, as well as other major orthopedic companies that carry a full line of reconstructive products. We also compete with Wright Medical Group, Inc., Small Bone Innovations, Inc., Tornier, Inc. and other companies in the extremity reconstruction market category. Our competitors in the spinal implant and orthobiologics markets include Medtronic, Inc., Johnson & Johnson, Synthes, Inc., Stryker Corporation, Zimmer, Inc., NuVasive, Inc., Globus Medical, Inc., Alphatec Spine, Inc., Orthofix and several smaller, biologically focused companies. In surgical instruments, we compete with V. Mueller, as well as the Aesculap division of B. Braun Medical, Inc. In addition, we compete with Johnson & Johnson and many smaller instrument companies in the reusable and disposable specialty instruments markets. Our private-label products face diverse and broad competition, depending on the market addressed by the product. Finally, in certain cases our products compete primarily against medical practices that treat a condition without using a device or any particular product, such as the medical practices that use autograft tissue instead of our dermal regeneration products, duraplasty products and nerve repair products.

Our current strategy involves growth through acquisitions, which requires us to incur substantial costs and potential liabilities for which we may never realize the anticipated benefits.

In addition to internally generated growth, our current strategy involves growth through acquisitions. Since the beginning of 2009, we have acquired 6 businesses or product lines at a total cost of approximately $171.9 million.

We may be unable to continue to implement our growth strategy, and our strategy ultimately may be unsuccessful. A significant portion of our growth in revenues has resulted from, and is expected to continue to result from, the acquisition of businesses complementary to our own. We engage in evaluations of potential acquisitions and are in various stages of discussion regarding possible acquisitions, certain of which, if consummated, could be significant to us. Any new acquisition could result in material transaction expenses, increased interest and amortization expense, increased depreciation expense, increased operating expense, and possible in-process research and development charges for acquisitions that do not meet the definition of a business, any of which could have a material adverse effect on our operating results. Certain businesses that we acquire may not have adequate financial, disclosure, regulatory, quality or other compliance controls at the time we acquire them. As we grow by acquisition, we must manage and integrate the new businesses to bring them into our systems for financial, disclosure, compliance, regulatory and quality control, realize economies of scale, and control costs. In addition, acquisitions involve other risks, including diversion of management resources otherwise available for ongoing development of our business and risks associated with entering markets in which our marketing and sales force has limited experience or where experienced distribution alliances are not

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available. Our future profitability will depend in part upon our ability to develop further our resources to adapt to these new products or business areas and to identify and enter into or maintain satisfactory distribution networks. We may not be able to identify suitable acquisition candidates in the future, obtain acceptable financing or consummate any future acquisitions. If we cannot integrate acquired operations, manage the cost of providing our products or price our products appropriately, our profitability could suffer. In addition, as a result of our acquisitions of other healthcare businesses, we may be subject to the risk of unanticipated business uncertainties, regulatory and other compliance matters or legal liabilities relating to those acquired businesses for which the sellers of the acquired businesses may not indemnify us, for which we may not be able to obtain insurance (or adequate insurance), or for which the indemnification may not be sufficient to cover the ultimate liabilities.

Our future financial results could be adversely affected by impairments or other charges.

Since we have grown through acquisitions, we have $293.0 million of goodwill and $50.2 million of indefinite-lived intangible assets as of December 31, 2011. Under the authoritative guidance for determining the useful life of intangible assets, we are required to test both goodwill and indefinite-lived intangible assets for impairment on an annual basis based upon a fair value approach, rather than amortizing them over time. We are also required to test goodwill and indefinite-lived intangible assets for impairment between annual tests if an event occurs such as a significant decline in revenues or cash flows for certain products, or the discount rates used in the calculations of discounted cash flow change significantly, or circumstances change that would more likely than not reduce our enterprise fair value below its book value. If such a decline, rate change or circumstance were to materialize, we may record an impairment of these intangible assets that could be material to the financial statements. See Management s Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Estimates of this report.

The guidance on long-lived assets requires that we assess the impairment of our long-lived assets, including finite-lived intangible assets, whenever events or changes in circumstances indicate that the carrying value may not be recoverable as measured by the sum of the expected future undiscounted cash flows. As of December 31, 2011, we had $186.9 million of finite-lived intangible assets.

Decisions relating to our trade names may occur over time as our re-branding strategy is implemented. Additionally, we may discontinue certain products in the future as we continue to assess the profitability of our product lines. As a result, we may need to record impairment charges or accelerate amortization on certain trade names or technology-related intangible assets in the future.

The value of a medical device business is often volatile, and the assumptions underlying our estimates made in connection with our assessments under the guidance may change as a result of that volatility or other factors outside our control and may result in impairment charges. The amount of any such impairment charges could be significant and could have a material adverse effect on our reported financial results for the period in which the charge is taken and could have an adverse effect on the market price of our securities, including the notes and the common stock into which they may be converted.

Current economic conditions may adversely affect the ability of hospitals, other customers, suppliers and distributors to access funds or otherwise have available liquidity, which could reduce orders for our products or interrupt our production or distribution or result in a reduction in elective and non-reimbursed operative procedures.

Current economic conditions, especially in Europe, may adversely affect the ability of hospitals and other customers to access funds to enable them to fund their operating and capital budgets. As a result, hospitals and other customers may reduce budgets or put all or part of their budgets on hold or close their operations, which could have a negative effect on our sales, particularly the sales of more expensive capital equipment such as our ultrasonic surgical aspirators, neuromonitors and stereotactic products, or result in a reduction in elective and non-reimbursed procedures. Governmental austerity policies in Europe and other markets have reduced and may continue to reduce the amount of money available to purchase medical products, including our products.

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To market our products under development we will first need to obtain regulatory approval. Further, if we fail to comply with the extensive governmental regulations that affect our business, we could be subject to penalties and could be precluded from marketing our products.

As a manufacturer and marketer of medical devices, we are subject to extensive regulation by the FDA and the Center for Medicare Services of the U.S. Department of Health and Human Services and other federal governmental agencies and, in some jurisdictions, by state and foreign governmental authorities. These regulations govern the introduction of new medical devices, the observance of certain standards with respect to the design, manufacture, testing, labeling, promotion and sales of the devices, the maintenance of certain records, the ability to track devices, the reporting of potential product defects, the import and export of devices and other matters. We are facing an increasing amount of scrutiny and compliance costs as more states are implementing regulations governing medical devices, pharmaceuticals and/or biologics which affect many of our products. As a result, we have been implementing additional procedures, controls and tracking and reporting processes, as well as paying additional permit and license fees, where required.

Our products under development are subject to FDA approval or clearance prior to marketing for commercial use. The process of obtaining necessary FDA approvals or clearances can take years and is expensive and uncertain. The FDA has implemented changes to the 510(k) premarket notification process. The FDA has issued a new Draft Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications 510(k).* These changes to the 510(k) process may result in more extensive testing, clinical trial data, more extensive manufacturing information and postmarket surveillance requirements. The FDA may inspect the manufacturing facility for certain products prior to clearance of the 510(k), which is similar to the requirements of a Class III device approved under the PMA process.

Our inability to obtain required regulatory approval on a timely or acceptable basis could harm our business. Further, approval or clearance may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed, warnings that may be required to accompany the product or additional restrictions placed on the sale and/or use of the product. Further studies, including clinical trials and FDA approvals, may be required to gain approval for the use of a product for clinical indications other than those for which the product was initially approved or cleared or for significant changes to the product. These studies could take years to complete and could be expensive, and there is no guarantee that the results will convince the FDA to approve or clear the additional indication. Any negative outcome in our clinical trials, including as a result of any interim analysis which we may do with respect to our clinical trials from time to time, could adversely affect our ability to launch new products, which could affect our sales and our ability to achieve reimbursement for new or existing products. In addition, for products with an approved PMA, the FDA requires annual reports and may require post-approval surveillance programs and/or studies to monitor the products safety and effectiveness. Results of post-approval programs may limit or expand the further marketing of the product. We are also seeing third-party payors require clinical trial data for products cleared through the 510(k) process in order to continue reimbursement coverage. These clinical trials could take years to complete and be expensive, and there is no guarantee that the FDA will approve the additional indications for use. There is also no guarantee that the payors will agree to continue reimbursement or provide additional coverage based upon these clinical trials. If the FDA does not approve the additional indications for use, our ability to obtain reimbursement for these products and our ability to compete against alternative products or technologies could suffer and, consequently, affect our sales.

Another risk of application to the FDA relates to the regulatory classification of new products or proposed new uses for existing products. In the filing of each application, we make a judgment about the appropriate form and content of the application. If the FDA disagrees with our judgment in any particular case and, for example, requires us to file a PMA application rather than allowing us to market for approved uses while we seek broader approvals or requires extensive additional clinical data, the time and expense required to obtain the required approval might be significantly increased or approval might not be granted. Furthermore, the timing of approvals in the U.S. and Europe is now dependent on the class of product. Any of our Class III devices (those categorized

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as supporting or sustaining human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury) and products of animal origin take an extensive amount of time to obtain approval in the European Union and all require clinical reports or clinical trial data which can be costly. Finally the FDA and AdvaMed (the principal United States trade association for the medical device industry) have agreed on a commitment letter regarding reauthorization of the Medical Device User Fee Authorization (MDUFA). This reauthorization is not expected to be finalized prior to October 2012 and the current proposal includes planned increases in fees over a five-year period. The amounts of such increases have not yet been published.

Our manufacturing facilities must be in compliance with FDA Quality System Regulations (current Good Manufacturing Practices). In addition, approved products are subject to continuing FDA requirements relating to quality control and quality assurance, maintenance of records, reporting of adverse events and product recalls, documentation, and labeling and promotion of medical devices. For example, some of our orthobiologics products are subject to FDA and certain state regulations regarding human cells, tissues, and cellular or tissue-based products, which include requirements for establishment registration and listing, donor eligibility, current good tissue practices, labeling, adverse-event reporting, and inspection and enforcement. Some states have their own tissue banking regulation. We are licensed or have permits as a tissue bank in California, Florida, New York and Maryland. In addition, tissue banks may undergo voluntary accreditation by the AATB. The AATB has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become a licensed tissue bank.

The FDA and foreign regulatory authorities require that our products be manufactured according to rigorous standards. These and future regulatory requirements could significantly increase our production or purchasing costs and could even prevent us from making or obtaining our products in amounts sufficient to meet market demand. If we or a third-party manufacturer change our approved manufacturing process, the FDA may require a new approval before that process may be used. Failure to develop our manufacturing capability could mean that, even if we were to develop promising new products, we might not be able to produce them profitably, as a result of delays and additional capital investment costs.

All of our manufacturing facilities, both international and domestic, are also subject to inspections by or under the authority of the FDA and other regulatory agencies. Failure to comply with applicable regulatory requirements could subject us to issuance of FDA Form 483 observations, warning letters or enforcement action by the FDA or other agencies, including product seizures, recalls, withdrawal of clearances or approvals, restrictions on or injunctions against marketing our product or products based on our technology, denials of requests for exportation certificates to foreign governments, cessation of operations and civil and criminal penalties, any of which could materially affect our business.

The FDA inspected our Plainsboro, New Jersey regenerative medicine manufacturing facility during the third quarter of 2011, at the conclusion of which it issued FDA Form 483 inspectional observations that described violations of quality system regulations. We subsequently received a warning letter from the FDA dated December 21, 2011 pertaining to that facility. We filed the warning letter as an exhibit to a Current Report on Form 8-K filed January 5, 2012. The effect of the warning letter is to require regular reports to the FDA of progress made on remediation of issues identified in the warning letter. Further, the FDA will not approve PMA s or supplements manufactured in that facility until the warning letter has been remediated.

We have incurred, and will incur, substantial expenses to remediate those observations and others issued in connection with other inspections at other facilities, and to prepare our manufacturing facilities for anticipated FDA inspections. The FDA has notified us that it will not grant requests for exportation certificates to foreign governments until the violations identified in the warning letter have been corrected. If such remediations cannot be completed in a timely manner we may not be able to produce certain products for a period of time or may not be able to sell such products in certain markets. There can be no assurance that such remediation and preparation

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activities will address all such observations to the FDA s satisfaction, or that the FDA will not impose additional regulatory sanctions with respect to such observations.

We manufacture medical devices that are subject to various electrical safety standards. Many countries have adopted the recommendations of the International Electrotechnical Commission (IEC) for the safety and effectiveness of medical electrical equipment. The IEC is a non-profit, non-governmental international standards organization that prepares and publishes International Standards for all electrical, electronic and related technologies. Their updated standards are being implemented in some markets starting in July 2012 and will continue to be adopted over the following years worldwide. If our products are not modified in time and we do not comply with these standards, then our products could no longer be sold in the markets that have adopted the IEC updated standards.

We are also subject to other regulatory requirements of countries outside the United States where we do business. For example, under the European Union Medical Device Directive, all medical devices must meet the Medical Device Directive standards in order to obtain CE Mark Certification prior to marketing in the EU. CE Mark Certification requires a comprehensive Quality System program, comprehensive technical and clinical documentation and data on the product, which a Notified Body in the EU reviews. In addition, we must be certified to the ISO 13485:2003 Quality System standards and maintain this certification in order to market our products in the EU, Canada, Japan, Latin America, countries in the Asia-Pacific region and most other countries outside the United States. The EU has revised the Medical Device Directive (93/42/EC as amended by 2007/47/EC). Compliance with these regulations requires extensive documentation, clinical reports for all products sold in the EU and other requirements. Requirements to meet these regulations can be costly and are mandatory to market our products in the EU. Many other countries have instituted new medical device regulations and/or revised current medical device regulations. These regulations often require extensive documentation, including clinical data and may require audits of our manufacturing facilities in order to gain approval to sell our products in that country. There are also associated fees with these new regulations. These regulations are required for all new products and re-registration of our medical devices, and may involve lengthy and expensive reviews.

Our products that contain human derived tissue, including those containing demineralized bone matrices, are not medical devices in the EU as defined in the Medical Device Directive (93/42/EC). They are also not medicinal products as defined in Directive 2001/83/EC. Today, regulations, if applicable, differ from one EU member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the EU, as well as for other countries, the approval process for human-derived cell or tissue based medical products may be extensive, lengthy, expensive, and unpredictable. Among others, some of our orthobiologics products are subject to EU member states regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. These EU member states regulations include requirements for registration, listing, labeling, adverse-event reporting, and inspection and enforcement. Some EU member states have their own tissue banking regulations. In addition, certain EU member states have instituted new requirements for additional testing that may be prohibitive to obtaining approval in those member states.

Certain of our products contain materials derived from animal sources and may become subject to additional regulation.

Certain of our products, including our dermal regeneration products, duraplasty products, biomaterial products for the spine, nerve and tendon repair products and certain other products, contain material derived from bovine tissue. Products that contain materials derived from animal sources, including food, pharmaceuticals and medical devices, are subject to scrutiny in the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease from animals to humans via those materials. This public scrutiny has been particularly acute in Japan and Western Europe with respect to products derived from

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animal sources, because of concern that materials infected with the agent that causes bovine spongiform encephalopathy, otherwise known as BSE or mad cow disease, may, if ingested or implanted, cause a variant of the human Creutzfeldt-Jakob Disease, an ultimately fatal disease with no known cure. Cases of BSE in cattle discovered in Canada and the United States have increased awareness of the issue in North America.

We take care to provide that our products are safe and free of agents that can cause disease. In particular, we have qualified a source of collagen from a country outside the United States that is considered BSE-free. The World Health Organization classifies different types of cattle tissue for relative risk of BSE transmission. Deep flexor tendon is in the lowest-risk categories for BSE transmission (the same category as milk, for example), and is therefore considered to have a negligible risk of containing the agent that causes BSE (an improperly folded protein known as a prion). Nevertheless, products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for the transmission of prions. Significant new regulation, or a ban of our products, could have a material adverse effect on our current business or our ability to expand our business.

Certain countries, such as Japan, China, Taiwan and Argentina, have issued regulations that require our collagen products be processed from bovine tendon sourced from countries where no cases of BSE have occurred, and the EU has requested that our dural replacement products and other products that are used in neurological tissue be sourced from bovine tendon sourced from a country where no cases of BSE have occurred. Currently, we purchase our tendon from the United States and New Zealand. We received approval in the EU, Japan, Taiwan, China and Argentina for the use of New Zealand-sourced tendon in the manufacturing of our products. If we cannot continue to use or qualify a source of tendon from New Zealand or another country that has never had a case of BSE, we will not be permitted to sell our collagen products in certain countries.

Certain of our products are derived from human tissue and are subject to additional regulations and requirements.

We manufacture medical devices derived from human tissue (demineralized bone tissue). The FDA has specific regulations governing human cells, tissues and cellular and tissue-based products, or HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient. Examples include bone, ligament, skin and cornea.

Some HCT/Ps also meet the definition of a biological product, medical device or drug regulated under the FD&C ACT. Section 361 of the PHSA authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as 361 HCT/Ps are subject to requirements relating to registering facilities and listing products with FDA, screening and testing for tissue donor eligibility, Good Tissue Practice, or GTP, when processing, storing, labeling, and distribution HCT/Ps, including required labeling information, stringent record keeping; and adverse event reporting. These biologic, device or drug HCT/Ps must comply both with the requirements exclusively applicable to 361 HCT/Ps and, in addition, with requirements applicable to biologics, devices or drugs, including premarket clearance or approval.

The American Association of Tissue Banks (AATB) has issued operating standards for tissue banking. Compliance with these standards is a requirement in order to become a licensed tissue bank. In addition, some states have their own tissue banking regulations. We are licensed or have permits as a tissue bank in California, Florida, New York and Maryland.

In addition, procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act (NOTA), which prohibits the transfer of certain human organs, including skin and related tissue for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue that they provide to us for processing. We include in our pricing structure amounts paid to

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tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses, and costs associated with development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we may recover in our pricing for our products, thereby reducing our future revenue and profitability. If we were to be found to have violated NOTA s prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our results of operations.

In the EU, regulations, if applicable, differ from one EU member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the EU, as well as for other countries, the approval process for human derived cell or tissue based medical products may be extensive, lengthy, expensive, and unpredictable. Among others, some of our orthobiologics products are subject to EU member states regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of human tissues and cells and cellular or tissue-based products. These EU member states regulations include requirements for registration, listing, labeling, adverse-event reporting, and inspection and enforcement. Some EU member states have their own tissue banking regulations.

Lack of market acceptance for our products or market preference for technologies that compete with our products could reduce our revenues and profitability.

We cannot be certain that our current products or any other products that we may develop or market will achieve or maintain market acceptance. Certain of the medical indications that our devices can treat can also be treated by other medical devices or by medical practices that do not include a device. The medical community widely accepts many alternative treatments, and certain of these other treatments have a long history of use. For example, the use of autograft tissue is a well-established means for repairing the dermis, and it competes for acceptance in the market with our collagen-based wound care products.

We cannot be certain that our devices and procedures will be able to replace those established treatments or that either physicians or the medical community in general will accept and utilize our devices or any other medical products that we may develop. For example, market acceptance of our bone graft substitutes will depend on our ability to demonstrate that our bone graft substitutes and technologies are an attractive alternative to existing treatment options. Additionally, if there are negative events in the industry, whether real or perceived, there could be a negative impact on the industry as a whole. For example, we believe that some in the medical community have lingering concerns over the risk of disease transmission through the use of natural bone graft substitutes.

In addition, our future success depends, in part, on our ability to develop additional products. Even if we determine that a product candidate has medical benefits, the cost of commercializing that product candidate could be too high to justify development. Competitors could develop products that are more effective, achieve or maintain more favorable reimbursement status from third-party payors, including Medicare, Medicaid and third-party health insurance, cost less or are ready for commercial introduction before our products. If we are unable to develop additional commercially viable products, our future prospects could be adversely affected.

Market acceptance of our products depends on many factors, including our ability to convince prospective collaborators and customers that our technology is an attractive alternative to other technologies, to manufacture products in sufficient quantities and at acceptable costs, and to supply and service sufficient quantities of our products directly or through our distribution alliances. In addition, unfavorable reimbursement methodologies, or adverse determinations of third-party payors, including Medicare, Medicaid and third-party health insurers, against our products or third-party determinations that favor a competitor s product over ours, could harm acceptance or continued use of our products. The industry is subject to rapid and continuous change arising from,

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among other things, consolidation, technological improvements, the pressure on third-party payors and providers to reduce healthcare costs, and healthcare reform legislation. One or more of these factors may vary unpredictably, and such variations could have a material adverse effect on our competitive position. We may not be able to adjust our contemplated plan of development to meet changing market demands.

Our intellectual property rights may not provide meaningful commercial protection for our products, potentially enabling third parties to use our technology or very similar technology and could reduce our ability to compete in the market.

To compete effectively, we depend, in part, on our ability to maintain the proprietary nature of our technologies and manufacturing processes, which includes the ability to obtain, protect and enforce patents on our technology and to protect our trade secrets. We own or have licensed patents that cover aspects of some of our product lines. Our patents, however, may not provide us with any significant competitive advantage. Others may challenge our patents and, as a result, our patents could be narrowed, invalidated or rendered unenforceable. Competitors may develop products similar to ours that our patents do not cover. In addition, our current and future patent applications may not result in the issuance of patents in the United States or foreign countries. Further, there is a substantial backlog of patent applications at the U.S. Patent and Trademark Office, and the approval or rejection of patent applications may take several years.

Our competitive position depends, in part, upon unpatented trade secrets which we may be unable to protect.

Our competitive position also depends upon unpatented trade secrets, which are difficult to protect. We cannot assure you that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, that our trade secrets will not be disclosed or that we can effectively protect our rights to unpatented trade secrets.

In an effort to protect our trade secrets, we require our employees, consultants and advisors to execute confidentiality and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements provide that, except in specified circumstances, all confidential information developed or made known to the individual during the course of their relationship with us must be kept confidential. We cannot assure you, however, that these agreements will provide meaningful protection for our trade secrets or other proprietary information in the event of the unauthorized use or disclosure of confidential information.

Our success will depend partly on our ability to operate without infringing or misappropriating the proprietary rights of others.

We may be sued for infringing the intellectual property rights of others. In addition, we may find it necessary, if threatened, to initiate a lawsuit seeking a declaration from a court that we do not infringe the proprietary rights of others or that their rights are invalid or unenforceable. If we do not prevail in any litigation, in addition to any damages we might have to pay, we would be required to stop the infringing activity or obtain a license for the proprietary rights involved. Any required license may be unavailable to us on acceptable terms, if at all. In addition, some licenses may be nonexclusive and allow our competitors to access the same technology we license.

If we fail to obtain a required license or are unable to design our products so as not to infringe on the proprietary rights of others, we may be unable to sell some of our products, and this potential inability could have a material adverse effect on our revenues and profitability.

We may be involved in lawsuits relating to our intellectual property rights and promotional practices, which may be expensive.

To protect or enforce our intellectual property rights, we may have to initiate or defend legal proceedings, such as infringement suits or interference proceedings, against or by third parties. In addition, we may have to

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institute proceedings regarding our competitors promotional practices or defend proceedings regarding our promotional practices. Litigation is costly, and, even if we prevail, the cost of that litigation could affect our profitability. In addition, litigation is time-consuming and could divert management attention and resources away from our business. Moreover, in response to our claims against other parties, those parties could assert counterclaims against us.

It may be difficult to replace some of our suppliers.

Outside vendors, some of whom are sole-source suppliers, provide key components and raw materials used in the manufacture of our products. Although we believe that alternative sources for many of these components and raw materials are available, any interruption in supply of a limited or sole-source component or raw material could harm our ability to manufacture our products until a new or alternative source of supply is identified and qualified. In addition, an uncorrected defect or supplier s variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired. We believe that these factors are most likely to affect the following products that we manufacture:

- our collagen-based products, such as the INTEGRA® Dermal Regeneration Template and wound dressing products, the DuraGen® family of products, and our Absorbable Collagen Sponges;
- our products made from silicone, such as our neurosurgical shunts and drainage systems and hemodynamic shunts;
- products which use many different electronic parts from numerous suppliers, such as our intracranial monitors and catheters; and
- products that use pyrolytic carbon (i.e., PyroCarbon) technology, such as certain of our reconstructive extremity orthopedic implants.

In addition, some of our orthobiologics products rely on a small number of tissue banks accredited by the American Association of Tissue Banks, or AATB, for the supply of human tissue, a crucial component of our bone graft substitutes. We cannot be certain that these tissue banks will be able to fulfill our requirements or that we will be able to successfully negotiate with other accredited tissue facilities on satisfactory terms.

If we were suddenly unable to purchase products from one or more of these companies, we would need a significant period of time to qualify a replacement, and the production of any affected products could be disrupted.

While it is our policy to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time, we remain at risk that we will not be able to qualify new components or materials quickly enough to prevent a disruption if one or more of our suppliers ceases production of important components or materials.

If any of our manufacturing facilities were damaged and/or our manufacturing or business processes interrupted, we could experience lost revenues and our business could be seriously harmed.

Damage to our manufacturing, development or research facilities because of fire, natural disaster, power loss, communications failure, unauthorized entry or other events, such as a flu or other health epidemic, could cause us to cease development and manufacturing of some or all of our products. In particular, our San Diego and Irvine, California facilities are susceptible to earthquake damage, wildfire damage and power losses from electrical shortages as are other businesses in the Southern California area. Our Anasco, Puerto Rico plant, where we manufacture collagen, silicone and our private-label products, is vulnerable to hurricane, storm, earthquake

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and wind damage. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs.

In addition, certain of our surgical instruments have some manufacturing processes performed by third parties in Pakistan, which is subject to political instability and unrest, and we purchase a much smaller amount of instruments directly from vendors there. Such instability could interrupt our ability to sell surgical instruments to our customers and could have a material adverse effect on our revenues and earnings. While we have developed a relationship with an alternative provider of these services in another country, and continue to work to develop other providers in other countries, we cannot guarantee that we will be completely successful in achieving all of these relationships. Even if we are successful in establishing all of these alternative relationships, we cannot guarantee that we will be able to do so at the same level of costs or that we will be able to pass along additional costs to our customers.

Further, we manufacture certain products in Europe and our European headquarters is located in France, which has experienced labor strikes. Thus far, strikes have not had a material impact on our business; however, if such strikes were to occur, there is no assurance that they would not disrupt our business, and any such disruption could have a material adverse effect on our business.

We implemented an enterprise business system to support certain of our transaction processing for accounting and financial reporting, supply chain and manufacturing. A third party hosts and maintains this system. Currently, we do not have a comprehensive disaster recovery plan for the Company s infrastructure but we have adopted alternative solutions to mitigate business risk, including backup equipment, power and communications. We also implemented a comprehensive backup and recovery process for our key software applications. Our global production and distribution operations are dependent on the effective management of information flow between facilities. An interruption of the support provided by our enterprise business systems could have a material adverse effect on the business.

We are exposed to a variety of risks relating to our international sales and operations, including fluctuations in exchange rates, local economic conditions and delays in collection of accounts receivable.

We generate significant revenues outside the United States in multiple foreign currencies including euros, British pounds, Swiss francs, Canadian dollars, Japanese yen and Australian dollars, and in U.S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. For those foreign customers who purchase our products in U.S. dollars, currency fluctuations between the U.S. dollar and the currencies in which those customers do business may have a negative impact on the demand for our products in foreign countries where the U.S. dollar has increased in value compared to the local currency.

Since we have operations based outside the United States and we generate revenues and incur operating expenses in multiple foreign currencies including euros, British pounds, Swiss francs, Canadian dollars, Japanese yen and Australian dollars, we experience currency exchange risk with respect to those foreign currency-denominated revenues and expenses.

Although we address currency risk management through regular operating and financing activities, and, on a limited basis, through the use of derivative financial instruments, those actions may not prove to be fully effective. For a description of our use of derivative financial instruments, see Note 5, Derivative Instruments.

We cannot predict the consolidated effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates.

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Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export, laws regarding transactions in foreign countries, the U.S. Foreign Corrupt Practices Act and local anti-bribery and other laws regarding interactions with healthcare professionals. Among other things, these laws restrict, and in some cases prohibit, U.S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices in foreign countries.

Local economic conditions, legal, regulatory or political considerations, disruptions from strikes, the effectiveness of our sales representatives and distributors, local competition and changes in local medical practice could also affect our sales to foreign markets. Relationships with customers and effective terms of sale frequently vary by country, often with longer-term receivables than are typical in the United States.

The adoption of healthcare reform in the United States may adversely affect our business, results of operations and/or financial condition.

In March 2010, significant reforms to the U.S. healthcare system were adopted in the form of the Patient Protection and Affordable Care Act (the PPACA). The PPACA includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes. Specifically, the law requires the medical device industry to subsidize healthcare reform by implementing a 2.3% excise tax on the sale of certain medical devices by a manufacturer, producer or importer of such devices in the United States starting after December 31, 2012. We are still evaluating the impact of this tax on our overall business. Other elements of this legislation, such as comparative effectiveness research, an independent payment advisory board, payment system reforms (including shared savings pilots) and other provisions, could meaningfully change the way health care is developed and delivered, and result in additional costs for us. The PPACA could reduce medical procedure volumes, impact the demand for our products or the prices at which we sell our products, and may have a material adverse effect on our business and/or results of operations.

Further, the PPACA encourages hospitals and physicians to work collaboratively through shared savings programs, such as accountable care organizations, as well as other bundled payment initiatives, which may ultimately result in the reduction of medical device purchases and the consolidation of medical device suppliers used by hospitals. While passage of the PPACA may ultimately expand the pool of potential end-users of our products, the above-discussed changes could adversely affect our financial results and business.

Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us.

Changes in the healthcare industry may require us to decrease the selling price for our products, may reduce the size of the market for our products, or may eliminate a market, any of which could have a negative impact on our financial performance.

Trends toward managed care, healthcare cost containment and other changes in government and private sector initiatives in the United States and other countries in which we do business are placing increased emphasis on the delivery of more cost-effective medical therapies that could adversely affect the sale and/or the prices of our products. For example:

- as mentioned above, new legislation, which is intended to expand access to health insurance coverage over time, will result in major changes in the United States healthcare system that could have an adverse effect on our business, including a 2.3% excise tax on U.S. sales of most medical devices, which is scheduled to be implemented in 2013, and which could have a material adverse effect on our earnings;

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- third-party payors of hospital services and hospital outpatient services, including Medicare, Medicaid and private healthcare insurers, annually revise their payment methodologies, which can result in stricter standards for reimbursement of hospital charges for certain medical procedures or the elimination of reimbursement;

- Medicare, Medicaid and private healthcare insurer cutbacks could create downward price pressure on our products;

- local Medicare coverage determinations will eliminate reimbursement for certain of our matrix wound dressing products in most regions, negatively affecting our market for these products, and future determinations could eliminate reimbursement for these products in other regions and could eliminate reimbursement for other products;

- there has been a consolidation among healthcare facilities and purchasers of medical devices in the United States who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices;

- we are party to contracts with group purchasing organizations, which negotiate pricing for many member hospitals, that require us to discount our prices for certain of our products and limit our ability to raise prices for certain of our products, particularly surgical instruments;

- there is economic pressure to contain healthcare costs in domestic and international markets;

- there are proposed and existing laws, regulations and industry policies in domestic and international markets regulating the sales and marketing practices and the pricing and profitability of companies in the healthcare industry;

- proposed laws or regulations will permit hospitals to provide financial incentives to doctors for reducing hospital costs (known as gainsharing), will award physician efficiency (known as physician profiling), and will encourage partnership with healthcare service and goods providers to reduce prices;

- the growing prevalence of physician-owned distributorships catering to the spinal surgery market has reduced and may continue to reduce our ability to compete effectively for business from surgeons who own such distributorships; and

- there have been initiatives by third-party payors to challenge the prices charged for medical products that could affect our ability to sell products on a competitive basis.

Both the pressures to reduce prices for our products in response to or despite these trends and the decrease in the size of the market as a result of these trends could adversely affect our levels of revenues and profitability of sales.

Oversight of the medical device industry might affect the manner in which we may sell medical devices and compete in the marketplace.

There are laws and regulations that govern the means by which companies in the healthcare industry may market their products to healthcare professionals and may compete by discounting the prices of their products, including for example, the federal Anti-Kickback Statute, the federal False Claims Act, the federal Health Insurance Portability and Accountability Act of 1996, state law equivalents to these federal laws that are meant to protect against fraud and abuse and analogous laws in foreign countries. Violations of these laws are punishable by criminal and civil sanctions, including, but not limited to, in some instances civil and criminal penalties, damages, fines, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. Although we exercise care in structuring our sales and marketing practices and customer discount arrangements to comply with those laws and regulations, we cannot assure you that:

government officials charged with responsibility for enforcing those laws will not assert that our sales and marketing practices or customer discount arrangements are in violation of those laws or regulations; or

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government regulators or courts will interpret those laws or regulations in a manner consistent with our interpretation. Correspondingly, federal and state laws are also sometimes open to interpretation, and from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that of our competitors.

AdvaMed, the principal United States trade association for the medical device industry, promulgates a model code of conduct that sets forth standards by which its members should abide in the promotion of their products. We have in place policies and procedures for compliance that we believe are at least as stringent as those set forth in the revised AdvaMed Code, and we provide routine training to our sales and marketing personnel on our policies regarding sales and marketing practices. Pursuant to the revised AdvaMed Code, we have certified our adoption of the revised AdvaMed Code. Nevertheless, the sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, and we believe that this trend will continue. For example, recent federal legislation and state legislation would require detailed disclosure of gifts and other remuneration made to health care professionals. In addition, prosecutorial scrutiny and governmental oversight, on the state and federal levels, over some major device companies regarding the retention of healthcare professionals as consultants has limited the manner in which medical device companies may retain healthcare professionals as consultants. Various hospital organizations, medical societies and trade associations are establishing their own practices that may require detailed disclosures of relationships between healthcare professionals and medical device companies or ban or restrict certain marketing and sales practices such as gifts and business meals.

Our private-label product lines depend significantly on key relationships with third parties, which we could be unable to establish and maintain.

Our private-label business depends in part on our entering into and maintaining collaborative or alliance agreements with third parties concerning product marketing, as well as research and development programs. The third parties with whom we have entered into agreements might terminate these agreements for a variety of reasons, including developing other sources for the products that we supply. Termination of our most important relationships could adversely affect our expectations for the growth of private-label products.

We may have significant product liability exposure and our insurance may not cover all potential claims.

We are exposed to product liability and other claims in the event that our technologies or products are alleged to have caused harm. We may not be able to obtain insurance for the potential liability on acceptable terms with adequate coverage or at reasonable costs. Any potential product liability claims could exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. Our insurance may not be renewed at a cost and level of coverage comparable to that then in effect.

We are subject to requirements relating to hazardous materials which may impose significant compliance or other costs on us.

Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. In addition, we own and/or lease a number of facilities at which hazardous materials have been used in the past. Finally, we have acquired various companies that historically have used certain hazardous materials and that have owned and/or leased facilities at which hazardous materials have been used. For all of these reasons, we are subject to federal, state, foreign, and local laws and regulations governing the use, manufacture, storage, handling, treatment, remediation, and disposal of hazardous materials and certain waste products (Environmental Laws). For example, our allograft bone tissue processing may generate waste materials, which in the United States, are classified as medical waste under Environmental Laws. Although we believe that our procedures for handling and disposing of hazardous materials comply with the Environmental Laws, the Environmental Laws may be amended in ways that increase our cost of compliance, perhaps materially.

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Furthermore, the risk of accidental contamination or injury from these materials cannot be eliminated, and there is also a risk that such contamination previously has occurred in connection with one of our facilities or in connection with one of the companies we have purchased. In the event of such an accident, or contamination we could be held liable for any damages that result and any related liability could exceed the limits or fall outside the coverage of our insurance and could exceed our resources. We may not be able to maintain insurance on acceptable terms or at all.

We may experience difficulties implementing our new global enterprise resource planning system

We are engaged in a multi-year implementation of a new global enterprise resource planning system (ERP) to improve our operational efficiency. The ERP is designed to accurately maintain our financial reporting data and provide information to our management team important to the operation of the business. Our ERP has required, and will require, the investment of significant human and financial resources. The implementation of this new ERP system involves numerous risks, including disruption to our normal accounting procedures and internal control over financial reporting, inaccuracies in the conversion of electronic data, difficulties integrating the systems and processes, additional costs to continue to refine the system s functionality, and disruption of our financial reporting process. We may not be able to successfully implement the ERP without experiencing significant delays, increased costs, or other difficulties. Any significant disruption or deficiency in the design or implementation of the ERP could adversely affect our ability to estimate supply chain needs, plan production requirements, process orders, ship product, send invoices and track payments, fulfill contractual obligations, accurately forecast sales, or otherwise operate our business, all of which could negatively impact sales and profits.

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ITEM 1B. ***UNRESOLVED STAFF COMMENTS***

As of the filing of this Annual Report on Form 10-K, we had no unresolved comments from the staff of the Securities and Exchange Commission that were received not less than 180 days before the end of our 2011 fiscal year.

ITEM 2. ***PROPERTIES***

Our principal executive offices are located in Plainsboro, New Jersey. Our principal manufacturing and research facilities are located in California, Massachusetts, New Jersey, Ohio, Pennsylvania, France, Germany, Ireland, Mexico, Puerto Rico and the United Kingdom. Our instrument procurement operations are located in Germany. Our primary distribution centers are located in Nevada, Ohio, Pennsylvania, Australia, Belgium, Canada and France. In addition, we lease several smaller facilities to support additional administrative, assembly, and distribution operations. Third parties own and operate the facilities in Nevada and Belgium. We own our facilities in Biot, France and Andover, United Kingdom, and certain facilities in Ohio and Pennsylvania and we lease all of our other facilities. We also have repair centers in California, Massachusetts, Ohio and Germany.

Our manufacturing facilities are registered with the FDA. Our facilities are subject to FDA inspection to ensure compliance with Quality System regulations. Our Plainsboro, New Jersey manufacturing facility was inspected by the FDA during the third quarter of 2011 which resulted in the issuance of FDA Form 483 observations, and we subsequently received a warning letter from the FDA on December 21, 2011 related to that inspection. We have undertaken significant efforts to remediate the observations that the FDA has made since the conclusion of the inspection, and continue to believe that all of our manufacturing facilities are in substantial compliance with Quality System regulations, suitable for their intended purposes and have capacities adequate for current and projected needs for existing products. We are converting or modifying the capacity in some of our plants to meet the current and projected requirements of existing and future products.

ITEM 3. ***LEGAL PROCEEDINGS***

Various lawsuits, claims and proceedings are pending or have been settled by us. The most significant of these are described below.

In January 2010, we received a notice from the seller s representative of the former Theken companies of a disagreement in the calculation of trade sales used in calculating a revenue performance payment that we made in November 2009 related to the first performance year that ended September 30, 2009. The notice alleged that we owed an additional $6.7 million and we recorded an accrual of $3.4 million for the settlement at that time. There were no additional amounts due under the unit purchase agreement for the second performance year that ended September 30, 2010. In January 2011, we received a notice from the seller s representative that the alleged amount owed had been reduced to $5.7 million. In June 2011, the Company and the seller agreed to settle the matter for $4.6 million, which was accrued at that time, and was paid in August 2011.

We also have various product liability claims pending against us. During 2011, we settled the most significant of these matters for approximately $4.6 million. This matter was covered by our insurance policies and we had previously recorded a corresponding receivable. Therefore, there is no impact on our consolidated statements of operations.

In addition to these matters, we are subject to various claims, lawsuits and proceedings in the ordinary course of business, including claims by current or former employees, distributors and competitors and with respect to our products. In the opinion of management, such claims are either adequately covered by insurance or otherwise indemnified, or are not expected, individually or in the aggregate, to result in a material adverse effect on our financial condition. However, it is possible that our results of operations, financial position and cash flows in a particular period could be materially affected by these contingencies.

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ITEM 4. ***MINE SAFETY DISCLOSURES***

Not applicable.

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PART II

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

Market Information, Holders and Dividends

Our common stock trades on The NASDAQ Global Market under the symbol IART. The following table lists the high and low sales prices for our common stock for each quarter for the last two years:

	2011		2010	
	High	Low	High	Low
Fourth Quarter	$ 38.80	$ 28.07	$ 49.85	$ 38.17
Third Quarter	$ 48.26	$ 34.92	$ 39.93	$ 33.63
Second Quarter	$ 52.90	$ 45.50	$ 46.73	$ 36.81
First Quarter	$ 51.79	$ 44.64	$ 44.99	$ 36.51

We have not paid any cash dividends on our common stock since our formation. Our credit facility limits the amount of dividends that we may pay. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Amended and Restated Senior Credit Agreement. Any future determinations to pay cash dividends on the common stock will be at the discretion of our Board of Directors and will depend upon our results of operations, cash flows, and financial condition and other factors deemed relevant by the Board of Directors.

The number of stockholders of record as of February 21, 2012 was approximately 573, which includes stockholders whose shares were held in nominee name.

Sales of Unregistered Securities

There were no sales of unregistered securities during the years ended December 31, 2011, 2010 or 2009.

Issuer Purchases of Equity Securities

On October 30, 2008, our Board of Directors authorized us to repurchase shares of our common stock for an aggregate purchase price not to exceed $75.0 million through December 31, 2010 (the 2008 Authorization). On October 29, 2010, our Board of Directors terminated the 2008 Authorization and authorized us to repurchase shares of our common stock for an aggregate purchase price not to exceed $75.0 million through December 31, 2012 (the 2010 Authorization). Shares may be purchased either in the open market or in privately negotiated transactions under both of these authorizations. As of December 31, 2011, there remained $29.1 million available for share repurchases under the 2010 Authorization. In addition to the authorizations above, on June 3, 2011, our Board of Directors separately authorized us to repurchase shares of common stock from the proceeds of the 2016 Notes (as hereinafter defined) in connection with that offering. See Note 6, Treasury Stock, in our consolidated financial statements for further details.

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A summary of repurchases during the year ended December 31, 2011 is as follows (amounts in thousands, except per share amounts):

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Be Purchased Under the Plans or Programs
Beginning Balance as of January 1, 2011				$ 75,000
February 1, 2011 to February 28, 2011	42			